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

Background Document

to the Opinion on the Annex XV report proposing restrictions on intentionally added microplastics

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About this report

The preparation of an Annex XV restriction report on 'intentionally-added 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 to ECHA from the Commission.

The proposal was 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 Annexes with more detailed information and analysis.

During the preparation of the Annex XV restriction report, the Commission asked ECHA to explore the potential for co-operating with Sweden. After preliminary discussions in May 2018, ECHA agreed that they would collaborate with KemI in the preparation of the Annex XV report, although Sweden would not be a formal Dossier Submitter. ECHA 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 in 2018, the stakeholder workshop held in May 2018 and in bilateral discussions during the subsequent development of the report. The Dossier Submitter would also like to thank the organisers and participants of the Micro2018 international microplastics conference (held in November 2018), who provided useful comments on the draft risk assessment described in the Annex XV report.

This report has been reviewed for confidential information.

This 'Background Document' is based on version 1.1 of the Annex XV report published on the ECHA website in March 2019 to coincide with the beginning of the six-month consultation on the proposal. The Background Document incorporates revisions to the proposal made by the Dossier Submitter in response to the consultation comments.

Summary

The term 'microplastic' is not consistently 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 described in this report. 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 could result in releases to the environment.

Microplastics can also be formed in the environment as a result of the progressive degradation of larger synthetic polymer-based articles (e.g. plastic packaging and discarded or lost fishing gear), typically articles that are present in the environment as a consequence of inappropriate or ineffective waste management (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. However, 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 (in rinse-off and leave-on products);
- detergents and maintenance products (e.g. as fragrance encapsulation[2] in laundry detergents and fabric softeners as well as in products for cleaning, polishing and air fresheners);
- infill material for synthetic sports surfaces (typically termed as 'rubber crumb');
- paints, coatings and inks (in professional and consumer uses);
- chemicals used in the oil and gas sector;
- construction products;
- medicinal products;
- medical devices; and
- food supplements and medical food.

Products containing microplastics have many different functions and are,

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

[2] While the majority of fragrance encapsulates is used in the detergents sector, a small part is also applied in rinse-off and leave-on cosmetics. It should be noted that these cosmetic applications are also covered in the assessment in Annex D6, even though the focus of that section is on detergents and maintenance products.

correspondingly, used in many different ways. This diversity of reasonably foreseeable conditions of use, affects how, and to what extent, intentionally-added microplastics are released to the environment. 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 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 susceptible to transfer within food chains;
- **are very resistant to (bio)degradation**, which will lead to them being present in the environment for a long time after their initial release;
- **degrade 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 currently allow a distinction between secondary and 'intentionally added' microplastics), these properties are known to result in a wide range of organisms, including invertebrates, fish, marine reptiles, birds and cetaceans being exposed to microplastics (either directly or via trophic transfer). Humans are known to be exposed to microplastics via their diet.

Based on these concerns, several EU Member States have banned products, or certain types of products that contain microplastics, typically 'microbeads' in rinse-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, feeding appendages or the gut. (Eco)toxicological hazards may arise from the polymers themselves, or from the presence of unreacted monomers, impurities (e.g. residual catalyst/initiators or derivative), additives (e.g. stabilisers) or other substances present within the polymer matrix that comprises a microplastic particle (e.g. pigments, lubricants, thickeners, anti-static agents, anti-fogging/clarifying agents, nucleating agents, plasticisers, flame-retardants, etc.). Microplastics, in effect, are particles of mixtures.

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[3]. However, the current scientific consensus on this issue suggests that ingestion of microplastics does not

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

significantly enhance the bioaccumulation of POPs compared to the ingestion of other types of particulate matter 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. In addition to the down-the-drain and solid waste pathways, granular synthetic infill material used on artificial sports surfaces (which is considered as a microplastic by the Dossier Submitter) is also released to the environment.

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 eventually be released to the environment. For example, almost all of the microplastics in a rinse-off cosmetic product can be assumed to be disposed down-the-drain, whilst for different leave-on cosmetic products the quantity disposed down-the-drain varies from approximately 30 to 95% (average of approximately 50%), depending on how different types of cosmetic products are typically used by consumers (i.e. microplastic containing wastes can be disposed of in municipal solid waste rather than down-the-drain). By way of comparison, only 1.5% of the microplastics in consumer paints are assumed to be released down-the-drain at the point of end use (with the remainder forming a film *in situ* and ceasing to be microplastics).

A large proportion of microplastics that are disposed of 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 (organic matter recycled from sewage) 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 recently been proposed for the marine environment by several authors. 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 of risks arising through secondary poisoning). Equally, the potential bioaccumulation properties and hazards of nanoplastics, that are thought to be formed during the degradation of microplastics, are currently poorly understood, which prevents an assessment of the risks posed by relevant breakdown/transformation products of microplastics in the environment. Theoretical considerations suggest that nanoplastics can be more readily taken up into cells than microplastics, which may 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 a 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 that must also be taken into consideration for an appropriate risk assessment of microplastics is their 'extreme', arguably permanent, persistence in the environment. As a result, any releases contribute to a progressively increasing environmental stock, which would eventually result in exposures exceeding safe thresholds in the future. 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 concludes 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 occurring, either presently or in the future. 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 non-threshold conclusions, the Dosser Submitter notes that the concentrations of microplastics at some 'hot spot' locations in the marine environment (primary and secondary microplastics) 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 regarding the non-threshold nature of the microplastic concern do not contradict these tentative quantitative risk assessments.

For each of the sectors assessed, the releases of microplastics per year to the environment were determined. In total, the quantity of intentionally added microplastics that are eventually released into the environment under reasonably foreseeable conditions of use, is estimated to be more than 42 000 tonnes per year (with lower and upper bounds of approximately 13 000 - 95 000 tonnes per year, respectively).

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 the release of 42 000 tonnes of microplastics per year is comparable to the microplastic fraction of a oceanic plastic garbage patch that is more than six times the present size of the 'Great Pacific Garbage Patch'.

A recent project initiated by the European Commission[4] estimated the scale of annual releases of [secondary] microplastics emitted by (but not intentionally added to) products to EU surface waters. This study reports releases to surface waters of 176 300 tonnes per year, with a lower and upper range of 71 800 to 280 600 tonnes per year. The greatest contributors were identified to be road 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 magnitude 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 is not 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 rinse-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.)

- an **'instructions for use and disposal' requirement** to minimise releases to the environment for uses of microplastics where they are not inevitably released to the environment but where residual releases could occur if they are not used or disposed of appropriately.

- a **reporting requirement** to monitor the effectiveness of the instructions for use and disposal requirement and improve the quality of information available to assess the risks from uses of microplastics in the future.

The proposed restriction is targeted at mixtures that present a risk to the environment that is not adequately controlled and will reduce these risks progressively over the eight years following the year of entry into force (assumed to be 2021).

The impact of a restriction on the use of microplastics as infill material for synthetic sports surfaces has also been assessed. The Dossier Submitter has assessed two restriction options in detail, and concluded that both could be considered to be

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

proportionate. 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 500 thousand tonnes of microplastics (250 thousand tonnes if infill material is excluded) over the 20 year period following its entry into force (a reduction of 70%[5] 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 €9.5 billion (NPV) (€10.8 or 19.1 billion (NPV) in total if one of the proposed restriction options for synthetic infill material is also included – See Table 37 and Annex D.13 for details). The cost effectiveness of avoided emissions, for sectors where those have been quantified, is estimated to range from €1/kg to €870/kg per year (Table 1). The costs of the instructions for use and disposal requirement could not be quantified, but are considered to be minor in comparison to other costs estimated (Table 2).

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

Table 1 Summary of impacts of the proposed restriction on sectors affected by the ban on placing microplastics on the market (excl. infill material), 20-year analytical period.

Sector	Emission 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	6 750 (2 250 - 12 000)	31 (11 – 63)	4.6 (0.9 – 27.8)	Table 25
Capsule suspension plant protection products (CSPs) and coated seeds	13 500 (4 950 – 23 400)	233 (60 – 545)	17.3 (2.6 - 110.1)	Table 25
Rinse-off cosmetic products containing microbeads[2)]	55 [2)]	Negligible	n/a	Table 27
Other rinse-off cosmetic products	50 200 (22 500 – 78 000)	1 080 (52 – 2 110)	22 (2 - 27)	Table 27
Leave-on cosmetic products	8 500 (4 200 – 12 200)	7 300 (1 600 – 15 500)	870 (380 – 1 30)	Table 27
Microbeads contained in detergents [2)]	100 [2)]	Negligible	n/a	Table 28
Polymeric	3 000	526	173	Table 28

[5] The actual effectiveness of the proposal depends on both the length of transitional periods and the effectiveness of the instructions for use and disposal requirement. Annual emission reduction after all transitional periods have expired is >90%.

Sector	Emission reduction (tonnes) (range)	Total costs (€ million, NPV) – central scenario (range) [1)]	Cost effectiveness (€/kg of emissions avoided) (range)	Reference in report
fragrance encapsulates [3)]	(2 000 – 4 100)	(293 – 812)	(71 - 337)	
Other microplastics contained in detergents	115 900 (72 000 – 159 800)	130 (29 – 1 330)	1 (0.4 – 9)	Table 28
Waxes, polishes and air care products	8 800	6 (1 - 20)	1 (0.1 - 2)	Table 28
Totals	**206 680 (116 670 - 298 290)**	**9 498 (2 106 – 20 796)**		

Notes: [1)] Costs are rounded to the nearest million. [2)] 2017 data, use expected to be phased out by 2020. [3)] The impacts outlined here are based on a 5 year transition period for fragrance encapsulates. The Dossier Submitter has also undertaken an analysis of the impacts under an 8 year transition period for fragrance encapsulates, which is outlined in Annex D6. With an 8 year transition period, the emissions reduction for this product group would be 2 400 tonnes (1 600 tonnes – 3 300 tonnes), the total costs would be €313 million (293 million – 652 million) and the cost effectiveness would be €128/kg (€89/kg - €329/kg). The Dossier Submitter is not making any recommendations on which of these two transition periods is more appropriate for fragrance encapsulates but discusses the differences in their impacts at the end of Annex D.6.7.

Table 2: Summary of the impacts on sectors affected by the instructions for use and disposal and 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 26
in vitro diagnostic devices (IVD)	ca 0.27 tonnes p.a. (0.25–0.29)[a]	Table 29
Medical devices (MD)	Not estimated (current estimated use of 10 tpa for the non-substance based types of MD).	Table 30
Medicinal products (solid dosage forms)	Not estimated (current emissions estimated to be 1 600 (500-2 700) tonnes p.a.)	Table 31
Medicinal products (Ion-exchange based controlled release)	Not estimated (current emissions estimated to be 700 (300-1 000) tonnes p.a.)	Table 31
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 31
Food supplements and medical food	No information available	Table 32
Paints and coatings	Not estimated (current emissions estimated to be 2 700 tonnes p.a., 49 000 tonnes over 20-year analytical period)	Table 33
3D printing	No information available	Table 34
Toners and printing ink	No information available	Table 35

Sector	Emissions reduction (tonnes / year) (range)	Reference in report
Oil & gas	270 tonnes p.a. (~0 to 550 tonnes p.a.)	Table 36
Polymeric infill material	14 400 kilotonnes p.a. on average	Table 37

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 provision of instructions for use and disposal.

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 the aim to minimise costs to society, without unnecessary delay in emission reduction. In this manner industry will have sufficient time to develop and transition to suitable alternatives, including biodegradable polymers where this is appropriate;
- Instructions for use and disposal requirement 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 monitor the effectiveness of the 'instructions for use and disposal' requirements and to improve the evidence base available for the risk management (if appropriate) of 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, for example 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 these 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 arrangements 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 transitional period of 5 years is justified to allow manufacturers to reformulate their products so that they achieve appropriate (bio)degradability in the environment (whilst retaining the benefits of the encapsulation technology 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 are to be synchronised with those for (bio)degradable polymers set in the EU Fertilising Products Regulation (EU 2019/1009).
- 'Microbeads' contained in detergents: 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.
- Fragrance encapsulates: a transitional arrangement of either 5 or 8 years is proposed. An 8-year transitional period would make it more likely that alternative encapsulates could be developed and implemented before entry into effect, thereby reducing the costs. On the other hand, there would be microplastic releases for three additional years. If industry did not have enough time to develop feasible alternative encapsulates within the end of the transitional period, companies would be forced to remove the polymeric encapsulates and reformulate products to increase the amount of perfume contained in them. The Dossier Submitter considers the proposed restriction proportionate for this product category both under a 5 and an 8 year transitional period. Ultimately, the decision on what transitional period is given depends on how much weight is given to the reduction of microplastic releases to the environment as compared to the associated societal costs.
- Other microplastics contained in detergents, waxes, polishes and air care products: a transitional arrangement of five years is considered appropriate to give industry sufficient time to substitute microplastics.
- 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 eight 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 as defined in Directive 93/42/EEC or in the classification rule 21 set in Annex VIII to Regulation (EU) 2017/: The measure is justified with reference to the cost effectiveness of previous restrictions for substances with similar concerns.

- Polymeric infill material for synthetic sports surfaces: The measures identified are justified with reference to the cost-effectiveness of previous restrictions for substances with similar concerns.

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 the framework of test methods and criteria for identifying biodegradable 'microplastics' will likely develop further on the basis of technical progress in this field.

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

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

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 wastewater and sludge (e.g. microbeads). For derogated uses, the proposed reporting requirement will allow information on them to be gathered and, where warranted, 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 (Safety Gate) system.

The Dossier Submitter believes that the proposed test methods and criteria for identifying biodegradable microplastics will be essential to ensure that the proposed restriction is targeted to the substances of concern and 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 five years after entry into force to see how the market has adapted to the restriction, how well biodegradable polymers perform for 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 particles containing solid polymer, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 0.1µm ≤ *x* ≤ 5mm, or (ii) a length of 0.3µm ≤ *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. Single molecules are not particles. d. 'particles containing solid polymer' means either (i) particles of any composition with a continuous solid polymer surface coating of any thickness or (ii) particles of any composition with a solid polymer content of ≥ 1% w/w. e. 'solid' means a substance or a mixture which does not meet the definitions of liquid or gas. f. 'gas' means a substance which (i) at 50 °C has a vapour pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at 20 °C at a standard pressure of 101.3 kPa. g. 'liquid' means a substance or mixture which (i) at 50 °C has a vapour pressure of not more than 300 kPa (3 bar); (ii) is not completely gaseous at 20 °C and at a standard pressure of 101.3 kPa; and (iii) which has a melting point or initial melting point of 20 °C or less at a standard pressure of 101.3 kPa; or (b) fulfilling the criteria in ASTM D 4359-90; or (c) the fluidity test (penetrometer test) in section 2.3.4 of Annex A of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). 3. Paragraph 2a and 2b shall not apply to:

	a. Natural polymers (as defined in REACH Guidance on monomers and polymers) that have not been chemically modified (as defined in REACH Article 3(40)). b. Polymers that are biodegradable, according to the criteria in Appendix X. c. Polymers with a solubility > 2 g/L, according to the criteria in Appendix Y. 4. Paragraph 1 shall not apply to the placing on the market of: a. Substances or mixtures containing microplastics for use at industrial sites. b. Medicinal products for human or veterinary use as defined in EU Directives 2001/83/EC and 2001/82/EC[6]. c. Substances or mixtures that are regulated in the EU under Regulation (EC) No. 2019/1009 on Fertilising Products. d. Substances or mixtures containing food additives as defined in EU Regulation (EC) No. 1333/2008. e. *In vitro* diagnostic devices. f. Sewage sludge (as defined in Directive 86/278/EEC) and compost. g. Food and feed. h. *[OPTION A: granular infill used on synthetic sports surfaces where risk management measures are used to ensure that annual releases of microplastic do not exceed 7g/m^2]* 5. Paragraph 1 shall not apply to the placing on the market of: a. Substances or mixtures containing microplastic where the microplastic is contained by technical means to prevent releases to the environment during end use. b. Substances or mixtures containing microplastic where the physical properties of the microplastic are permanently modified during end use, such that the polymers no longer fulfil the meaning of a microplastic given in paragraph 2(a). c. Substances or mixtures containing microplastics where microplastics are permanently incorporated into a solid matrix during end use. 6. Paragraph 1 shall apply from: a. EiF for cosmetic products (as defined in Article 2(1)(a) of Regulation (EC) No 1223/2009) and other substances or mixtures containing microbeads.

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

	b. EiF + 6 years for medical devices as defined in Directive 93/42/EEC or in the classification rule 21 set in Annex VIII to Regulation (EU) 2017/745. c. EiF + 4 years for 'rinse-off' cosmetic products (as defined in Regulation (EC) No 1223/2009) not already included in paragraph 6(a). d. EiF + *[5/8]* years for the encapsulation of fragrances in detergents (as defined in Regulation (EC) No 648/2004), cosmetic products (as defined in Regulation (EC) No 1223/2009) or other mixtures. e. EiF + 5 years for detergents (as defined in Regulation (EC) No 648/2004), waxes, polishes and air care products not already included in paragraphs 6(a) or 6(d). f. EiF + 5 years for fertilising products not regulated in the EU as fertilising products under Regulation (EC) No 2019/1009 that do not meet the requirements for biodegradability contained in that Regulation. g. EiF + 8 years for plant protection products as defined in Regulation (EC) No 1107/2009 and biocides as defined in Regulation (EU) 528/2012. h. EiF + 5 years for other agricultural and horticultural uses including seed treatments. i. EiF + 6 years for 'leave-on' cosmetic products (as defined in Regulation (EC) No 1223/2009). *j. [Either* *i. EiF + 3 years for granular infill used on synthetic sports surfaces (if 4(h) retained – <u>OPTION A</u>) or,* *ii. EiF + 6 years for granular infill used on synthetic sports surfaces (if 4(h) not retained– <u>OPTION B</u>)]* 7. From [EiF + 24 months] any supplier[7] of a substance or mixture containing a microplastic derogated from paragraph 1 on the basis of paragraphs 4(a), 4(b), 4(d), 4(e) or 5 shall ensure that, where applicable, either the label and/or SDS and/or 'instructions for use' (IFU) and/or 'package leaflet' provides, in addition to that required by other relevant legislation, any relevant instructions for use to avoid releases of microplastic to the environment, including at the waste life-cycle stage. The instructions shall be clearly visible, legible and indelible. Instructions may be in the form of pictograms.

[7] According to REACH definition in article 3(32), a supplier means "manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture".

	Where written instructions are given, these shall be in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. In addition, any supplier of a substance or mixture containing a microplastic derogated from paragraph 1 on the basis of paragraph 4(a) shall identify, where applicable, either on the label and/or SDS and/or 'instructions for use' (IFU) and/or 'package leaflet' that (i) the substance or mixture is subject to the conditions of this restriction (ii) the quantity (or concentration) of microplastic in the substance or mixture and (iii) sufficient information on the polymer(s) contained in the substance or mixture for downstream users or suppliers to comply with paragraph 8. 8. From [EiF + 36 months], any [industrial] downstream user using microplastic(s) derogated from paragraph 1 on the basis of paragraph 4(a) shall send to ECHA in the format required by Article 111 of REACH, by 31 January of each calendar year: a) a description of the use(s) of microplastic in the previous calendar year, b) For each use, generic information on the identity of the polymer(s) used, c) For each use, an estimate of the quantity of microplastic released to the environment in the previous calendar year. Any supplier placing a microplastic derogated from paragraph 1 on the market for the first time for a professional or consumer end use allowed on the basis of paragraphs 4(b), 4(d), 4(e), or 5 shall send to ECHA in the format required by Article 111 of REACH, by 31 January of each calendar year: d) a description of the intended end use(s) of microplastic placed on the market in the previous calendar year, e) For each intended end use, generic information on the identity of the polymer(s) placed on the market, f) For each intended end use, an estimate of the quantity of microplastic released to the environment in the previous calendar year. ECHA shall publish a report summarising the information received by 30 June every year.

Note: In the event that the proposed restriction is added to Annex XVII of REACH Appendix X and Appendix Y will be an appendix to Annex XVII. The details of Appendix X and Appendix Y can currently be found in Table 22 and Table 23, respectively, in Section 2.2.1.6 of this document.

Report

1 Problem analysis

1.1 Background

1.1.1 'Microplastic' concern

The concern associated with 'microplastic' particles stems 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 susceptible 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.
- fragment into smaller and smaller particles in the environment, 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 in the scientific literature conclude with the observation that contamination will continue to increase into the foreseeable future with the result that exposure is therefore largely unavoidable and likely to increase in magnitude in the future.

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, 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 microplastics 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 detrimental effects of microplastics, including intentionally-added microplastics, but provides 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[8] of products that intentionally contain them[9].

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[10], 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 the assessment were to consider:

a) How microplastics that are intentionally-added to products should be appropriately identified (definition) in a regulatory context, 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 material used in sports pitches).

The microplastics concern is not limited to the pollution of the marine environment, although the increased awareness of the occurrence of plastic litter in the marine environment over recent years has undoubtedly raised awareness of the potential impacts of microplastics, both for scientists and policy makers. In addition to the literature of the occurrence of microplastics in the marine environment, microplastic particles have been reported to have been found in treated and untreated sewage

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

[9] 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.

[10] The terms primary and secondary microplastics are used inconsistently 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 here considered to be secondary microplastics.

effluent (wastewater), sewage sludge (that is often applied to agricultural land as biosolids), freshwater as well as 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. The terminology 'microplastic' is used by the Dossier Submitter throughout this report, as well as in the conditions of the proposal restriction. However, the Dossier Submitter acknowledges that the term itself is potentially misleading and does not necessarily need to be used in the conditions of a restriction listed in Annex XVII of REACH.

The Dossier Submitter notes 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 small (typically microscopic) solid particles in the environment, and which is resistant to (bio)degradation, should be considered to be consistent with the concerns associated with the term 'microplastic'.

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

1.1.2 Request to develop an Annex XV restriction proposal

The request from the Commission was received by ECHA on 9 November 2017[11] 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.

[11] Entered into the ROI on 17 January 2018; and was submitted on 11 January 2019.

- 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.
- 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[12] and professional[13] 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[14] 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 therefore be considered as a rather broad starting point.

The 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.

The Commission's choice to address the intentional use of microplastics by means of a restriction under the REACH regulation was part of the recently published 'European strategy for plastics in a circular economy', often simply referred to as the 'plastics strategy',[15] that included a raft of both legislative and non-legislative initiatives to address plastic pollution and the long-term sustainability of plastic use in the EU, whilst also fostering growth and innovation[16].

As a REACH restriction was specifically identified in the plastics strategy, the assessment of other novel union wide legislative risk management options (RMOs), e.g. the relative merits of an EU Directive on intentionally added microplastics, were not specifically considered as it was presumed that during the development of the plastics strategy due consideration was given to the most appropriate means to effectively achieve each of its

[12] 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.

[13] 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.

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

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

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

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

Nevertheless, the relative merits of the proposed restriction have been compared with risk management via existing union-wide legislation, such as the Water Framework Directive (WFD), Marine Strategy Framework Directive (MSFD), and the Urban Wastewater Treatment Directive (UWWTD), as per the requirements of Annex XV. This is outlined in further detail in Section 2.1 of this report and in the Annex.

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 EU Member States have not yet taken action with regard to the microplastics concern.

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

Country	Ban on manufacture	Ban on placing on the market	Regulatory action overview
Belgium			Plan to ban plastic particles (microbeads) in all rinse-off cosmetic products and toothpastes by 2019.
Denmark		X	Plan to ban the placing on the market of rinse-off cosmetic products containing microplastics. Microplastics are defined as plastic in a solid state that are less or equal to 5 mm in all dimensions and that are insoluble in water, and that do not meet the criteria of being easily biodegradable according to OECD Test Guideline 301. TRIS consultation: Q3-2019
France		X	Ban the placing on the market of rinse-off cosmetic products for exfoliation or cleaning that contain solid plastic particles (define as microbeads smaller than 5 mm made of plastic in whole or in part, obtained by a hot-shaping process). Exemption for particles of natural origins (i) not persisting in the environment, (ii) not releasing active or biologic substance, (iii) not affecting animal food chain Entry into force: 1 January 2018
France		X	Plan to ban the placing on the market of substances or mixtures containing microplastics in concentration above 0.01%. Transitional periods are proposed for different product types (MD, IVD, cosmetics, detergents, other products type). In addition, the sites manufacturing, using and transporting plastic pellets (nurdles) shall be equipped and have procedures in place to avoid the loss of plastic pellets into the environment. Draft law – expected entry into force January 2024
Ireland	X	X	Plan to prohibit the manufacture and use of certain products containing plastic microbeads (rinse-off cosmetic products and household cleaning products). Public consultation in 2018. Not yet in force.

Country	Ban on manufacture	Ban on placing on the market	Regulatory action overview
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 by the Dossier Submitter

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.
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

Country	Ban on manufacture	Ban on placing on the market	Regulatory action overview
			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 13 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. Furthermore, it 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[17].

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.

1.1.5.2 Scientific Advice Mechanism (SAM)

The EU Commission's Group of Chief Scientific Advisors[18] decided at its 12th meeting (27 April 2018) to launch work leading to scientific advice on microplastic pollution based on

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

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

a review of scientific evidence by SAPEA. The Group of Chief Scientific Advisors adopted an Initial Statement on the subject on 9 July 2018 during its plenary meeting in Toulouse[19]. The Scientific Advisors planned to deliver an Explanatory Note to the Commission before the end of 2018 based on a SAPEA scientific evidence review report, and a Scientific Opinion in 2019[20].

The Dossier Submitter co-operated with the EU SAM throughout the development of this report.

1.1.5.3 EU funded scientific research projects

Significant research efforts are being expended in order to further the understanding of 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)[21], 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)[22]:

- 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 five-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.

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

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

[20] SAPEA published an 'evidence review report' on microplastics in nature and society in January 2019.

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

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

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[23]. 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 implemented (or proposed) regulations in different countries (or jurisdictions within countries) to address the microplastic concern (for examples see Annex A).

In some instances the terms 'microbead' and 'microplastic' are used 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 use for exfoliating, scrubbing or polishing, although it is noteworthy that the English regulations use the term microbead without specifying its function[24].

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."

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

[24] 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.

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, some use variations of the REACH polymer definition, whilst others list specific polymers (e.g. polyethylene). It is worthwhile to note that the REACH definition of polymer covers both natural 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 have reflected on how to appropriately define the term 'microplastic', resulting in a host 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 either specified a size criterion of < 5 mm in one dimension, in all dimensions or not specified a dimension. The upper limit of 5 mm 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 solely on (eco)toxicological considerations. Nevertheless, a size limit of 5 mm 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).

Polymer solubility [in water] was discussed at length during the preparation of the proposal (detailed in the Annex XV report[25] as well as in the note published prior to the submission of the Annex XV report on 'substance identification and the potential scope of a restriction on uses of microplastics'[26]). Polymers that are soluble are not typically

[25] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73

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

consistent with microplastics.

Whilst solubility is an intuitive criterion used in many other definitions of microplastics, including definitions in EU Member State legislation, the Dossier Submitter considered that a solubility criterion would not be straightforward to implement. For example, polymers may appear to be dissolved in a solvent but are in fact present as a 'dispersion' of microscopic or nanosized particles suspended in the solvent. Equally, 'soluble' polymers may be bound to solid carrier particles via chemical reaction(s).

Therefore, the Dossier Submitter initially concluded that 'solubility' [in water] would not be used as a criterion to describe a microplastic but that, instead, the concept of the presence of a solid particle would be emphasised, as this was more relevant to the microplastic concern. The Dossier Submitter considered that as a polymer that was not present as a solid particle would not be a microplastic then this was, to all intents and purposes, equivalent to derogating 'soluble' polymers. However, during the opinion-making phase this rationale was revisited and a derogation for polymers with water solubility greater than 2 g/L was included as an additional derogation from the restriction. Further justification for this revision is provided in Section 2.2.1.1.

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 introduced 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. The definition has been updated based on the consultation on the Annex XV proposal during RAC/SEAC opinion development. Further details are outlined in Section 2.2.1.1 and in Annex B.

- **'microplastic'** means a particles containing solid polymer, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 1nm ≤ *x* ≤ 5 mm, or (ii) a length of 3nm ≤ *x* ≤ 15 mm and length to diameter ratio of > 3. Natural polymers that have not been chemically modified are excluded, as are polymers that are (bio)degradable or have a water solubility > 2 g/L.
- **'microbead'** means a microplastic used in a mixture as an abrasive i.e. to exfoliate, polish or clean.
- **'polymer'** means a substance within the meaning of Article 3(5) of Regulation (EC) No 1907/2006 (REACH).
- **'particle'** is a minute piece of matter with defined physical boundaries; a defined physical boundary is an interface. Single molecules are not particles.
- **'particles containing solid polymer'** means either (i) a particle of any composition with a continuous solid polymer surface coating of any thickness or (ii) a particle of any composition with a solid 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 ºC has a vapour pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at 20 ºC at a standard pressure of 101.3 kPa.
- '**liquid**' means a substance or mixture which (i) at 50 oC has a vapour pressure of not more than 300 kPa (3 bar); (ii) is not completely gaseous at 20 oC and at a standard pressure of 101.3 kPa; and (iii) which has a melting point or initial melting point of 20 oC or less at a standard pressure of 101.3 kPa; or (b) fulfilling the criteria in ASTM D 4359-90; or (c) the fluidity test (penetrometer test) in section 2.3.4 of Annex A of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).

When deriving the relevant size range of particles that should be considered as microplastics (i.e. particles consistent with the microplastic concern) the Dossier Submitter has concluded that particles between 1nm and 5mm (3nm and 15mm for fibre-like particles) are microplastics. However, this consideration is different from setting an appropriate scope for a restriction under REACH, which must also take into account issues of practically (including the availability of analytical methods for enforcement) and legal certainty. For this reason the Dossier Submitter has proposed a size range of 100nm to 5mm for particles (and 300nm and 15mm for fibre-like particles) in the conditions of the restriction. The practicality of the proposed restriction is elaborated in Section 2.6.

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 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. Therefore, the Dossier Submitter does not differentiate between organic and inorganic polymers within the regulatory definition of 'microplastic'. It should be noted that REACH Article 3(5) does not make a differentiation between different polymers either.

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, literature searches or the consultation on the Annex XV report. 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 a 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 (waxes, polishes and air care products[27]) to provide a range of functions, including as abrasives, fragrance encapsulations, opacifying agents and anti-foam agents. They can be used e.g. in surface cleaning products, fabric softeners, dishwashing liquids, waxes, polishes and air care products.

[27] Air care products cover aerosol, electric, gel and liquid air fresheners as well as scented candles and car air fresheners (in accordance with information submitted by A.I.S.E., e.g. #2382). These products are not known to be defined in any existing legislation.

Product group	Brief details of use and technical function(s)
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.
Granular infill material for synthetic sports surfaces	Microplastics are a key component of the latest generation of synthetic sports fields where they are used as infill material. They are polymeric granules usually produced from end-of-life (ELT) tyres or other synthetic elastomers.
in vitro diagnostic devices	*In vitro* diagnostic devices (IVDs) are non-invasive tests performed on biological samples (for example blood, urine or tissues). They can be used for human health applications (including medical devices IVDs covered by (EU) 2017/746 (aka IVDR)), but not only: IVDs are also used in research and development (various fields), and in veterinary and pest control applications. Microplastics, often with inorganic (e.g. iron oxide) cores and chemically functionalised surfaces, are ubiquitous as reagents, assays or calibration in IVDs and are essential in all automated IVD tests conducted worldwide. There is no overarching EU Regulation to regulate all types of IVDs. Therefore, in case a legal definition of IVDs would be needed, the Dossier Submitter proposes to define '*In vitro* diagnostic devices' as 'reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from living organisms', which is adapted from the IVD MD definition set in EU Regulation (EU) 2017/746 (aka IVDR).
Medical devices	Microplastics have various functions in medical devices (MD). Microplastics in medical devices are used as polymeric filters, adsorber and absorber granulates and in ultrasound devices. Microplastics are also frequently used in the manufacturing of IVD reagents and devices (e.g. chromatography columns used to purify antibodies). They are also present in (substance-based) medical devices used by healthcare professionals and consumers to prevent or treat oral, nasal, skin or eye conditions (e.g. toothpaste, denture adhesives, sun protection[28] etc). In (substance-based) medical devices, microplastics have similar functions to those reported for cosmetic products: i.e. gel forming agent, emulsifiers, film-forming, thickening agent. Medical devices are regulated by EU Regulation (EU) 2017/745.
Medicinal products for human and veterinary use	In medicinal products, microplastics are the backbone of many 'controlled-release' medicines: in contrast to immediate release (to the stomach), these formulations can deliver drugs with a delay after administration (delayed release), or for a prolonged period of time (extended release), or to a specific target organ in the body (targeted release). Controlled-release mechanisms allow the active substance to be protected 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, film coating, binding, filling and disintegrant function. In medicinal products, microplastics are often classified as excipients, but they can also be used as an active pharmaceutical ingredient (API).
Food additives	Similarly to the medicinal products use, microplastics are used as authorised food additives in the formulation of food supplements (e.g. vitamins) and 'food for special medical purposes' as film-coating, 'controlled-release' agent, and to 'mask/disguise' unpleasant tastes. Microplastics can also have binding, filling or disintegrant functions.
Paints, inks and other	Microplastics are an integral part of polymer dispersion binders in water-based

[28] This includes sun protection products that do not claim SPF (sun protection factor) protection on their label, and can be used to treat or prevent a medical condition according to the MDR regulation.

Sunscreen under the EU Cosmetics regulation is "any preparation intended to be placed in contact with the human skin with a view exclusively or mainly to protecting it from UV radiation by absorbing, scattering or reflecting radiation". SPF should be indicated on the label of cosmetic sunscreen.

Product group	Brief details of use and technical function(s)
coatings	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 sometimes referred to as '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 number 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 typically ranges from 0.15-2.5 mm with a relative density of > 1 000 kg/m3, indicating that particles would not float.
Adhesives	Intentionally added microplastics can be used as spacers 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.
Toners and printing inks	The toner in laser printing is typically made of granulated plastic to make the powder electrostatic. Some printing inks contain microplastics.
Substance of mixture used as toys or for arts and crafts	Microplastics are reported to be used in toys or for arts and crafts. For example, glitters, certain sequins (that are not articles) and modelling clays.
Bulk IER for water purification	Professional and consumer uses reported where the IER (Ion Exchange Resins) would be placed on the market in bulk, and would not be contained in a closed cartridge or envelop.
Substance or mixture used for glass sheet transportation	Used between panes of sheet glass for protection during transportation.

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 is based on a comprehensive structured literature screening.

Numerous comprehensive assessments of the (eco)toxicity of microplastics have been published in recent years, such as those reported by the 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[29] published 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[30]. This review has been conducted independently from the assessment presented in this report and should be considered as complementary to it. With regard to the environmental exposure and risk assessment, SAPEA (2019) concludes that "while ecological risks are very rare at present for 'microplastics', there are at least some locations in coastal waters and sediments where ecological risks might currently exist. If future emissions to the environment remain constant, or increase, the ecological risks may be widespread within a century."

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, 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 a predicted no-effect concentration (PNEC) and a quantitative risk characterisation (PEC/PNEC or RCR approach),

2. PBT/vPvB perspective (non-threshold approach), and

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

A 'case-by-case'[31] 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.

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

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

[31] According to Annex I para 0.10 to 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 CSR-IR 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.

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 between 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[32], which resulted in the identification of around 900 articles relevant in some respect to the risk assessment of microplastics (e.g. 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 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. More details can be found in Annex C.

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.

SAPEA (2019) reach a similar conclusion: "The number of papers is growing exponentially in this field, but knowledge is not. (…)[The Members of the working group] conclude that there is a need for improved quality and international harmonisation of the methods used to assess exposure, fate and effects [of microplastics] on biota and humans. We have a fair knowledge of microplastic concentrations for freshwaters and the ocean surface, but little is known about air and soil compartments and about concentrations and implications of NMPs [nano- and microplastics] below the ocean

[32] 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

surface."

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 into the environment (Figure 1):

- ***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 an overlap occurs, e.g. where product packaging disposed of in municipal solid waste leads to wastewater releases through the washing of shredded material during recycling. An overview of how releases are apportioned between the three principal pathways are given in Table 7 for each of the sectors/product groups that have been assessed. In certain cases, only a single pathway is relevant, whilst in others releases can occur as a consequence of multiple pathways. Different pathways can be relatively more or less important depending on how a product is used and subsequently disposed. There are significant differences between different categories of cosmetic products, for example, as some are rinsed off with water when used (e.g. facial scrubs, shower gels), whilst others may be removed with a tissue or wipe that is disposed of in a bin. In the latter case, individual consumer behaviour will influence via which pathway releases will occur (as tissues can also be disposed on in a toilet)Table 7 does not provide information on the magnitude of the releases that occur from each of the sectors/product groups. The information is provided in subsequent sections of the report.

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 to which they are likely to be subjected 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 '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 an evaluation of the 'effectiveness' of certain consumer behaviours and waste management practises to prevent or minimise releases of intentionally added microplastics to the environment.

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.

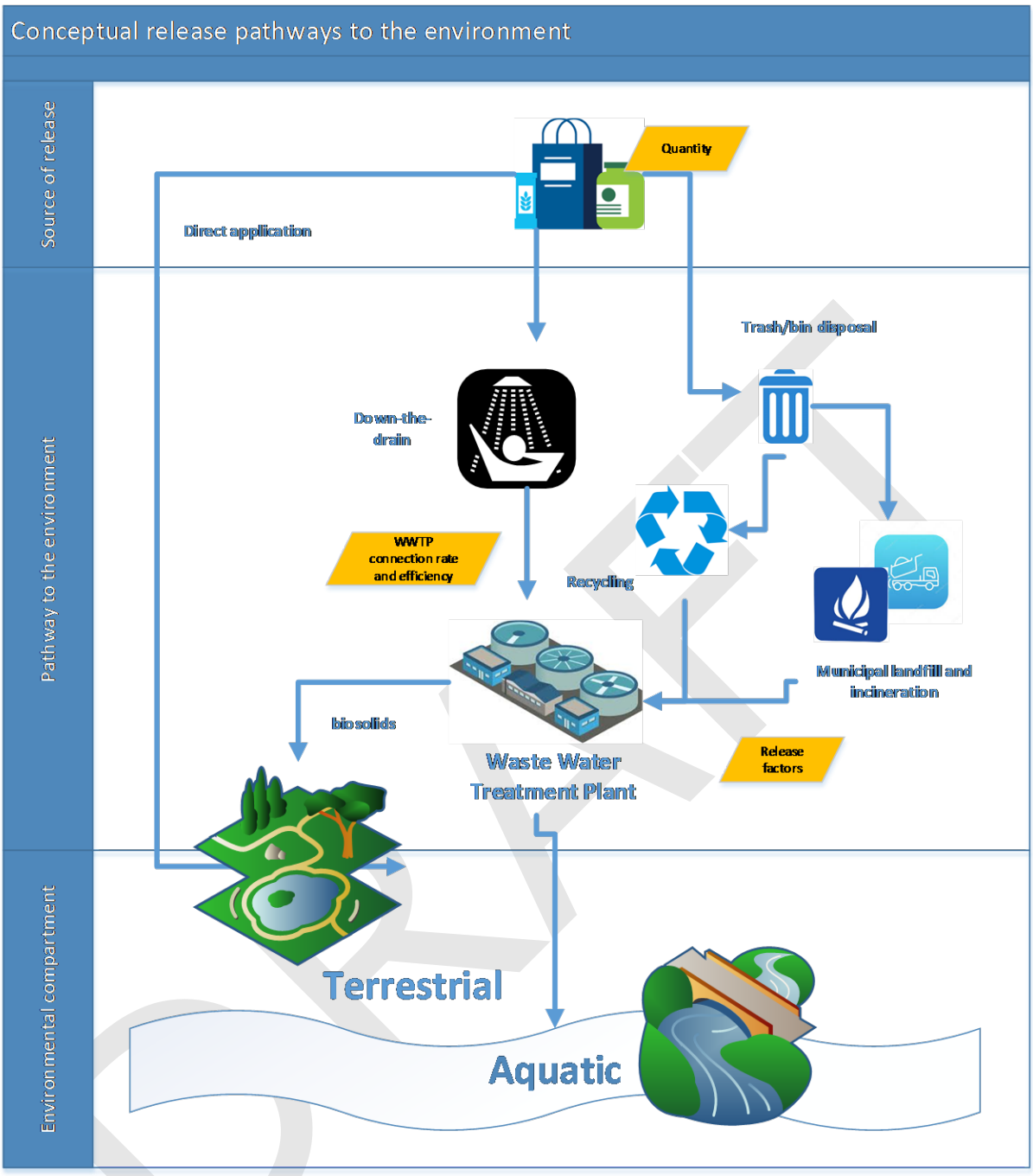


Figure 1 Conceptual source, pathway, receptor relationships for microplastics used in consumer and professional products.

Table 7 Relative proportion of microplastic releases via each of the three principal pathways to the environment for the sectors/product groups assessed.

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	55%[i]	45%	-
Detergents and maintenance	-	-	-
- Polymeric fragrance encapsulates	100%	-	-
- Other microplastics contained in detergents	100%	-	-
- Waxes, polishes and air care products[d]	67%	-	33%
Agriculture and horticulture	-	-	-
- Controlled release fertilisers	-	-	100%
- Fertiliser additives	-	-	100%
- Treated seeds	-	-	100%
- Capsule suspension PPPs/biocides	-	-	100%
Infill material	~15%	-	~85%
Oil and gas	-	-	100%[f]
Paints and coatings[e]	-	-	-
- Consumer uses	100%	-	-
- Professional uses	100%		
***In vitro* diagnostic devices**[h]			
- Analytical and purification chemistry	-	-	-
- Reagents, assays and calibration for human health applications	10%	14%	
- Reagents, assays and calibration for veterinary applications	15-20%	15-20%	
Medical devices (MD)[j]			
- (substance-based) medical devices (SB-MD)	50%	50%	-
- Medical devices (other than substance-based MD)	-	-	-
Medicinal products and food additives[g]	95%	5%	-

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: it is assumed that 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. The same assumptions could be made for the food additives. See Annex D for further information.
h: during use, microplastics are essentially contained in equipment or cartridge and treated as hazardous waste/incinerated at their end of life. Only a portion of the microplastics used would be discarded as municipal solid waste or down the drain. 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 a toilet) the following leave on products, as follows: skin care – 81%, sun/tanning products - 88%, make-up and lipstick– 33%, deodorant/antiperspirant products – 93%, nail varnish/remover – 28%, hair styling & other – 95% (Consultation on Annex XV report, #2220). Other studies show higher share of DTD releases. In addition, it was assumed the 5% of cosmetic products are disposed of in MSW without use.

Sector / Product group	Percentage of overall release to each pathway		
	DTD[a]	MSW[b]	DRE[c]
j: On one hand, in MD applications (other than SB-MD), microplastics are contained in equipment without direct release to the environment (e.g. polymeric filters, adsorber and absorber granulates for blood treatment in critical and intensive care, and ultrasound transducers). On the other hand, for SB-MD (e.g. tooth paste, skin treatment), their modes of release are expected to be similar to the one from cosmetic products: hence the same proportion of release is assumed for DTD and MSW pathway. See Annex D for further information.			

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. In a study, 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 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 preliminary wastewater treatment is less often studied compared to other stages of the treatment train and thus it is less well characterised with respect to fate and behaviour of microplastics.

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 primary and secondary wastewater treatment processes are engineered to remove particulates from wastewater (usually termed as suspended solids). Tertiary treatment technologies, however, are usually focussed on 'polishing' effluent quality in terms of specific parameters, such as to remove nutrients or disinfect effluents. Depending on the type of tertiary treatment used it may or may not be effective in removing microplastics from effluents.

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) reports a median concentration of microplastics in dewatered sludge sampled from five WWTWs (wastewater treatment works) 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.

The considered studies were categorised using criteria such as 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[33]) 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 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 also 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

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

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 'intentionally 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 during wastewater treatment derived 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).

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) 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% (25th to 75th percentile) based on mass and 93.7 to 93.8% based on number of particles. The authors consider that the greater removal efficiency observed when removal was estimated based on mass could be as larger particles (that contribute predominantly to the overall mass) are more efficiently removed during primary settling than smaller ones. In general, a higher fraction of smaller particles were observed in treated effluent compared to influent, which was proposed to be either a consequence of different removal rates depending on particle size or the fragmentation of larger particles during treatment. The authors report that the removal efficiency of different polymers was similar.

Ziajahromi et al. (2017) were 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 (%) used in the down-the-drain release pathway assessment

Treatment type	Microplastic retention (%)	References
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	

Notes – retention is expressed relative to influent concentrations not the preceding treatment step.

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 was obtained from Eurostat[34].

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% or 14% of releases to the environment via the down-the-drain 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.

[34] 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 Member State (MS)	
Estimate of the quantity of microplastics released to wastewater per year in MS	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 combined sewer overflow 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' (both terms used in Eurostat reporting) 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 released 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

Element	Details
3:http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=env_ww_spd&lang=en	

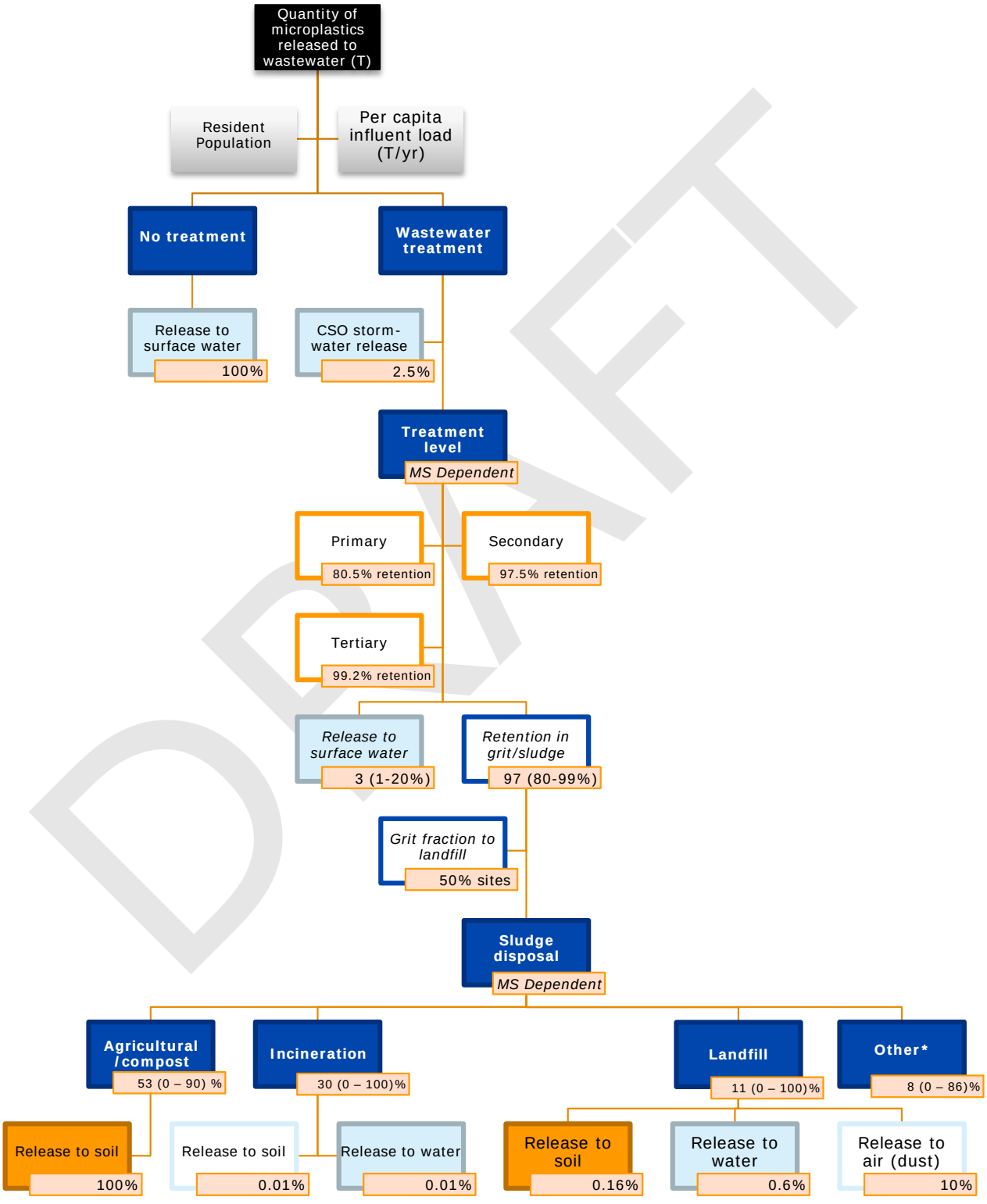


Figure 2 Summary of the down-the-drain release pathway

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).

In addition to releases to air, water and soil from landfill and incineration, the Dossier Submitter 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 disposed of unused in packaging). Releases are assumed to occur via the shredding and washing processes common to plastics recycling operations. Releases to the environment through 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 (because 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

Quantity of waste in EU disposed by different routes in 2014
<table>
<tr><th>Incineration (incl. energy recovery</th><th>Landfill (incl. backfill)</th><th>Other</th></tr>
<tr><td>139 million t/y</td><td>208 million t/y</td><td>13 million t/y</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>

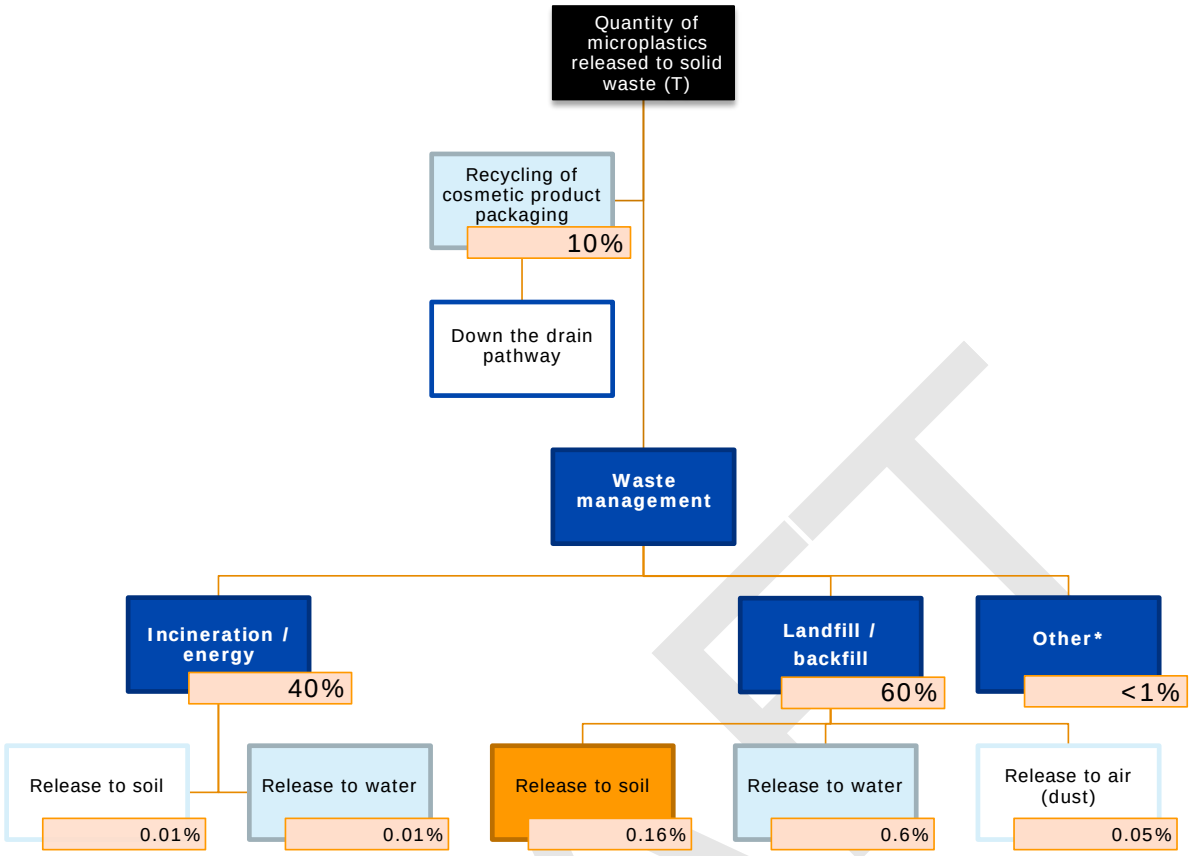


Figure 3 Summary of the municipal solid waste release pathway

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.

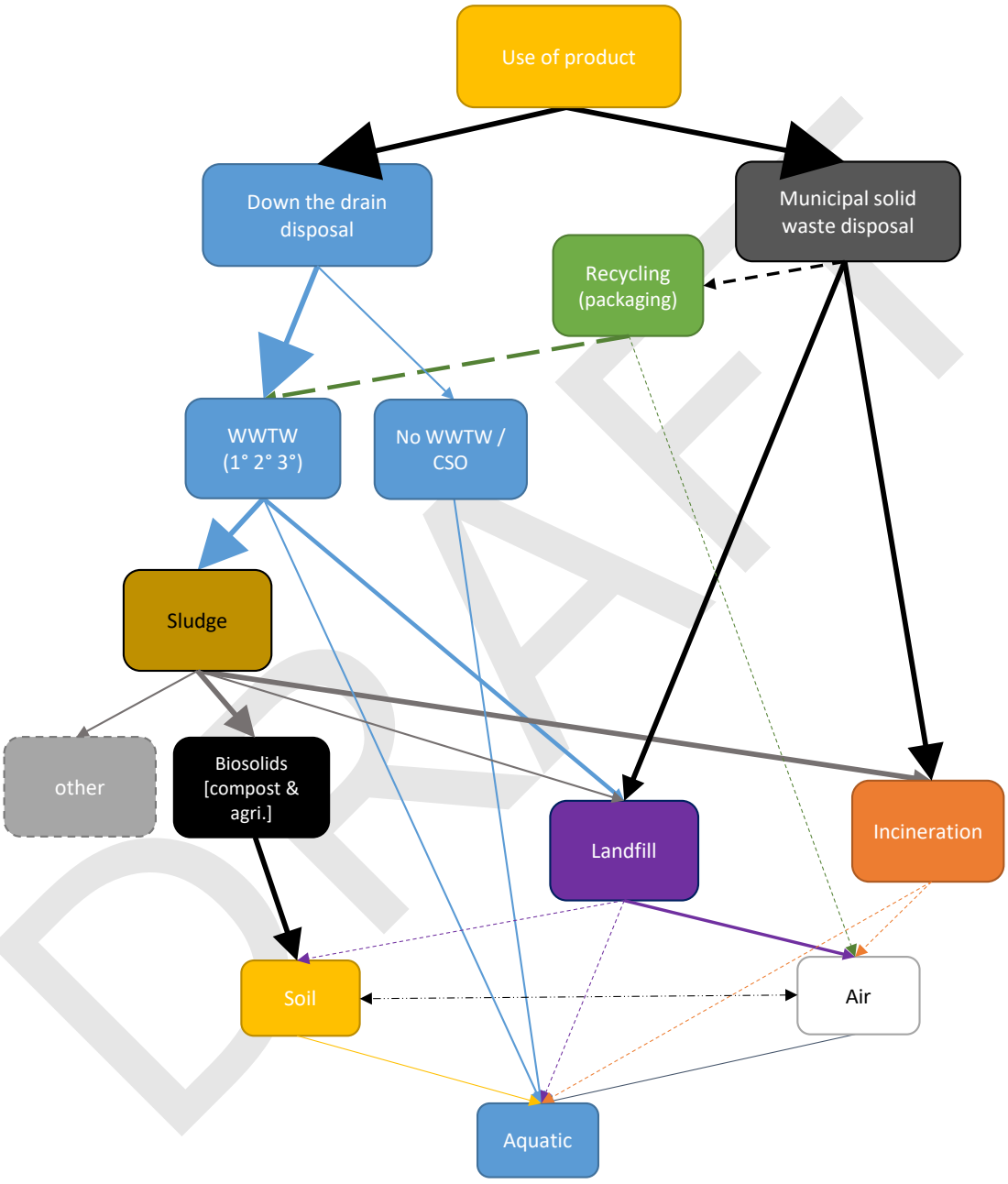


Figure 4 Mass flow of microplastics from leave on cosmetic products after disposal down-the-drain or in municipal solid waste.

1.4.3 Environmental fate and behaviour

Once released to environmental compartments (air, soil, aquatic) microplastics will be subject to transport and degradation (i.e. fragmentation) and so some extent biodegradation processes. Microplastics are themselves sources of secondary microplastics, releasing progressively smaller particles due to embrittlement, abrasion or fragmentation , theoretically including nanoplastics (GESAMP, 2015, Koelmans et al., 2015, Koelmans et al., 2017b). The mechanisms and rate of degradation and biodegradation of microplastics in the environment are discussed further in Section 1.4.6.

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 'Conventional' (eco)toxicological risk assessment

1.4.4.1 Classification and labelling

Not applicable.

1.4.4.2 Summary of scientific and grey literature

This section of the Background Document 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. Detailed information is also available in the Annex C to the Background Document.

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[35]. 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

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

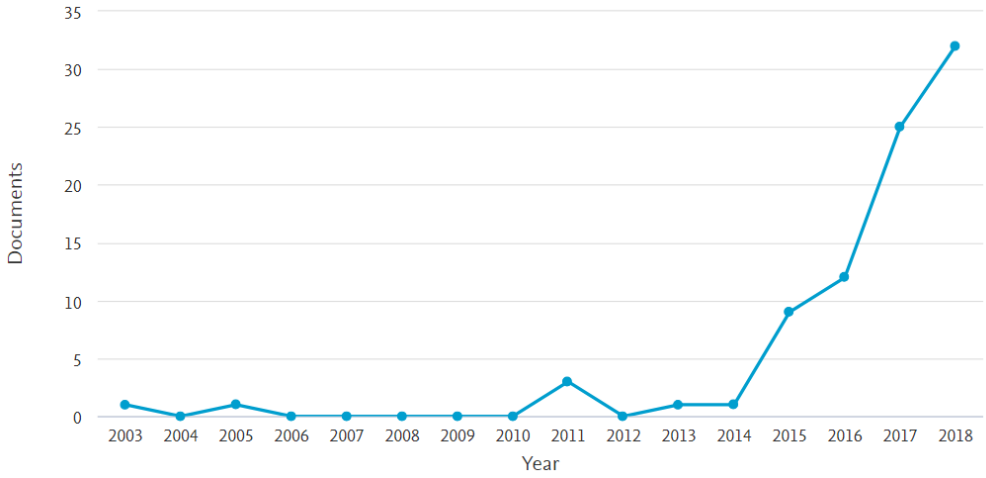


Figure 5. Number of review articles published since 2003, based on the search term 'microplastic' in Scopus in October 2018

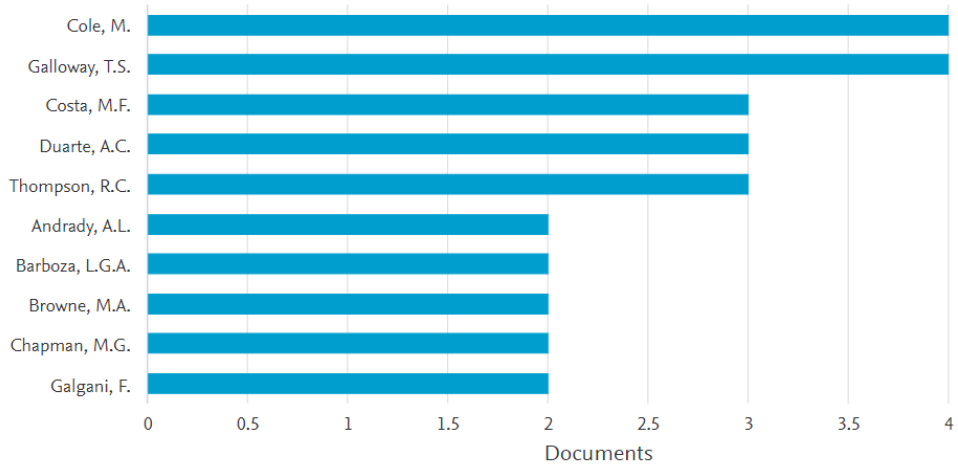


Figure 6. Top 10 authors publishing review articles in the area of microplastics

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[36].

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

[36] 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[37]. 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 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 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).

[37] 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.

1.4.4.4 Influential articles

The top 25 'influential articles' on the (eco)toxicity of microplastics were identified from the literature[38]. 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
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

[38] 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
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[39]. 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 1 g 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 microplastics tested by Zhu et al. (2018a) is similar to the microplastic concentration that has been reported in some sewage sludge (Danish Environmental Protection

[39] 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).

Agency, 2017).

Not all studies report effects on terrestrial organisms as a result of 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	$6.9 \times 10^{-9} – 2 \times 10^{5}$	0.02 - 400
		Brackish	23.5	0.04 – 0.1	$6.9 \times 10^{-9} – 1.8 \times 10^{4}$	0.4 - 313
		Marine	-	-	$9.1 \times 10^{-3} – 2.5 \times 10^{3}$	2×10^{-3} - 510
	Nano	Fresh	4 - 36	0.5 – 1.6	$4.5 – 1 \times 10^{3}$	0.5 - 1
		Brackish	0.2 – 2.2	-	-	1 - 313
		Marine	0.8 – 3.9	13	0.1 - 250	10 - 100
Sediment/food (g.kg DW)	Micro	Fresh	-	-	-	700
		Brackish	-	-	-	-
		Marine	-	-	0.1 - 100	0.3 - 100
	Nano	Fresh	-	-	1	-
		Brackish	-	-	-	-
		Marine	-	-	-	-

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 of 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 (SSD) together with an assessment factor of 5. The HC5 is the concentration which causes a toxic effect in five percent of the species in the SSD. 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 1.67 µg/L (95% confidence interval of 0.086 to 32.6 µg/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 0.85. 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 magnitude factor of 380, emphasising the uncertainty in the estimates.

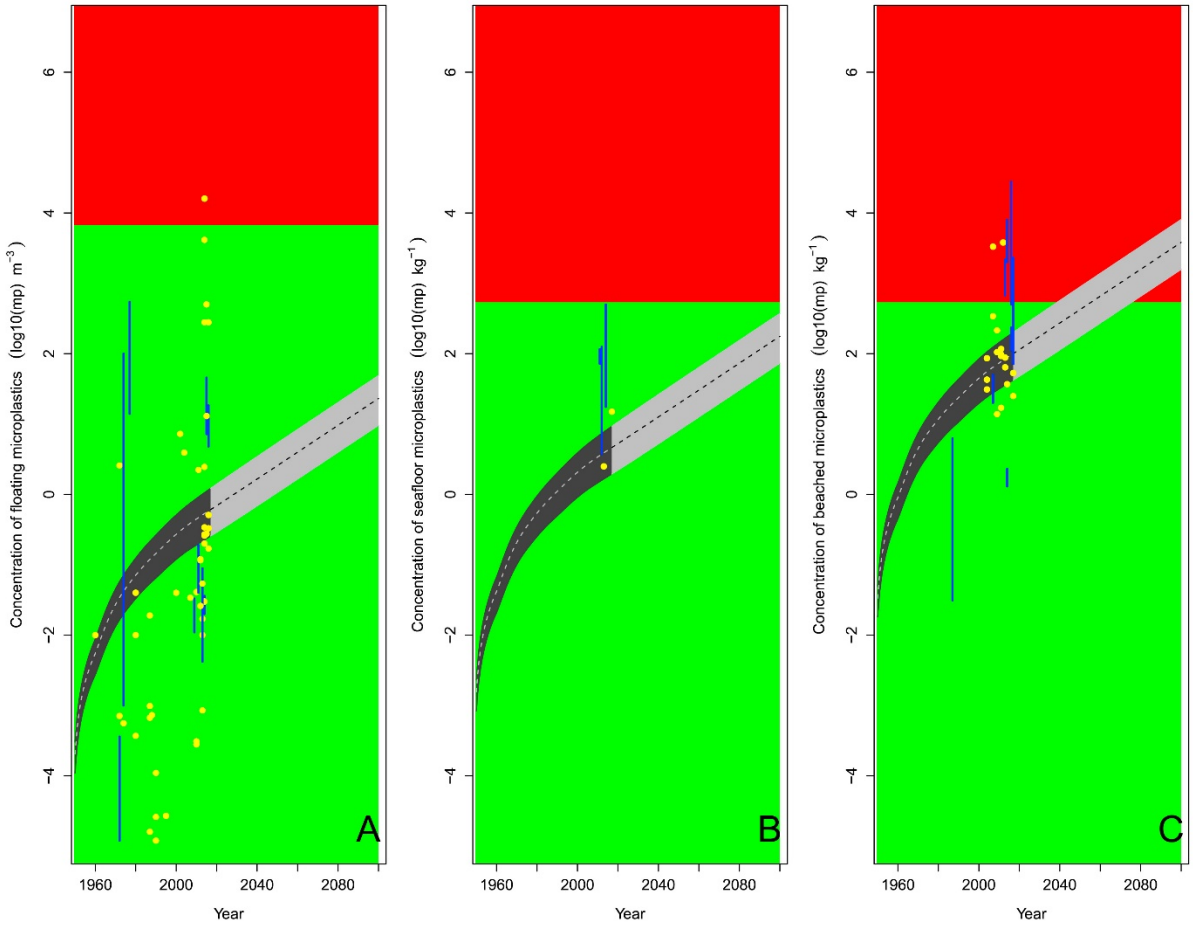
The corresponding HC5 value for nanoplastic was 5.4 µg/L (95% confidence interval from 0.93 to 31 mg/L, R^2 value of 0.93). The curve was comprised of data from 10 species from five taxonomic groups (one rotifer, four crustaceans, three algae, one echinoderm and one amphibian).

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 0.33 µg/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 the most sensitive species. Should the PSS value of 0.33 µg/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.

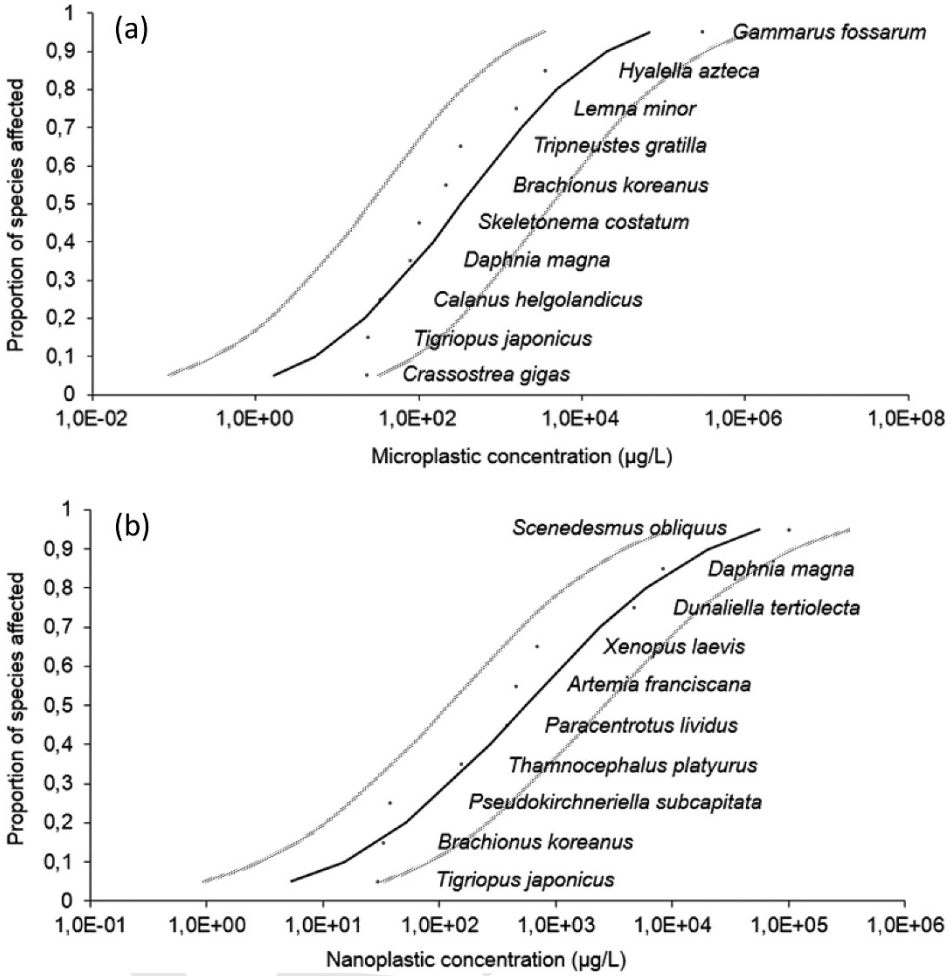
The conventional approach to threshold derivation in the absence of the extensive ecotoxicity datasets necessary for robust application of SSDs would be to apply assessment factors to the most sensitive reliable and relevant NOEC/EC10 value from the ecotoxicity dataset, with the size of the factor dependent on the scale of the residual uncertainty (typically ranging from 10 to 1 000 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. (2018), 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 >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

Another potential hazard of microplastics has been attributed to hydrophobic organic contaminants (HOCs) or metals adsorbed/absorbed onto microplastic particles which are released after ingestion.".

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, whilst there is 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 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 that could be elicited in response to exposure to microplastics, and by which mechanisms these arise; particularly after long-term exposure to environmentally-relevant 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) appears to be less significant than initially considered (Koelmans et al., 2016), understanding the role of plastic additives (such as fillers, UV stabilisers and plasticisers) with regard 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 (documented in REACH Guidance) required for a conventional chemical safety assessment. 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 cause adverse effects (Everaert et al., 2018, Besseling et al., 2018). Given the persistent nature of microplastics (without potential for remediation) it is clear that the scale of these effects, should they be occurring, will 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 exposure 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 quantify 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 absorption 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 to human health) 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 the risks posed by microplastics. Therefore, the absence of a definitive conclusion on risk should not be interpreted as evidence that risks are not occurring now, or would not occur in the future. As discussed, there is already some evidence that the tentative threshold concentrations proposed by some authors may already be exceeded in the environment at hot spot locations, 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.

Quantitative risk assessment approaches based on the derivation of ‘no effect’ thresholds, irrespective of the application of assessment/safety factors, may not be appropriate to assess the risks posed by micro and nanoplastics.

On the basis of the considerations above, the risk assessment of microplastics by means of the application of quantitative risk assessment is not considered to be appropriate or practicable. In this respect, microplastics are similar to PBT/vPvB substances that are not assessed under REACH using ‘no effect’ thresholds.

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 substances may lead to an impact 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 undertake a classical PBT/vPvB assessment for microplastics as, based on the currently available information, the criteria in REACH Annex XIII may not be applicable to microplastics. Specifically, the concept of bioaccumulation and biomagnification, established on a molecular level, may not be satisfied by polymer particles despite evidence that microplastics are present in top predators and can be subject to trophic transfer (Lohmann, 2017). On this basis, the risk assessment of microplastics by means of the application of the REACH PBT/vPvB assessment approach is not considered to be appropriate or practicable.

Nevertheless, non-biodegradable microplastics will readily meet the criteria for very persistent substances outlined in Annex XIII to REACH, having half-lives of several hundred years or more. This combination of 'extreme' persistence in the environment, potential for trophic transfer and evidence of adverse effects if ingested, whilst not strictly consistent with the Annex XIII criteria, suggests that the obligation established under REACH to minimise releases of PBT/vPvB substances to environmental compartments throughout the life-cycle of the substance should be equally applicable to uses of microplastics, despite uncertainties surrounding the bioaccumulation and toxicity properties of these substances/mixtures. This rationale is further elaborated in Section 1.4.6, below, as a 'case-by-case' risk assessment.

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 in 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 plastic 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

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[40]. 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 to REACH.

Tentative 'effect' thresholds for microplastics have been recently proposed by various

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

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

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

An important property that must also be taken into consideration for an appropriate risk assessment of microplastics is their ‘extreme’, arguably permanent, persistence in the environment. As a result, any releases contribute 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 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 contribute to 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 increasing exposure concentrations, if the use of intentionally added microplastics were to be continued. 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.

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 in the Annex XV report that in 2017 more than 51 000 (11 000 - 63 000) tonnes of microplastics were used in the EEA. Based on the responses to the consultation on the Annex XV report, the Dossier Submitter has revised the tonnage and release estimates (Table 15). The revised estimate is that 145 000 tonnes of microplastics are currently used per year with a lower and upper range of 35 000 to 256 000 tonnes, respectively. The increase in use tonnage relative to the Annex XV report is due to the explicit inclusion of the quantities of polymeric granular infill that is used on synthetic sports surfaces. The total use volume excluding granular infill is 45 000, with a lower and upper range of 20 000 to 71 000 tonnes, respectively. The use volume in agriculture that falls into the scope of this restriction[41] has been reduced compared to the Annex XV report (to 10 000 tonnes from an initial estimate of 23 500 tonnes), whilst the tonnage in detergents and maintenance products has increased (to 17 000 tonnes from an initial estimate of 9 700 tonnes).

Around 30% of the total volume of microplastics are subsequently emitted to the EEA environment. If synthetic infill material is excluded from these estimates then around 60% of the quantities of intentionally used microplastics are released to the 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

[41] This reduction is based on information provided by Fertilizers Europe indicating that 95% of fertilising products marketed in the EU are to be CE-marked and hence would fall already under the microplastics ban set up by the Fertilising Product Regulation (EC) 2019/1009.

allowed quantification. Table 15 summarises the baseline situation.

Table 15 Summary of microplastic use volumes and quantities released to the environment

Sector / Product group	**Use [a] (tonnes/year)**	**Release to the environment [b] (tonnes/year)**
Cosmetic products	8 700 (4 100 – 13 100)	3 800 (1 800 – 5 900)
- Rinse-off containing microbeads (exfoliators/cleansers)[c] - Other rinse-off - Leave-on	107 6 500 (2 900 – 10 000) 2 100 (1 100 – 3 000)	55 3 100 (1 400 – 4 900) 600 (300 – 900)
Detergents and maintenance	17 000 (11 100 – 23 000)	8 500 (5 600 – 11 600)
- Microbeads contained in detergents[c] - Fragrance encapsulation - Other microplastics contained in detergents - Waxes, polishes and air care products	95 400 (260 – 540) 15 200 (9 440 – 20 960) 1 300	50 200 (0 – 150) 7 700 (4 800 – 10 650) 585
Agriculture and horticulture	10 000 (3 500 – 18 000)	10 000 (3 500 – 18 000)
- Controlled release fertilisers - Fertiliser additives - Treated seeds - Capsule suspension PPPs	5 000 (1 000 – 10 000) 4 000 (2 000 – 6 000) 500 (250 – 1 000) 500 (250 – 1 000)	5 000 (1 000 – 10 000) 4 000 (2 000 – 6 000) 500 (250 – 1 000) 500 (250 – 1 000)
Oil and gas	1 200 (300 – 2 000)	270 (~0 – 550)
Paints and coatings [d]	5 300 (10 200)	2 700 (5 200)
- Consumer uses - Professional uses	5 300 (4 900)	2 700 (2 500)
Construction products	Not known	Not known
In vitro diagnostic devices [e]	50 (0.5 – 100)	0.27 (0.25 – 0.29)
Medical devices (MD)		
- (substance-based) MD - MD other than (substance-based)	Not known ~10	Not known -
Medicinal products	2 300 (800 – 3 700)	1 100 (400 – 1 800)
- Ion exchange resins - Matrix or polymer film for controlled release - Immediate release	700 (300 – 1 000) 1 600 (500 – 2 700) Not known	300 (100 – 500) 800 (300 – 1 300) Not known
Food additives	Not known	Not known
Infill material for synthetic sports surfaces[f]	100 000[g] (15 400 – 184 800)	16 000 (2 000 – 52 000)
Total (excluding infill material)[g]	**44 600 (19 800 – 70 000)**	**26 400 (11 200 – 43 000)**
Total (including infill material)[g]	**144 500 (35 200 – 254 800)**	**42 400 (13 200 – 95 000)**

Notes:
[a] Releases via down-the-drain (wastewater), municipal solid waste (trash/bin) and/or direct application/deposition to soil pathways;
[b] eventual release to the environment;
[c] represents values for 2017. The use is expected to be phased out by 2020 and therefore the restriction is not expected to have an impact on the use and emissions;
[d] most microplastics in paints and coatings will be bound in a solid matrix (film) once correctly applied, however a residue on brushes/rollers is assumed to be disposed down the drain. The tonnage reported in the table represents the quantity disposed down the drain[e]
[e] during use, microplastics are typically contained in equipment or cartridges and treated as hazardous

waste/incinerated at their end of life, hence the limited release to the environment;
[f] Assumes 21 000 full-sized and 72 000 small-sized pitches in the EU by 2020;
[g] All figures are rounded so may not add up precisely to the totals presented.

A recent project initiated by the European Commission estimated the scale of annual releases of secondary microplastics emitted to EU surface waters (Eunomia, 2018). The Eunomia 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). The comparison between primary and secondary microplastic emissions emphasize that, despite much higher annual releases of microplastics from unintentional sources to surface waters, the quantity of intentionally added microplastics estimated to be released to the environment per year is not insignificant, particularly when the 'stock' effects of microplastics are considered.

One 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.[42] 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 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% (lower bound: 0.1%; upper bound: 0.5%) of the total plastic waste that is disposed without proper control in the EU28+ in 2016 (see Figure 9).

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

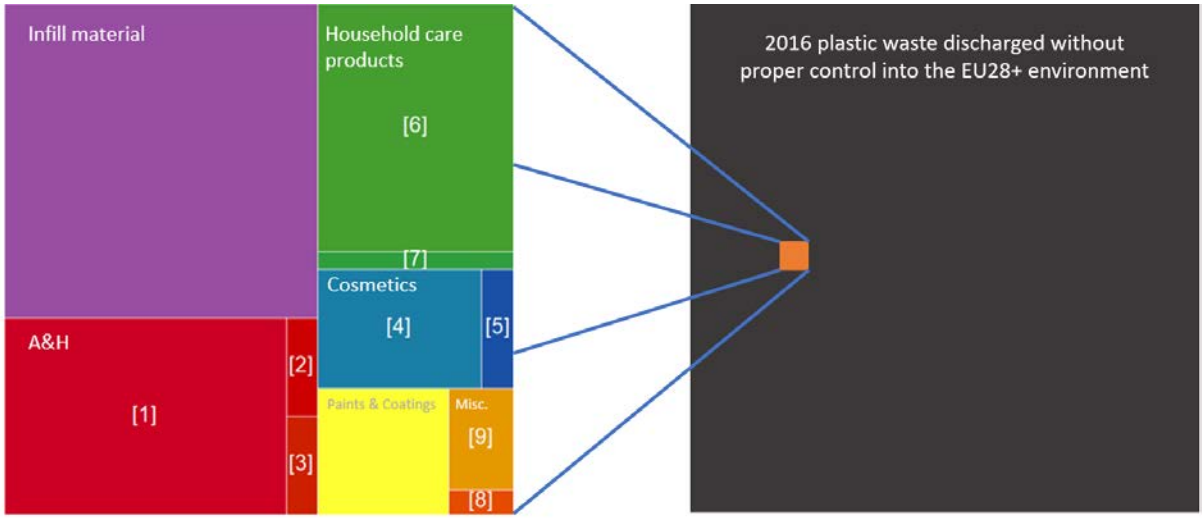


Figure 9 Weight-based comparison of microplastics to overall plastic waste; [1] Fertilising products, [2] PPPs, [3] Coated seeds, [4] Rinse-off cosmetics, [5] Leave-on cosmetics, [6] Detergents, [7] Waxes, [8] Oil & Gas, [9] Medicinal uses.

An additional, and perhaps more relevant, illustration can be made by expressing the release estimate of 42 400 tonnes of microplastics per year in terms of the microplastic fraction of a oceanic plastic garbage patch. 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)[43]. Using the relative proportions of plastics across different size classes reported for the GPGP, the microplastics in scope of this restriction (estimated based on the data reported in Lebreton et al. (2018) to be comprised of 11.5 trillion particles) can be estimated to correspond to a weight of plastic waste of 524 kilotonnes, which corresponds to 6.65 times the total weight of the GPGP (79 kilotonnes).

1.6.2 Use and emission forecast

The future use and emissions of microplastics will depend on several factors, such as demand and supply conditions as well as planned regulatory changes, which are often unique to each of the sectors within the scope of the proposed restriction. The baseline scenario presented in Table 15 takes into account existing trends (e.g., as a result of a voluntary phase out of microbeads use in some rinse-off cosmetics and detergents) as well as planned regulatory changes under the EU Fertilising Products Regulation (FPR). It further considers the work of two opposing influences:

[43] Lebreton et al. (2018) estimate 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 42 400 tonnes of microplastics in the scope of this restriction correspond to 11.5 trillion microplastic particles. Given the composition of the GPGP, this suggests a garbage patch more than 6 times larger than the GPGP. Crucially, the comparison assumes that plastic litter is of the same composition as the GPGP, which is the result of more than 70 years of degradation and fragmentation.

- 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[44] 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 of and concern over microplastic emissions to the environment.

As it is challenging to estimate the impact of awareness on future use of microplastics, it is assumed that the downward trend is equal in size but opposite to the upward trend due to increasing demand. The result of this assumption is that no discernible net changes in microplastic emissions are expected from 2020 through to 2040 (the temporal scope of the Dossier Submitter's analysis); i.e., without a restriction in place the intentional use of microplastics is expected to exceed 145 kilotonnes annually (ranging from 35 kilotonnes to 255 kilotonnes per year under the Low and High tonnage scenarios for uses with quantitative information).[45]

Corresponding use volumes for the different sectors in the baseline year 2017 are shown in Table 15. It is however important to recall that this represents the status quo which is likely to change even without the proposed restriction. Annex D elaborates further on the assumptions for the Low, Central and High use scenarios and discusses the uncertainties and their impact on the effectiveness of the proposed restriction.

Future emissions of intentionally added microplastics will depend on future use trends 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, a forecast of the emissions from products (incl. infill material) containing intentionally added microplastics can be made over the 20-year period after the restriction enters into force. In the central case, it is assumed that in the absence of the proposed restriction microplastic emissions will remain at 2020 levels for five years when the ban on polymeric material in EU-marketed fertilising products will enter into effect. Thereafter, the expected annual emissions would go down to about 34 kilotonnes. Over the entire analytical period microplastic emissions of approximately 720 kilotonnes would be expected from the uses identified without a restriction (see Figure 10). Evidently, such a long-term forecast is associated with relatively large uncertainties. These are likely to be captured in the Low and High tonnage scenarios which predict that cumulative releases to the environment could range from 220 kilotonnes to 1.61 megatonnes.

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

[45] This ignores any other regulatory measures to tackle the microplastics problem.

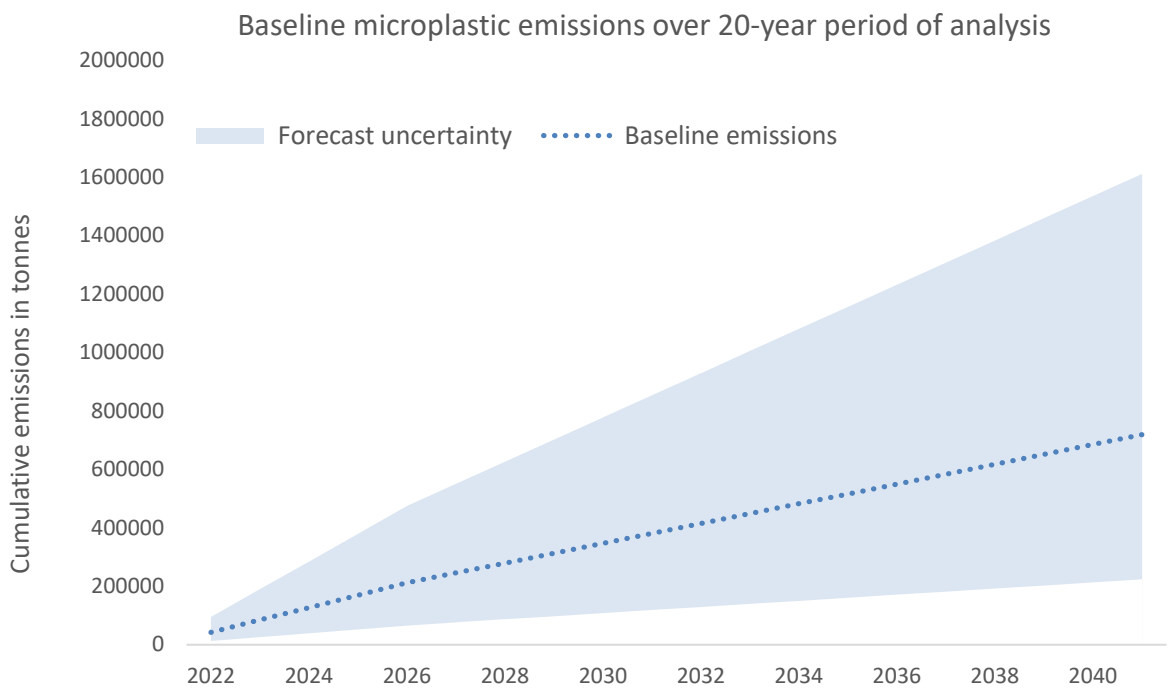


Figure 10 Microplastic emissions under the baseline scenario (cumulative, 20-year analytical period)

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 1.4.4.12, 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 option for addressing the identified risks, including various permutations of a REACH restriction.

The Dossier Submitter notes that the Commission's choice to address the intentional use of microplastics by means of a restriction under the REACH regulation was part of the recently published 'European strategy for plastics in a circular economy', often simply referred to as the 'plastics strategy'[46] that included a raft of both legislative and non-legislative initiatives to address plastic pollution and the long-term sustainability of plastic use in the EU, whilst also fostering growth and innovation[47].

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

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

In addition, the Dossier Submitter compared the relative merits of the proposed restriction with risk management via **existing** union-wide legislation, such as the Water Framework Directive (WFD), Marine Strategy Framework Directive (MSFD), and the

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

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

Urban Wastewater Treatment Directive (UWWTD), as per the requirements of Annex XV of REACH.

In a first step, the possibility was examined to address the risks posed by microplastics with other REACH regulatory measures and existing or proposed Union-wide legislation and other possible Union-wide RMOs. Whilst it was recognised, and taken into account when developing the scope of the proposed restriction, that some existing or proposed EU legislation or other measures could have an impact on the risk management of certain sectors—FPR—these were deemed inappropriate to address *all* of the sectors and products identified to be contributing to risk that is not adequately controlled.

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 'contains microplastics'** – *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 only** - *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 only (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 maximum size** (1mm) - *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 only** – *restriction on thermoform and thermoset organic polymer 'plastics' only (> 0.01% w/w)*;

Each of these options was assessed against the three main criteria for a restriction identified in Annex XV of REACH: effectiveness, practicality and monitorability.

As a result of this assessment, the restriction option presented in Section 2.2 Table 17 is proposed, whilst those summarised in Table 16 below were discarded. The detailed rationale for not proposing the discarded restriction options is presented in Annex D. In summary, the restriction proposed in 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 in Section 2.2 Table 17)

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

Notes: (+) increase related to the proposed restriction option; (-) decrease related to the proposed restriction option; (=) equal to the proposed restriction option; (?) unclear effect; 1:assumes that industry highlighted all significant uses during the Dossier preparation process.

2.2 Restriction scenario

Brief title: Restriction on intentionally-added microplastics.

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 particles containing solid polymer, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 0.1µm ≤ *x* ≤ 5mm, or (ii) a length of 0.3µm ≤ *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. Single molecules are not particles. d. 'particles containing solid polymer' means either (i) a particle of any composition with a continuous solid polymer surface coating of any thickness or (ii) particles of any composition with a solid polymer content of ≥ 1% w/w.

	e. 'solid' means a substance or a mixture which does not meet the definitions of liquid or gas. f. 'gas' means a substance which (i) at 50 °C has a vapour pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at 20 °C at a standard pressure of 101.3 kPa. g. 'liquid' means a substance or mixture which (i) at 50 °C has a vapour pressure of not more than 300 kPa (3 bar); (ii) is not completely gaseous at 20 °C and at a standard pressure of 101.3 kPa; and (iii) which has a melting point or initial melting point of 20 °C or less at a standard pressure of 101.3 kPa; or (b) fulfilling the criteria in ASTM D 4359-90; or (c) the fluidity test (penetrometer test) in section 2.3.4 of Annex A of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). 3. Paragraph 2a and 2b shall not apply to: a. Natural polymers (as defined in REACH Guidance on monomers and polymers) that have not been chemically modified (as defined in REACH Article 3(40)). b. Polymers that are (bio)degradable, according to the criteria in Appendix X. c. Polymers with a solubility > 2 g/L, according to the criteria in Appendix Y. 4. Paragraph 1 shall not apply to the placing on the market of: a. Substances or mixtures containing microplastics for use at industrial sites. b. Medicinal products for human or veterinary use as defined in EU Directives 2001/83/EC and 2001/82/EC[48]. c. Substances or mixtures that are regulated in the EU under Regulation (EC) No. 2019/1009 on Fertilising Products. d. Substances or mixtures containing food additives as defined in EU Regulation (EC) No. 1333/2008. e. *In vitro* diagnostic devices. f. Sewage sludge (as defined in Directive 86/278/EEC) and compost. g. Food and feed.

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

	h. *[OPTION A: granular infill used on synthetic sports surfaces where risk management measures are used to ensure that annual releases of microplastic do not exceed 7g/m^2]* 5. Paragraph 1 shall not apply to the placing on the market of: a. Substances or mixtures containing microplastic where the microplastic is contained by technical means to prevent releases to the environment during end use. b. Substances or mixtures containing microplastic where the physical properties of the microplastic are permanently modified during end use, such that the polymers no longer fulfil the meaning of a microplastic given in paragraph 2(a). c. Substances or mixtures containing microplastics where microplastics are permanently incorporated into a solid matrix during end use. 6. Paragraph 1 shall apply from: a. EiF for cosmetic products (as defined in Article 2(1)(a) of Regulation (EC) No 1223/2009) and other substances or mixtures containing microbeads. b. EiF + 6 years for medical devices as defined in Directive 93/42/EEC or in the classification rule 21 set in Annex VIII to Regulation (EU) 2017/745. c. EiF + 4 years for 'rinse-off' cosmetic products (as defined in Regulation (EC) No 1223/2009) not already included in paragraph 6(a). d. EiF + *[5/8]* years for the encapsulation of fragrances in detergents (as defined in Regulation (EC) No 648/2004), cosmetic products (as defined in Regulation (EC) No 1223/2009) or other mixtures. e. EiF + 5 years for detergents (as defined in Regulation (EC) No 648/2004), waxes, polishes and air care products not already included in paragraphs 6(a) or 6(d). f. EiF + 5 years for fertilising products not regulated in the EU as fertilising products under Regulation (EC) No 2019/1009 that do not meet the requirements for biodegradability contained in that Regulation. g. EiF + 8 years for plant protection products as defined in Regulation (EC) No 1107/2009 and biocides as defined in Regulation (EU) 528/2012. h. EiF + 5 years for other agricultural and horticultural uses including seed treatments. i. EiF + 6 years for 'leave-on' cosmetic products (as defined in Regulation (EC) No 1223/2009).

	j. [Either *i. EiF + 3 years for granular infill used on synthetic sports surfaces (if 4(h) retained – <u>OPTION A</u>) or,* *ii. EiF + 6 years for granular infill used on synthetic sports surfaces (if 4(h) not retained– <u>OPTION B</u>)]* 7. From [EiF + 24 months] any supplier[49] of a substance or mixture containing a microplastic derogated from paragraph 1 on the basis of paragraphs 4(a), 4(b), 4(d), 4(e) or 5 shall ensure that, where applicable, either the label and/or SDS and/or 'instructions for use' (IFU) and/or 'package leaflet' provides, in addition to that required by other relevant legislation, any relevant instructions for use to avoid releases of microplastic to the environment, including at the waste life-cycle stage. The instructions shall be clearly visible, legible and indelible. Instructions may be in the form of pictograms. Where written instructions are given, these shall be in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. In addition, any supplier of a substance or mixture containing a microplastic derogated from paragraph 1 on the basis of paragraph 4(a) shall identify, where applicable, either on the label and/or SDS and/or 'instructions for use' (IFU) and/or 'package leaflet' that (i) the substance or mixture is subject to the conditions of this restriction (ii) the quantity (or concentration) of microplastic in the substance or mixture and (iii) sufficient information on the polymer(s) contained in the substance or mixture for downstream users or suppliers to comply with paragraph 8. 8. From [EiF + 36 months], any [industrial] downstream user using microplastic(s) derogated from paragraph 1 on the basis of paragraph 4(a) shall send to ECHA in the format required by Article 111 of REACH, by 31 January of each calendar year: a) a description of the use(s) of microplastic in the previous calendar year, b) For each use, generic information on the identity of the polymer(s) used, c) For each use, an estimate of the quantity of microplastic released to the environment in the previous calendar year. Any supplier placing a microplastic derogated from paragraph 1 on the market for the first time for a professional or consumer end use

[49] According to REACH definition in article 3(32), a supplier means "manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture".

	allowed on the basis of paragraphs 4(b), 4(d), 4(e), or 5 shall send to ECHA in the format required by Article 111 of REACH, by 31 January of each calendar year: d) a description of the intended end use(s) of microplastic placed on the market in the previous calendar year, e) For each intended end use, generic information on the identity of the polymer(s) placed on the market, f) For each intended end use, an estimate of the quantity of microplastic released to the environment in the previous calendar year. ECHA shall publish a report summarising the information received by 30 June every year.

Note: Appendix X can be found in Table 22 in Section 2.2.1.6; Appendix Y can be found in Section 2.2.1.7

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. It 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 transitional period assessed as necessary to avoid disproportionate socio-economic impacts (see Annex D). Moreover, a review of substitution progress is proposed for certain uses (see Section 4).

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

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 E 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 hosted a stakeholder 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[50] and in conjunction with the Micro2018 international conference

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

on microplastics in November 2018[51].

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

The consultation on the proposal received 477 responses. As part of the consultation, several additional uses of intentionally added microplastics were identified by respondents to the consultation; e.g. the use as packaging material for plate glass. The impact of the proposed restriction on these uses are discussed in the Annex to the Background Document in Section D.14.

Therefore, on the basis of the available information and the analysis conducted for this proposal, the Dossier Submitter considers that the scope of the restriction is justified, despite its inclusive nature. If, despite the extensive efforts to identify additional uses, the proposal were to capture a use that had not been previously identified and assessed, the Dossier Submitter considers that the impact to society would likely be limited. This conclusion is based on the limited examples of legitimately new uses that were identified during the consultation and the fact that some were industrial uses that are permitted to continue under the conditions of the restriction if appropriate instructions for use and disposal and reporting is undertaken. The sectors that have reported new professional and consumer uses will be invited to provide relevant information, and a socio-economic impact assessment of the proposed restriction during the SEAC draft opinion consultation. Such information will allow SEAC to consider the need or not for other restriction options than a ban from placing on the market at entry into force.

It should be recognised that the inclusive scope is also an important means to prevent novel uses of intentionally added microplastics outside of the sectors specifically assessed in this analysis.

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

The restriction applies to microplastics that are substances on their own or in mixtures. The Dossier Submitter assumes that microplastics are not articles or substances in articles, based on version 4.0 of the ECHA Substances in Articles Guidance (specifically section 2.2) that discusses manufactured solid materials[52]. 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 (a restriction on polymers in specific articles). Specifically, this relates to the status of fibres, which are currently considered in the ECHA Guidance to be articles in their own right, irrespective of the type of object that they are subsequently incorporated into (e.g. clothing). The Dossier Submitter considers that fibre-like particles (within the relevant

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

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

size dimensions identified in the proposal) are intentionally-added microplastics that should be within the scope of the restriction. Therefore, the precise conditions of the restriction may need to be revised to ensure that 'polymers in articles (with the relevant physical properties)' are included in order to specifically address intentionally added microplastics with a fibre-like morphology. Such a revision would not extend the scope of the proposed restriction as is still consistent with the intention of the Dossier Submitter and analysis reported in the Background Document and Annexes.

A blanket extension of the restriction to all polymers in articles with the relevant physical properties is not recommended as there are numerous examples of small engineered articles that would be inadvertently affected by such a restriction; e.g. in medical devices and consumer products (e.g. certain pieces of 'Lego'™).

The Commission's request was to investigate the restriction of intentionally added microplastics. However, as the wording 'intentionally added' could lead to enforcement issues, the Dossier Submitter instead has included a concentration limit to discourage intentional addition of microplastics and an exemption for industrial uses[53] (that take place at industrial sites). The Dossier Submitter considers that a concentration limit of 0.01% w/w would be appropriate to prevent intentional use. This is the concentration of microplastics that is reported to be present in a number of different product categories such as detergents, waxes and polishes as well as in fertilisers. Table 18 outlines the concentration of microplastics present in different types of products and allows the consequences of different concentration limits to be appreciated.

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	CRFs: 1-12% w/w; Anticaking agents: 0.01-5% w/w
Capsule suspension PPPs (CSPs) and treated seeds	CSPs: 0.1-6% w/w; Seed coatings: ≤4% w/w
Rinse-off cosmetic products containing microbeads (exfoliating & cleansing)	See note [A]
Other rinse-off cosmetic products	See note [A]
Leave-on cosmetic products	See note [A]
Microbeads contained in detergents	Not known
Fragrance encapsulates	>0.01% and likely to be <0.1% for a share of the products
Other microplastics contained in detergents	Median 0.73%. Reported values range from <0.01% to 26.9%.
Waxes and polishes	Median 1.14%. Reported values range from 0.03% to 14.85%.
Air care products	Median 1.6%. Reported values range from 0.56% to 32%.
Construction products (fibre-reinforcement of concrete and other adhesives)	Not known
in vitro diagnostic devices (IVD): reagents and assays	Reported values[B] range from 0.0003 -4.6%

[53] The REACH legal text differentiates between industrial and professional use [activity] in definitions 13, 25 and 35, as well as section 6 of Annex VI. In Annex XVII also the terms 'industrial installation' and activity of a 'professional outside industrial installations' are used. The Guidance R.12 on Use description (ECHA, 2015) provides a non-exhaustive list of characteristics associated with industrial sites. Further details are available in Annex D2.

in vitro diagnostic devices (IVD): calibration	Reported values[B] range from 0.001-10%
Medicinal products (Diffusion controlled systems)	Estimated[C] value range from 5 to 50% w/w in matrix-diffusion system Estimated[C] value 1-20% w/w in membrane-diffusion system (e.g. film coated tablets)
Medicinal products (Ion-exchange based controlled release)	Estimated[C] value range from 2 to 70%
Medicinal products (Osmotic systems)	Estimated[C] value 3-5% w/w
Substances or mixtures containing food additives (e.g. food supplements and medical food)	Similar to the medicinal products (Diffusion controlled systems), i.e.: Estimated[C] value range from 5 to 50% w/w in matrix-diffusion system Estimated[C] value 1-3% w/w in membrane-diffusion system (film coated tablets)
Paints and coatings	Reported concentrations range from 1% to 20%
3D printing	Not known
Toners and printing inks	Toners consist for 100% of microplastics while the microplastic concentration in printing inks would in general be above 1% to be effective (but can be up to 80%).

Notes:
[A]: According to information from the CfE and the consultation, the concentration of microplastics in cosmetic products can be as low as 0.00003% w/w and as high as 100% (e.g. glitter) with an average of 3.35% for the formulations included in the Cosmetics Europe survey. The concentration distribution is as follows: 0.5% for 1st quartile, 1.6% for 2nd, 5% for 3rd.The percentage of cosmetic products with a concentration lower than 0.01% or between 0.01% and 0.1% is not known.
[B]: According to the definition of microplastic used in the ECHA call for evidence.
[C]: Estimated values based on literature research

2.2.1.1 Regulatory definition of a microplastic (incl. revisions during the opinion making on the Annex XV proposal)

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

Further explanation is given below with regard to point 2.d on 'particles containing solid polymer'[54] as outlined in Table 17. A particle containing solid polymer 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 solid 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 solid polymer content in the particles is greater than 1% w/w, and if the other criteria in paragraph 2 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 solid 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

[54] In the Annex XV report this was referred to as a 'polymer-containing particle'. This terminology was amended by the Dossier Submitter during the opinion-making phase of the proposal in response to comments submitted in the consultation. See Annex B for further details.

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 of less importance compared to the final particles that are created by the coating application.

The Dossier Submitter concluded in the Annex XV report that the lower size limits for a microplastics particles should be 1 nm, apart for particles with a fibre-like morphology for which the lower size limit should be 3 nm. In the consultation on the proposal, stakeholders highlighted several negative implications arising from the use of 1 nm as the lower size limit, including:

a) Practical/technical difficulties in demonstrating, with sufficient reliability, that polymer particles are (or are not) present in a substance / mixture at the nanoscale; as well as their corresponding state (e.g. solid/liquid).

b) Presence of 'molecular particles' (particles comprising single molecules) at this measurement scale confounding the interpretation of particle size analysis.

c) Presence of colloidal dispersions, detergent micelles and other particles with dynamic surface structure that cannot be distinguished from solid polymer particles and soluble polymer macromolecules at the nanoscale measurement range (including aggregates) confounding the interpretation of particle size analyses at the nanoscale.

A lower limit was considered to be important for enforcement purposes as well as to provide legal certainty for actors placing products on the EU market. A limit of 1 nm was set on the basis that this was the lower limit already established by the EU nanomaterial definition (1 to 100 nm)[55]. An alternative lower limit of 1 µm was considered but excluded on the basis that microplastics particles smaller than this size are known to be widely used in products; e.g. as opacifiers, fragrance encapsulation, binder particles in latex/emulsion paints (see below).

A particle with 1 nm dimensions is equivalent to the length of three water molecules in row, or a single molecule of octane (C8). Other examples of nanoscale structures include 'carbon buckyballs' with a diameter of ~1 nm and carbon nanotubes with a diameter of ~1.3 nm. DNA has a diameter of ~2.5 nm. ATP synthase (a protein) has a diameter of ~10 nm. Certain grades of carbon black (not a REACH polymer) have been characterised as having a mean particle size distribution of 40 nm. According to information provided by the European Crop Protection Association, polymers with an estimated molecular weight of >~500 g/mol or ~35 C/N/O atoms potentially become large enough to trigger their categorisation as microplastics under the adopted lower limit of 1 nm.

Although it is technically possible for a substance to be a polymer (under REACH) at the nanoscale, e.g. <100 nm, it is not certain that such materials would be consistent with the 'microplastic concern', which is associated with particles containing solid polymers present in a network polymer matrix; possibly together with other substances (e.g. impurities from manufacture, pigments, plasticisers, etc.).

It cannot be excluded that there might be polymers in a solid state in the size range of 1-100 nm. Based on the properties of NLP ('no longer polymer') substances, polymer particles with dimensions below 100 nm may be (viscous) liquids, which would exclude them from being microplastics. However, identifying the physical state of a particle with

[55] https://ec.europa.eu/environment/chemicals/nanotech/faq/definition_en.htm

nanoscale dimensions is analytically challenging, if not impossible as standard methods have been developed for establishing bulk chemical properties.

Some of the concerns of stakeholders are addressed by the Dossier Submitter's clarification made during opinion-making that, consistent with the conclusions of the JRC[56], single molecules are not particles and thus cannot be microplastics. However, this would not address the analytical difficulties foreseen at the relevant measurement scale (as it is challenging to distinguish a polymer particle from a single molecule at the nanoscale). On this basis it appears that, if a lower limit is necessary for enforcement purposes, it may be appropriate to increase the lower size limit of the restriction from 1 nm to reduce the likelihood that potentially complex (and perhaps analytically impossible) characterisations of mixtures would be necessary to differentiate microplastics (solid polymer particles) from non-microplastic entities including liquid polymer particles, single molecules and dynamic assemblages of single molecules (e.g. detergent micelles).

Dossier Submitter has made every effort to identify uses of microplastics, in which the particles have a size < 100 nm. In general these applications are not common. However, the Dossier Submitter is aware for example of uses of polymer coated inorganic particles used in cosmetic products where some or the majority of particles are smaller than 100nm[57]. However, as the Dossier Submitter has suggested a cut-off based on a particle size distribution with 1 (w/w)% threshold, the Dossier Submitter considers that also the majority of these uses are likely to fall under the scope of the proposed restriction.

A solution to the practical difficulties of the 1 nm lower limit would be to increase the lower limit of the restriction to 100 nm to harmonise with the upper limit of the EU nanomaterial definition.

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

In addition, as noted above, it should also be remembered that, as a microplastic is defined based on a particle size distribution, substances/mixtures with particles <100 nm would still be considered microplastics if >1% of the weight of the particles was within the relevant range (i.e. 0.1 to 5 000 µm).

The Dossier Submitter concluded in the Annex XV report that 'solubility' [in water] would not be an appropriate criterion to describe a microplastic but that, instead, the concept of the presence of a solid particle would be emphasised. The Dossier Submitter considered that as a polymer that was not present as a solid particle would not be a microplastic then this was, to all intents and purposes, equivalent to derogating 'soluble'

[56] JRC (2019). An overview of concepts and terms used in the European Commission's definition of nanomaterial. JRC science for policy report. https://publications.jrc.ec.europa.eu/repository/bitstream/JRC113469/kjna29647enn.pdf

[57] SCCS opinion on Zinc oxide (nano form) COLIPA S 76, 2012, https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_103. SCCS/1518/13

polymers. However, stakeholders noted in the consultation that the consequences of a release of microplastics that would inevitably and immediately lose their particle form once in the environment (e.g. soluble polymers) are different from microplastics that would retain their particle form once released to the environment (e.g. pre-production pellets). As both of these microplastics are treated similarly under derogation 5(b), stakeholders argued that the requirements outlined in paragraphs 7 and 8 are disproportionate for soluble polymers.

The Dossier Submitter agrees with these comments and has revised the conditions of the restriction to derogate water soluble polymers from the scope of the restriction via an additional derogation in paragraph 3. It should be emphasised that a particle may lose its particle form without degradation of the polymer chains.

Stakeholders suggested that OECD 120 (solution/extraction behaviour of polymers in water) or OECD 105 (water solubility) tests could be used as the basis for such as derogation. The conditions for the testing and pass/fail criteria have been implemented as an Appendix to the restriction (Appendix Y), which is further described in the sections below.

2.2.1.2 Derogations

Specific derogations have been included in the restriction proposal where the polymers are not expected to be emitted to the environment in the form of a microplastic or in order to avoid double regulation (e.g. where there are overlaps with requirements in the FPR or for human and veterinary medicines) or on socio-economic consideration.

Table 19 Derogations from the scope of the proposed restriction

Paragraph	Derogation	Explanation
3.a	Natural polymers that have not been chemically modified.	To clarify that natural polymers, as long as their chemical structure has not been chemically modified, are exempt from the restriction as they are inherently biodegradable and therefore do not contribute to the microplastics concern. This is consistent with Annex V of REACH and the Guidance on monomers and polymers (April 2012 Version 2.0) and the Single Use Plastic Directive ((EU) 2019/904). The derogation is required to ensure that the restriction is targeted to the substances contributing to the identified risk.
3.b	Polymers that are (bio)degradable, as set out in the criteria in Appendix X.	To clarify that (bio)degradable polymers are exempt from the restriction on the basis that they do not contribute to the microplastic concern, even though they could remain in the environment for some time after use/release. The criteria are set out in an Appendix to the entry (currently referred to as Appendix X) and are described below in Section 2.2.1.6. The derogation is required to ensure that the restriction is targeted to the substances contributing to the identified risk.
3.c	Polymers with solubility > 2 g/L	To clarify that that microplastics particles that would inevitably and immediately lose their particle form once in the environment are different from microplastics that would retain their particle form once released to the environment.
4.a	Substances or mixtures containing microplastics for use at industrial sites.	This is required to prevent regulation on industrial uses as previously described. As there could be some releases of microplastics under reasonably foreseeable conditions of use the downstream users benefiting from this derogation shall be required to report the quantities used and released to the market to the Agency (paragraph 8), so the legislator can decide on any further EU

Paragraph	Derogation	Explanation
		action if needed. Instructions on appropriate use and disposal should also be communicated down the supply chain to minimise releases to the environment (paragraph 7).
4.b	Medicinal products for human or veterinary use as defined in EU Directives 2001/83/EC and 2001/82/EC.	Derogation from the scope of the restriction on use to avoid potential double regulation, and the risk to affect the availability of medicines. The Commission is also developing a strategy on pollution from medicines' uses. As there could be some releases of microplastics under reasonably foreseeable conditions of use the importers or downstream users placing medicinal products on the market, and benefiting from this derogation shall be required to report the quantities used and released to the market to the Agency (paragraph 8), so the legislator can decide on any further EU action if needed. In addition, medicinal products shall be required to communicate appropriate use and disposal instructions to minimise releases to the environment (paragraph 7). Regarding the veterinary medicinal products, the EU Directive 2001/82/EC will be repealed by Regulation (EU) 2019/6. The reference to the veterinary Regulation might therefore need to be updated.
4.c	Substances or mixtures that are regulated in the EU under Regulation (EC) No. 2019/1009 on Fertilising Products.	Complete derogation of EU regulated fertilisers from the scope of the restriction to avoid double regulation. The Fertilising Products Regulation includes provisions to phase out the use of non-biodegradable polymers in EU Fertilising Products.
4.d	Substances or mixtures containing food additives as defined in EU Regulation (EC) No. 1333/2008.	Derogation from the scope of the restriction on use to avoid potential double regulation, and market-distortion (food supplements or medical food containing food additives might be regulated by different type of legislation in EU). As there could be some releases of microplastics under reasonably foreseeable conditions of use the importers or downstream users placing products on the market containing food additives, and benefiting from this derogation shall be required to report the quantities used and released to the market to the Agency (paragraph 8), so the legislator can decide on any further EU action if needed. In addition, products shall be required to communicate appropriate use and disposal instructions to minimise releases to the environment (paragraph 7).
4.e	*In vitro* diagnostic devices (IVD).	Derogation from the scope of the restriction on use based on cost-effectiveness and socio-economic considerations. As there could be some releases of microplastics under reasonably foreseeable conditions of use the importers or downstream users placing IVD devices and components (e.g. IVD kits, calibration kits) on the market, and benefiting from this derogation shall be required to report the quantities used and released to the market to the Agency (paragraph 8). This action also sends a signal that substitution of microplastics or implementation of containment measures can be sought and encouraged without disrupting the access to IVDs. This could be made via 'voluntary' actions from the sector. In the event, the information gathered via the reporting would reveal that the voluntary measures put in place by the sector do not lead to progressive reduction of release of microplastics into the environment, further regulatory action could be initiated by the EU Commission. In addition, suppliers of products shall be required to communicate appropriate use and disposal instructions to minimise releases to the environment (paragraph 7).

Paragraph	Derogation	Explanation
		As IVDs might be used in many areas (e.g. human health, animal health, pest control, research and development field etc.), the wording of the derogation should remain generic and should not refer to in vitro diagnostics undertaken under any specific regulation. *In vitro* diagnostic devices could also be defined as "reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from living organisms".
4.f	Sludge and compost.	Complete derogation from the scope of the restriction as this was not intended to be part of the scope. Microplastics are indeed not intentionally added into sludge and composts. However, they might be present in industrial sludge and compost supplied or sold to professionals (e.g. farmers) or consumers as a result of water treatment (where microplastics will be removed from the water effluents and partition in sludge) or composting process (where secondary microplastics might be present due to the non-degradability of some composting inputs e.g. partially degradable plastics). These microplastics will be present unintentionally and it is not the intention of this restriction to prevent the placing on the market of these products.
4.g	Food and feed.	A REACH restriction can cover food and feed. As these can unintentionally contain microplastics above the specific concentration limit then it is prudent to ensure that they are specifically derogated.
[4.h]	Infill used at pitches with RMMs to achieve minimal releases.	Option A to address infill material.
5.a	Substances, mixtures or articles containing microplastic where the microplastic is contained by technical means to prevent releases to the environment during end use.	Generic derogation from the restriction for uses where OC and RMM are implemented that are appropriate to adequately control the risk from the use of microplastics. Includes a requirement that appropriate OCs and RMMs are identified on product labelling, leaflet or instructions for use (IFU). This derogation is generic but is primarily intended to cover uses of microplastics in non-industrial professional or consumer settings, including water purification applications (cartridges containing Ion Exchange Resins), continence pads, nappies or menstrual pads. Therefore, uses benefiting from this derogation shall be required to communicate appropriate use instructions to minimise releases to the environment (paragraph 7) and report the quantities used and released to the Agency (paragraph 8).
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, detergents 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).

Paragraph	Derogation	Explanation
		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. Permanence is intended to relate to the useful (service) life of the solid matrix, not the waste life-cycle stage. This would derogate certain applications of microplastics in paints/coatings and in materials used in construction (concrete and adhesive). It is not considered to apply to any use that could be considered as temporary, such as use in cosmetics. Any necessary preceding steps (e.g. mixing before the matrix becomes solid) should also be derogated from paragraph 1. However, as there could be some releases of 'uncontained' microplastics under reasonably foreseeable conditions of use (e.g. during the preparation, application and curing/setting of a solid matrix), these releases should be minimised. Therefore, uses benefiting from this derogation shall be required to communicate appropriate use instructions to minimise releases to the environment (paragraph 7) and report the quantities used and released to the market to the Agency (paragraph 8). Appropriate use instructions could include advice to avoid disposal of unused material to drains and watercourses and to clean up areas thoroughly after use.

It should be noted that with respect to the derogations from paragraph 1 described in paragraphs 5(a), 5(b) and 5(c) the Dossier Submitter assumed that all upstream uses related to the end uses of microplastics are industrial uses and would be derogated under paragraph 4(a).

2.2.1.3 Transitional periods

Paragraph 6 introduces specific transitional periods for different sectors or product types. Table 20 gives an overview of the respective Entry-into-Force (EiF) dates for various sectors or product types and an overview of the reason for the specific transition period proposed. Further information can be found in Annex D.

Table 20 Transitional arrangements for specific sectors

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.
Microbeads contained in detergents	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

Subject of transitional period	Entry into force	Examples	Reason for transition period
			use decreasing rapidly.
'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
Medical devices as defined in Directive 93/42/EEC or in the classification rule 21 set in Annex VIII to Regulation (EC) 2017/745	EiF + 6 years	(substance-based) medical devices such as: toothpaste, denture cleansing material, cream for topical application, vaginal gels, sun protection[58], etc.	Uses very similar to some cosmetics applications. To allow sufficient time to reformulate and transition to alternatives. Note that the reference to the classification rule 21 might or might not be needed. The legislator will decide about the most appropriate wording to identify this use.
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 functions other than exfoliating or cleansing	To allow sufficient time to reformulate and transition to alternatives
Polymeric fragrance encapsulates	EiF + 5/8	Laundry detergents and fabric softeners	To allow sufficient time to develop and implement alternatives
Other microplastics contained in detergents	EiF + 5	Laundry detergents, manual dishwashing liquid and automatic dishwashing detergents	To allow sufficient time to reformulate and transition to alternatives
Waxes, polishes and air care products (maintenance products)	EiF + 5	Floor polishes, air fresheners, scented candles	To allow sufficient time to reformulate and transition to alternatives
Fertilising products not regulated in the EU as fertilising products under Regulation (EC) No	EIF + 5		Time is required for development of biodegradable polymers suitable for this function; alignment with the Fertilising products regulation.

[58] This includes sun protection products that do not claim SPF (sun protection factor) protection on their label, and can justify to treat or prevent a medical condition according to the MDR regulation.

Sunscreen under the EU Cosmetics regulation is "any preparation intended to be placed in contact with the human skin with a view exclusively or mainly to protecting it from UV radiation by absorbing, scattering or reflecting radiation". SPF should be indicated on the label of cosmetic sunscreen.

Subject of transitional period	Entry into force	Examples	Reason for transition period
2019/1009 on Fertilising Products that do not meet the requirements for biodegradability contained in that Regulation.			
Plant protection products as defined in Regulation (EC) No 1107/2009 and biocides as defined in Regulation (EU) 528/2012.	EiF + 8		Time is required for development of biodegradable polymers suitable for this function and for regulatory reapproval.
Other agricultural and horticultural uses including seed treatment.	EiF + 5		Time is required for development of biodegradable polymers suitable for this function.

2.2.1.4 Instructions for use and disposal requirement (for certain derogated uses)

The 'instructions for use and disposal (IFUD) requirement' set out in paragraph 7 of the proposal (also referred to, in the Annex XV initially prepared by the Dossier Submitter, as the 'labelling' requirements') is complementary to other elements of the restriction proposal and is intended to facilitate the minimisation of release of microplastics to the environment that could occur due to downstream users (industrial or professional) or consumers adopting inappropriate or inadequate conditions of use or disposal whilst using microplastics or products containing microplastics for derogated uses i.e. uses at industrial sites or the 'end use specific' derogations set out in paragraph 5. The IFUD requirement is also intended to enhance information availability in industrial supply chains in relation to the presence of microplastics in substances and mixtures with the aim to facilitate compliance with the proposed restriction. Last but not least, some derogated uses (4a ,4b , 4d, 4e and 5) are conditional to the IFUD requirement.

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

This requirement is in line with, and aims at complementing the REACH requirements laid down in Articles 31 and 32[59] with regard to the duty to communicate information down the supply chain for substances on their own or in mixtures restricted under REACH Title VIII, as well as existing sector specific requirements (e.g. Cosmetics, Medicinal products, Medical Devices, Food additives etc…). It also clarifies the information to be communicated within the supply chain. Specifically, Article 32 requires, alongside the details of any REACH restriction imposed, that *'any other available and*

[59] Article 31 is about supply chain communication duties for substances or mixtures for which an SDS is required. Article 32 applies when an SDS is not required. In both cases, Article 31 and 32, requires either the SDS (if applicable) or the Information for safe use (if there is no SDS) to be updated once a restriction has been imposed (Article 31(9c), and 32(1c)).

relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied….'.

During the consultation on the restriction proposal multiple respondents requested clarification of the proposed IFUD requirements. In response to these comments, the Dossier Submitter has provided further details of the intention of the IFUD requirement, and its justification, below. The proposed IFUD requirements described in the Background Document are largely unchanged from those described in the original Annex XV report. However, several modifications have been proposed in response to comments received in the consultation.

In response to comments that it will be difficult for (i) formulators to know whether specific ingredients contain microplastics and (ii) to comply with the proposed reporting requirements (see Section 2.2.1.5), the Dossier Submitter has proposed to extend the IFUD requirement to oblige actors placing substances or mixtures on the market for downstream use at industrial sites (paragraph 4(a)) to clearly identify that the substance/mixture is subject to the conditions of the proposed restriction (complementing the existing REACH requirements for suppliers described in Article 31(9c) (when an SDS is needed), and Article 32(1c) (when the SDS is not applicable)) and to include on, where relevant, either the label or package leaflet or SDS or instructions for use the quantity (or concentration) of microplastics present and sufficient information on polymer identify for downstream users or suppliers to comply with the proposed reporting requirements.

The second revision relates to the proposed transitional period for this requirement after entry into force. The original proposal specified that the IFUD requirement should be satisfied 18 months after entry into force. Respondents to the consultation highlighted difficulties with the proposed duration in relation to the need to recall products with long-shelf lives that would not have the correct labelling when the restriction entered into force and that the duration would not coincide with normal product labelling update cycles, necessitating additional costs. Some sectors (such as IVD MD – human health applications) highlighted also the need to take into account the transition periods set in the 'new' IVDR: indeed some IVD MD devices, with certificates issued under the IVDD, may continue to be placed on the market until 27 May 2024 and made available until 27 May 2025.

Taking into consideration the comments received during the consultation, a longer implementation period of at least 24 months would appear to be justified, without significantly compromising the risk reduction capacity of the proposed restriction, to allow affected industrial supply chains to identify affected products, develop appropriate instructions for use and disposal whilst also increasing the likelihood that the required updates could be synchronised with already planned labelling updates, thus minimising costs.

The implementation of the IFUD requirement is fundamental to the justification for including derogations from the restriction on the placing on the market uses that could feasibly, but not inevitably, result in releases of microplastics to the environment. The IFUD requirement, obliges actors placing products containing microplastics on the market derogated from paragraph 1 on the basis of paragraphs 4(a), 4(b), 4(d), 4(e) or 5 to provide instructions for appropriate conditions of use, including appropriate waste disposal, in order to minimise the potential release of microplastics to the environment from the uses. If the IFUD requirements were not included as an element of the

restriction the Dossier Submitter would not necessarily support the derogations set out in paragraphs 4(a), 4(b), 4(d), 4(e) or 5.

The IFUD requirement is intended to cover end uses as well as preceding life-cycle steps, such as those that take place at industrial sites. The IFUD requirement does not apply to polymers that are (bio)degradable (as set out in paragraph 3(b) of the conditions of the restriction) or have solubility in water > 2 g/L (as set out in paragraph 3(c) of the proposal).

The proposal has been deliberately worded to allow flexibility in its application so that market actors have the freedom to apply the most efficient and effective means to communicate relevant information to downstream users and/or consumers given the particular circumstances of the affected substances or mixtures (including any existing sector-specific labelling obligations).

As such, the conditions of the restriction clearly state that relevant information can be provided either on a safety data sheet (SDS), package leaflet, instructions for use or on the product label itself. It is not intended that all these means of communication should be satisfied; one is considered to be sufficient to meet the proposed obligation.

In terms of SDS, the Dossier Submitter acknowledges that if a substance or mixture does not fulfil the conditions of REACH Article 31(3) then there is no requirement for an SDS. Nevertheless according to Article 32 of REACH (and sector specific Regulations), suppliers who do not need to supply an SDS still need to provide relevant information about the substance to enable appropriate risk management measures to be identified and applied e.g. an SDS can be supplied on a voluntary basis. As such, the requirements under paragraph 7 would not be different for substances/mixtures that are not required to have SDS. In this case, an SDS can be provided on a voluntary basis[60] or the other allowed forms of communicating appropriate instructions can be used instead.

If the information is included as part of the SDS, sections 2, 6, 7, 8, 13, 14, 15, 16 and/or the appended exposure scenarios may be relevant, depending on the specific circumstances. Section 15 of the SDS for 'Regulatory Information' is likely to be the appropriate place to identify that a substance or mixture is subject to the proposed restriction and provide sufficient information on the composition of the substance/mixture to allow downstream users to comply with the paragraph 8 reporting requirements.

For the cases, where the CLP Regulation does not apply (CLP Article 1(5)), the Dossier Submitter considers that pictograms, potentially developed and agreed on a sector-level, may be used in addition to, or instead of, written instructions for use or disposal if they are understandable and effective. It is acknowledged that relevant instructions for use and disposal could be usefully supplemented with additional information that is only available online. For example, QR codes, hyperlinks or any similar means of linking to online content may be an effective means of communicating relevant information to users, particularly to consumers. For example, instructional videos or where detailed information is required in multiple EU languages. In addition to the information on use provided in the SDS or leaflet or label, supply chain actors could provide additional

[60] It has been clarified that the SDS format can be used even if an SDS is not required: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Safety+data+sheet – Question 'When does a safety data sheet with annexed exposure scenario have to be provided to customers?'

information, including brochures, educational videos or raise awareness through campaigns e.g. to inform downstream users and consumers about the meaning of any new pictograms developed to comply with the requirements of the proposed restriction. It is important to note that the proposed IFUD requirement **does not** require suppliers to mention that a substance or mixture for supply to consumers (i.e. the general public) "contains microplastics".

Where appropriate instructions for use and disposal (i.e. those that minimise releases) are already indicated on the SDS OR package leaflet OR product label, no further revisions are needed by suppliers to comply with the IFUD requirement, although it is envisaged that suppliers would undertake sufficient research and/or collate documentary evidence that instructions proposed are understandable and implementable for downstream users and, where relevant, consumers as well as being effective in minimising releases (this information will also be relevant for demonstrating compliance with the reporting requirement described in paragraph 8 of the conditions of the proposed restriction, see Section 2.2.1.5).

This scenario is likely to be the case for many existing substance and mixtures, including medicinal products that, on the basis of existing EU legislation, already include appropriate instructions for the disposal of unused medication. Products regulated under the WEEE Directive are also likely to already have sufficient instructions for use and disposal to satisfy the proposed IFUD requirement.

Existing instructions for use and disposal should be updated only if they are in conflict with the aim of the restriction and lead to release of microplastics into the environment e.g. if disposal is currently recommended via wastewater.

The underlying justification for including a requirement for instructions for use is based on an understanding that they are effective tools for risk management (e.g. influencing consumer / professional behaviour) in many circumstances. The most effective means to communicate instructions for use will depend on the product type. As identified in literature, both attention and knowledge influence their effectiveness. In order to draw user attention, instructions for use must be clearly visible and convey information. Therefore, the most critical factors affecting the effectiveness of labels are their size, colour, and location as well as the use of appropriate pictorals and signal words (Laughery (2006); Laughery and Wogalter (2014)).

The more familiar and easy-to-use a product is, the less likely its instructions for use are to draw attention. In contrast, the more hazardous a product is, the more likely its users are to pay attention to the instructions for use (U.S. ENVIRONMENTAL PROTECTION AGENCY (2016)). In addition to drawing attention, instructions for use must improve knowledge by making the reader aware of the hazard, consequences and how to avoid the hazard. This could be achieved with brief explicit messages and symbols which convey meaning quickly (Laughery and Wogalter (2014)).

The results of a Eurobarometer 360 study (European Commission (2011)) aimed at understanding consumer behaviour in relation to instructions for use on products are summarised in Table 21.

Table 21 How EU citizens treat labels on chemical products. Source: European Commission (2011)

How EU citizens find out about hazards of chemical products	How often EU citizens say that they read instructions on products	How often EU citizens say that they follow the instructions once they have read them	What EU citizens say they do when they see a pictogram on an unfamiliar product that they are about to use
66% of EU citizens say they read the safety instructions, whereas 65% consult the warning symbols	50% always read the instructions to pesticides and insecticides	74% follow the instructions to pesticides and insecticides	76% read the safety instructions on the product label (with 19% of these going further by also trying to find further information from other sources)
43% say the packaging is a good way to assess a product's hazards	43% always read the instructions to 'other' cleaning products	63% follow the instructions to 'other' cleaning products and gardening products	10% say that they just use the product as they would any other product
32% say that they rely on their previous experience with the product	37% always read the instructions for gardening products	57% follow the instructions to DIY and building products	9% say spontaneously that they would not use the product
25% of respondents use information they get in the shop to help them determine the potential risks	36% read the instructions before they use DIY and building products for the first time	54% follow the instructions to car/vehicle care products	
21% use the product's smell as a guide, while 13% use information passed on by friends and family	27% always read car/vehicle care product instructions	48% follow the instructions to everyday detergents	
11% consider the type of shop that the product comes from, while 6% rely on the colour of the product	26% read the instructions that come with everyday detergents		

2.2.1.5 Reporting requirement for derogated uses

The proposed reporting requirement for derogated uses of microplastics is intended to be complementary to the requirement for suppliers[61] to provide instructions for use and disposal (described above). Together, these elements will enhance both the effectiveness and monitorability of the proposed restriction.

The specific information to be reported has been carefully re-evaluated in response to the comments submitted in the consultation. The information requested has been revised by the Dossier Submitter to maximise the availability of useful data to both companies and the Agency, whilst minimising administrative burden.

The primary justification for the reporting obligation is that despite the proposal for certain uses of microplastics to be derogated from the proposed restriction (e.g. uses at industrial sites, or the various generic 'end use' derogations outlined in paragraph 5) there is a paucity of good quality data on specific uses and their associated releases to the environment. The reporting requirement will address this data gap.

It should be kept in mind that the definition of 'use' in REACH is broad enough to capture the uses where potential releases of microplastics could occur (REACH Article 3(24)): a use is indeed defined as 'any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation'.

The information gathered will be collated and published (in an anonymised form if necessary) and will allow the effectiveness of the instructions for use requirements, as well as any sector-specific voluntary measures to minimise releases of microplastics (where these exist) to be evaluated by suppliers, downstream users, sector associations and the Agency; driving minimisation of releases over time whilst potentially identifying uses where further risk management is needed. As respondents will know their own responses, benchmarking of relative performance within a sector could also be undertaken. Equally, where releases from uses are demonstrated to be low then complete derogation from the restriction could be justified at an appropriate point in the future.

Respondents to the consultation requested clarification of the proposed reporting requirements as well as highlighted potential difficulties in implementation with respect to issues such as confidential business information (with respect to specific polymer identity) and the potential for double counting quantities of microplastics at different levels of the supply chain. The revisions to the reporting requirement made by the Dossier Submitter are intended to address the concerns raised, whilst retaining the core purpose of the reporting requirement.

As revised, the reporting requirement obliges any downstream user using a microplastics at an industrial site (i.e. under the derogation described in paragraph 4(a)) or any supplier placing a substance or mixture containing a microplastics on the market for the

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

first time[62] for an end use allowed on the basis of paragraphs 4(b), 4(d), 4(e), or 5 to report certain information to ECHA using a prescribed format[63]. Revisions to the proposal made during opinion-making now oblige uses of IVD kits 4(e) and food additives 4(d) to report information, in addition to the medicines 4(a) included in the original Annex XV proposal. To aid the interpretation of the reporting requirement the Dossier Submitter has separated and clarified the obligations for downstream users to report their own uses from the obligation of suppliers to report information about the end uses (predominantly of professionals and consumers) derogated from paragraph 1 by means of paragraph 5.

The reporting requirement would therefore apply for industrial uses (e.g. use of pellets to produce articles), but also where a substance or mixture containing microplastics is processed at an industrial site (e.g. formulation) before being supplied further down in the supply chain either to a consumer or a professional end user. It is envisaged that only the industrial formulator placing the product on the market for the first time has to comply with the reporting requirement, not retailers (even if they undertake further formulation – e.g. mixing of custom paint colours on retailer premises). Products containing microplastics which are directly exported, thus not placed on market, are not subject to the reporting requirement.

Supply chain actors are responsible for reporting the relevant information for their own operations, and the reporting obligation cannot be transferred to third-parties, such as national authorities. The Dossier Submitter envisages that existing tools, such as REACH IT, could be used, negating the need for the development of completely new IT tools. ECHA will summarise the reported data and publish it in an annual report. The reporting requirements expire when the use no longer requires the derogation to continue i.e. when a product no longer contains microplastics.

Consumers and professional users are exempted from the reporting requirements. Nevertheless, downstream users (excluding retailers) placing on the market products for consumer or professional users are required to estimate releases from these consumer and professional uses. These can be sector-specific release estimates, such as those described by spERCs. spERCs should be regularly reviewed to ensure that they are fit-for-purpose and reflect latest consumer/professional behaviour and the effectiveness of the instructions and labelling.

During the consultation, stakeholders raised concerns that the reporting requirement could result in stigmatisation of products, blacklisting or consumer pressure for reformulation. While actors across the supply chain might try to find an alternative without microplastic so that they would not be subject to the reporting requirements

[62] Article 3(12) of REACH defines 'placing on the market' as supplying or making available, whether in return for payment or free of charge, to a third party. Import is deemed to be placing on the market.

'Placing on the market for the first time' limits the scope of the restriction to the first natural or legal person who supplies or makes available substances, mixtures or articles on the market in the EU. The first placing on the market in the EU will either be by the manufacturer or the importer of the substance, mixture or article concerned.

[63] An electronic format is likely to be the most efficient means to obtain the necessary information. The electronic format will need to be designed and tested by the Agency before use (justifying a portion of the 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.

themselves, ECHA does not consider that the reporting requirements have a negative impact on the behaviour of the consumers or professionals. The annual report which is to be published by ECHA will summarise the reported information on a broader level, without disclosing any identifiers of the specific stakeholders or products.

With regard to the obligation to report ***generic information on the identity of the polymer(s) used - 8(b), 8(d)***, The Dossier Submitter considers that precise information on the identity of the polymer will not be necessary. The Dossier Submitter acknowledges the concerns raised during the consultation in relation polymer identity, namely the disclosure of confidential business information and the considerable administrative burden. Thus, taking these concerns into consideration, compliance with the 8(a), 8(d) requirement could be achieved by adopting a light-touch system that predominantly uses pick lists for polymer identity. This will allow the stakeholders subject to the reporting requirements to use the category used in suppliers safety data sheet for example (or the information provided by suppliers as part of the paragraph 7 obligations.

Reporting a ***description of the use(s) of the microplastic in the previous calendar year 8(a), 8(d)*** should be possible without requiring the disclosure of confidential business information. For reporting description of use, actors could use the existing system outlined in ECHA Guidance R12[64]. Alternatively, use descriptions could also be developed and adopted by industry sectors. As part of the development of the reporting system, and similar to polymer identify, it may be possible to standardise use descriptions and allow the use of pick-lists during reporting.

During the consultation, several stakeholders highlighted that, as proposed in the Annex XV report, reporting the ***quantity of the polymer used in the previous year*** would add a significant burden to industry, for instance in international pharmaceutical companies. Furthermore, reporting of the quantities used along the supply chain could lead to multiple reporting and therefore unrealistic high tonnage reported to ECHA.

The Dossier Submitter acknowledges this and has removed this obligation from the reporting requirements. The Dossier Submitter is now proposing that releases to the environment only are reported. This is in line with the objectives of the reporting requirement. Where releases for a certain use or sector are noted to be high then further research on the quantities of microplastics uses could be undertaken.

With regard to ***reporting quantity of microplastics released to the environment, either estimated or measured in the previous year 8(c) & 8(f)***, the Dossier Submitter considers that the standard methodologies for exposure assessment of chemicals, e.g. including the use of default values i.e. those established for ERCs[65]or in OECD emission scenario documents, are expected to be sufficient to satisfy the reporting requirements in the absence of refined approaches. Refined default-based approaches for specific uses/sectors, such as those used in REACH spERCs[66], are envisaged to be usefully applied to meet the reporting obligation. Indeed, where spERCs are periodically reviewed and updated based on the adoption of best-practices, spERC approaches to

[64] https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

[65] https://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf

[66] https://echa.europa.eu/documents/10162/15669641/sperc_factsheet_guidance_en.pdf/4c94f0fb-07dd-4e9f-842a-3f21a63bd3fe

estimate releases may be particularly useful to demonstrate minimisation of releases for a particular sector over time.

The Dossier Submitter considers that these revisions to the reporting obligation are sufficient to facilitate microplastic release minimisation and provide useful information to the Agency and decision makers without undue administrative burden. However, an alternative scenario for a reporting obligation could be envisaged that further reduces administration for industry, but with commensurate reduction in information. For example, the reporting obligation could be limited to actors that create or import microplastics, rather than actors using microplastics. This information could be submitted confidentially to ECHA. Similarly, this requirement could be linked to a minimum reporting threshold, such as 100 kg/y for example. There would be fewer administrative costs associated with such a scenario and there could be less incentive for underreporting. The benefits of such an approach, in terms of reduced administrative burden, would need to be balanced against the loss of information on releases and, potentially, uses.

Implementation period for reporting revised (increased) from 12 months to 36 months

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 particle containing solid polymer that does not persist in the environment, including by means of solubilisation, 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[67], *in the period after the release resulting from the end use*.

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 for assessing (bio)degradability have been standardised at international level for many years (e.g. there are numerous relevant OECD and ISO testing guidelines available).

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 if

[67] 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.

the (bio)degradation of a substance cannot be demonstrated using screening tests. The conventional rationale for using screening 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. Variations to existing standardised (bio)degradation testing methods, or potentially entirely new standardised testing methods, may be necessary to appropriately assess the (bio)degradation 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 the new 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 22.

During the consultation the proposed tiered approach for establishing if a particle containing solid polymer can be considered to be (bio)degradable, and therefore derogation from the scope of the proposed restriction, received a lot of attention. In response to these comments, the rationale behind the proposed criteria for (bio)degradability and other introduced changes is further elaborated below.

The proposed criteria take into account the following elements:

- The highly variable chemical composition of polymers, together with other substances, that comprise microplastics;
- Existing legal basis and guidance for assessing (bio)degradability / persistence assessments under REACH and other chemical regulations (further details given in the Annex of the Background Document);
- The available standard test methods for assessing (bio)degradability and their applicability to polymer-based materials;

- It was also considered important by the Dossier Submitter that the criteria rule out the use of additives meeting the criteria for PBT/vPvB set in REACH Regulation, Annex XIII.

Variable composition of the polymers/microplastics leads also to variable degradation potential and creates a need for flexibility in terms of the test methods. Flexibility was introduced by permitting the use of several screening methods for demonstrating the potential for degradation. These methods, namely OECD 301B/C/D/F, 306, 310, 302C were selected based on their regulatory acceptance and applicability for polymers/microplastics. As described above, these methods and associated pass/fail criteria are routinely used to assess the degradation potential of substances in the environment. Therefore, a pass in any standard screening test was considered to rule out the potential for extreme persistency in the environment or "microplastic concern" that is intended to be addressed by the proposed restriction.

Uncertainty on the applicability of simulation tests OECD 307, 308 and 309 for polymers/microplastics was acknowledged and reflected in the criteria. When considering the pass/fail criteria for simulation tests, the fact that this derogation is solely based on the (bio)degradation potential, omitting at this point of time the other fate descriptors such as bioaccumulation potential, was taken into account. To benefit from the derogation it needs to be demonstrated that a polymer/microplastic would be unlikely to be persistent in the environment. The Dossier Submitter considered that to demonstrate the above by simulation tests, the half-life should be below the criteria set for vP substances under REACH Annex XIII which are equal to criteria for Persistent Organic Pollutants (POP).

The Dossier Submitter considers that ISO test methods for plastics (included in Group 4 of the methods in Appendix X) covering aquatic and solid test environments, even if with less regulatory experience, are the most applicable methods for polymers/microplastics among all of those proposed. Similarly to the environmental compartment specific half-life criteria in REACH Annex XIII, the proposed timeframes for when the required biodegradation must be reached differs depending on the applied ISO method, 6 months in aquatic environment and 24 months in soil or water/sediment systems. The test conditions and as stated in the ISO 22403:2020, the conditions in the environment, the potential to biodegrade and available surface area and the shape of the test material influence the level and rate of biodegradation. While for example higher bioavailability and potential for fast hydrolysis in aquatic environment may favour the biodegradation of some test materials, the same environment may hinder biodegradation of another test material due to lack off potential degraders such as fungi. Even if the test media could be similar to OECD simulation tests e.g. natural soil or sediment, due to the test set up, ISO methods are considered as screening tests. Therefore, similar to the OECD screening tests it was considered that a pass in any ISO screening test was considered to rule out the potential for extreme persistency in the environment or "microplastic concern". When setting the pass/fail criteria for the ISO methods the following aspects were taken into account: the boundaries of the test guidelines, degradability requirements set for mulching films (relative biodegradation of 90 % in 24 months in soil), packaging materials (relative biodegradation of 90% in 6 months in compost simulation test) and fertilisers (at least 90 % of the organic carbon converted into carbon dioxide in a maximum period of 48 months after the end of the claimed functionality period of the EU fertilising product). Furthermore, based on ISO 22403:2020, mineralisation of the whole test material or each individual constituent into carbon dioxide for at least 90 % or for

the same extent of the reference material within 2 years is considered a positive result of ISO 18830, ISO 19679, ISO22404, ASTM D6691-17, ISO 23977-1:-, or ISO 23977-2:-. ISO 22403:2020 describes methods and criteria for the intrinsic (i.e. potential) biodegradability in marine environment of virgin plastic materials and polymers.

Further information on these approaches can be found from the Annex of the Background Document.

The test method specific pass/fail criteria within the permitted test methods are defensible due to differences in the conduct of the OECD screening test, ISO screening tests and simulation test.

- OECD screening tests measure ultimate degradation (mineralisation) of the substance in terms of amount of its C converted into CO_2. Result are expressed as biodegradation % after specified time frame.
- ISO screening tests measure the amount of its C converted into CO_2. Results are expressed as biodegradation % relative to a reference material generally recognised as biodegradable (GRAB) at maximum of 6 months in aquatic test and 24 months in soil and sediment.

OECD simulation tests measure degradation rate with results expressed as half-lives for water, soil and sediment. The approach and related criteria presented in Table 22 have been modified from those presented in the Annex XV report in response to the comments on the acceptability of the pass/fail criteria, applicability and availability of the test methods, relevance of the test compartment, and test material description.

In first instance, there was a need to clarify that the criteria are grouped based on the stringency of the methods and were not intended to be mandatory steps to be followed i.e. from tier 1 to tier 5. Depending on the properties of the test material as well as available information, the most appropriate tests may be selected to be performed. In principle, the criteria are structure in such way that (bio)degradability may be demonstrated by any of the permitted test methods. Based on the comments received, one newly published standard method (ISO 22404:2019) was introduced and one method removed (OECD TG 302B) as it was not applicable to microplastics. The consultation provided valuable information which resulted in more flexibility in the description of the acceptable test material form. Significantly, the consultation raised a concern related to biodegradation testing when a polymer-containing particle consists of more than one polymeric component. Therefore, the Table 22 was updated to introduce a specific scenario for testing microplastics consisting of polymer blends. Furthermore, GLP certification was included as an alternative to ISO 17025 accreditation due to many requests during the consultation and the acknowledgement of the Dossier Submitter that the quality assurance provided by each of these schemes was equivalent for these types of tests (both schemes are permissible under the biodegradation testing required for the demonstrating compliance with the EU Detergents Regulation).

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.

Table 22 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 criteria described below.

A test material can be considered to be (bio)degradable, and therefore derogated from the restriction, if it achieves the pass criteria specified in any of the permitted test methods included in groups 1-4, below. If a test material does not meet any of the pass criteria for the test methods in groups 1-4, further assessment information (test methods in group 5) can be used to demonstrate (bio)degradability.

The permitted test methods are organised into different groups corresponding to their underlying test design and rationale. It is not necessary to achieve the pass criteria in tests from each group. Achieving the pass criteria in any of the permitted test methods specified in groups 1 to 5 is sufficient to demonstrate that a test material should be derogated from the restriction (as long as the requirement set out in the paragraph below in relation to the presence of PBT/vPvB substances in a test material is also met). For example, if a test material achieves the pass criteria in a test method specified in group 1 it is not necessary to undertake additional testing. Similarly, if a test material does not achieve the pass criteria in a test method specified in group 1, but achieves the pass criteria in a permitted test specified in group 4 then this is sufficient to demonstrate that a test material should be derogated (as long as the requirement set out in the paragraph below in relation to the presence of PBT/vPvB substances in a test material is also met). In addition to achieving the pass criteria in permitted test methods, the test material shall not contain substances 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.

Demonstrating (bio)degradability using screening test methods.

Group 1. Ready biodegradation

- Pass criteria: 60% mineralisation measured as evolved CO_2 or consumed O_2 in 28 days (10-day window does not apply).
- ***Permitted test methods:***
  i. *Ready Biodegradability (OECD TG 301 B,C,D,F)*
  ii. *Ready Biodegradability – CO2 in sealed vessels (Headspace Test) (OECD TG 310).*

Or

Group 2. Enhanced / modified ready biodegradation

- Test duration may be extended to up to 60 days and larger test vessels used
- Pass criteria: 60% mineralisation measured as evolved CO_2 or consumed O_2 in 60 days (10-day window does not apply)
- *Permitted test methods:*
- *Ready Biodegradability (OECD TG 301 B,C,D,F)*
- *Ready Biodegradability – CO2 in sealed vessels (Headspace Test) (OECD TG 310)*

- *Modified Biodegradability in Seawater (OECD TG 306, mineralisation measured as evolved CO_2)*

Or

Group 3. Inherent biodegradation

- Pass criteria: ≥ 70% mineralisation (measured as O_2 uptake or evolved CO_2) fulfilling the TG specific criteria as indicated below.
- *Permitted test method[68]:*
    i. *%Inherent Biodegradability: Modified MITI Test (II) (OECD 302C), ≥ 70% mineralisation within 14 days, pre-adaptation of the inoculum is not allowed.*

Or

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

- Pass criteria: ultimate degradation of ≥ 90% relative to the degradation of the reference material within 6 months in aquatic test, or 24 months in soil or 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 18830:2016)[69], pre-adaption of the inoculum is not allowed.*

iii. *Ultimate aerobic biodegradability of plastic materials in soil (EN ISO 17556:2019), pre-adaption of the inoculum is not allowed.*

iv. *Plastics - Determination of the aerobic biodegradation of non-floating materials exposed to marine sediment (ISO 22404:2019), pre-adaption of the inoculum is not allowed.*

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

[69] ISO 22403:2020 *Plastics – Assessment of the intrinsic biodegradability of materials exposed to marine inocula under mesophilic aerobic laboratory conditions – Test methods and requirements* provides specifications on test methods and criteria for intrinsic biodegradability in marine environments.

Demonstrating (bio)degradability using simulation test methods

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.

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

- Pass criteria: The degradation half-life in marine, fresh or estuarine water is less than 60 days or
- Pass criteria: The degradation half-life in marine, fresh or estuarine sediment is less than 180 days or
- Pass criteria: The degradation half-life in soil is less than 180 days.

Permitted test methods:

i. Aerobic and Anaerobic Transformation in Soil (OECD TG 307: 2002)
ii. Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (OECD TG 308: 2002)
iii. Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test (OECD TG 309: 2004)

Results should be interpreted with caution and the half-life should be estimated with care when the particle size (surface area) is a degradation rate-limiting factor and the degradation is not following the first order kinetics.

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

Where microplastics are deliberately applied to soil or foliage (e.g. controlled-release fertilising products) test methods and pass criteria applicable to this compartment (any test method in groups 1 to 3, test method 4(iii) or test method 5(i)) shall be used.

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

Test material in (bio)degradation tests

The test material should be comparable (in terms of composition, form, size and surface area) to the particles that are produced or, if not technically feasible, to the particles that are disposed or released to the environment. Comparability is important as the composition, form, size and surface area of particles affect (bio)degradation

behaviour.

Polymers used for encapsulation may be tested (i) in the form placed on the market, (ii) in form of isolated coating or (iii) the organic core of the material may be replaced by an inert material such as glass. The test material shall be of comparable thickness to the solid polymer coating of the particle placed on the market.

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

Where the test material consists of more than one polymeric component (i.e. it is a blend), in addition to demonstrating the (bio)degradation of the microplastic as described above, the biodegradation potential of each of the polymeric components in the blend must also be demonstrated. This can be done by:

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

Or

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

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

2.2.1.7 Solubility criteria

When considering the suitable test methods both OECD Guideline 105[70] and OECD Guideline 120[71] were considered, as well as ECHA Guidance which was referred to by some stakeholders as a basis for setting a threshold. The test proposed for polymer solubility is set out in Table 23. The Dossier Submitter notes that the OECD Guideline 120 refers to solution/extraction behaviour of polymers also in other conditions then those set in Table 23, namely at 20°C at pH 2 and pH 9 and at 37°C at pH 7. In the received comments it was considered that solubility in all or many environmentally relevant conditions should be assessed. Dossier Submitter concludes that for the purpose of the derogation, assessing the solubility with one set of conditions is sufficient as the proposed threshold is conservative.

The Dossier Submitter is aware that there are concern raised for the usage of OECD Guideline 105 (and therefore also OECD Guideline 120) regarding their applicability for nanomaterials and that there is a need to adapt it to make it more useful, especially for nanomaterials. Regulation 2018/1881[72] also states that *"For nanoforms the potential confounding effect of dispersion shall be assessed when conducting the study."* In

[70] http://www.oecd.org/chemicalsafety/risk-assessment/1948185.pdf

[71] https://www.oecd-ilibrary.org/environment/test-no-120-solution-extraction-behaviour-of-polymers-in-water_9789264069886-en

[72] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1881

addition, OECD Guideline 318 provides advice on investigation of the dispersion of nanoparticles. Based on the comments received during the consultation, Dossier Submitter proposed to increase the lower limit of the restriction to 100nm. A lower limit of 100 nm would improve the applicability of the criteria proposed in Appendix Y.

Based on the comments received from stakeholders, the Dossier Submitter also considered the kinetics of the dissolution as a potential means to define the proposed derogation. It was noted that considering a parameter as dissolution rate could be appropriate for derogation for solubility in line with the derogation described for biodegradability. Such an approach would allow using environmentally relevant conditions. However, on balance, the Dossier Submitter considered that applying a known standard method such as OECD Guideline 120 could ensure better enforceability of proposed derogation.

The Dossier Submitter notes that several comments submitted during the consultation supported using a cut-off solubility limit of >1mg/L citing REACH and ECHA Guidance[73]. With respect to the REACH Regulation, a substance's water solubility is used as a trigger for waiving certain physicochemical and ecotoxicological information requirements during registration (such as short term aquatic toxicity). In this context a solubility of ≤1mg/L is used to identify substances which are considered to be sufficiently insoluble (termed as poorly soluble) that the information requirement would not be applicable.

However, a corresponding solubility value of >1mg/L, as proposed by some respondents to the consultation, should not necessarily be considered to be the logical threshold for identifying substances that are sufficiently water soluble to no longer be consistent with the microplastic concern. Stakeholders have also proposed a limit of 100 mg/L as outlined in the OECD Guidance document on aquatic toxicity testing of difficult substance and mixtures[74]. In addition, the Dossier Submitter is aware that for example the solubility criteria laid out in the European Pharmacopoeia (Ph. Eur. (has been applied in the context of other EU legislation[75] (e.g. EFSA[76], SCCS[77]) and this could potentially be applicable.

However, as the Dossier Submitter has already suggested a derogation for (bio)degradation and as the purpose of the proposed derogation is to identify particles which have sufficiently high water solubility to be of no concern the Dossier Submitter proposes to apply a criterion linked to (bio)degradation derogation. The maximum allowed test material concentration in ISO 14852 and 14851 is 2 g/L. The Dossier submitter considers that if the solid microplastic particle has a solubility above this 2g/L threshold, it is sufficiently soluble that no microplastic particles would be present in the test system and, therefore, (bio)degradation testing would not be needed.

It should be also emphasised that "microplastic" particles with a [water] solubility below 2g/L may in certain circumstances not be within the scope of the restriction proposal.

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[73] https://echa.europa.eu/documents/10162/23047722/ir_csa_r7b_pbt_msc_bpc_en.pdf

[74] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?doclanguage=en&cote=env/jm/mono(2000)6

[75] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0231&from=EN

[76] https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2014.EN-660

[77] https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_228.pdf

This would be the case, for example, if the particles are placed on market in water solution where the concentration is lower than the solubility of the particles in question. In such case solid particles would not exist and thus the regulatory definition of "microplastic" is not met. This highlights the fact that all the elements of the proposed definition need to be fulfilled in order to state that the substances meets the regulatory definition of "microplastic".

Table 23 Criteria for demonstrating solubility > 2 g/L according to Paragraph 3c (APPENDIX Y).

The conditions for the test are the following: • Temperature 20ºC • pH 7 • Loading: 10g/1000mL • Test time: 24h Quantification can be done either via the procedure described in OECD Guideline 120 or in OECD Guideline 105. Test is to be carried out with the particles as they are placed on market. As "particle containing solid polymer" may refer to particles which are comprised of polymers and inorganic elements (e.g. capsulation or for example particles where polymer is grafted onto inorganic carrier). In such cases it will be sufficient to demonstrate that the polymer part meets the suggested criteria. In practice this may mean testing the polymer(s) prior to the formation of the particle. Test should be conducted by laboratories certified to GLP or accredited to ISO 17025. It shall be ensured that the particles are dissolved and that they do not form colloidal solutions. This can be confirmed by examination for the Tyndall effect. Presence of such particles invalidates the results, and the test should be repeated with improvements in the filtering action of the column.

2.3 Approach to impact assessment

Microplastics have various applications in consumer, professional, agricultural or industrial products. These products have various modes and conditions 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 and use sectors 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, toners and printing inks, and polymeric infill of synthetic turf pitches.

This sector-specific assessment strategy results in sector-specific assumptions regarding

the cost of substituting microplastics with alternatives and other impacts on society. On one hand, differences in substitution costs are related to the different functionalities and use conditions that need to be achieved by any alternative to the current use of microplastics in these sectors; on the other hand, it reflects that for some sectors (e.g. the cosmetics sector) more detailed information on substitution costs is available to the Dossier Submitter than for other sectors.

Where the information is available, and where the socio-economic impacts within a sector are likely to vary substantially, the analysis is performed at 'product group' level rather than sector level. For example, within the cosmetics sector, the availability of alternatives for rinse-off and leave-on products varies, as do the resources required to transition to identified 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 categories of cosmetics that are disposed of via household trash such as make-up/lip/nail products) was prepared for sensitivity purposes.

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

The geographical scope of the impact assessment was the European Economic Area (EEA or EU28 plus Iceland, Liechtenstein and Norway) 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.[78] For the temporal scope of the analysis, 2022 was presumed to be the first full year of entry into force of the proposed restriction and the next 20 years were used as analytical horizon. Unless otherwise specified. all costs are expressed 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.

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

[78] At the time of writing, the future relationship between the EU and the United Kingdom is uncertain and it is thus unclear to what extent future amendments of Annex XVII of REACH would be applicable on the territory of the UK. Under the baseline it is assumed that the current status of the UK in the EU/EEA is maintained for the temporal scope of the analysis.

evaluating restriction proposals for PBT/vPvB (-like) substances.[79]

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 provided in Section 0 and in sector-specific assessments in Annex D.

2.4 Environmental and human health impacts

As discussed in the risk assessment reported in Section 1.4 of this report, 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 non-threshold substances and their releases are considered a proxy for risk. Therefore, the impact of the restriction can be appreciated by the reduction in predicted releases that were forecast to occur without the restriction.

The proposed restriction is estimated to result in a cumulative emission reduction of approximately 500 thousand tonnes of microplastics (central scenario) over the 20-year period following its entry into force. This is a reduction of 70%[80] of the quantified emissions of intentionally added microplastics that would have occurred in the absence of the restriction entering in effect (Figure 11).

The reduction in releases will contribute to minimising emissions 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). In particular, 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 with (possibly ingesting) these materials either directly, or via their food.

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

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

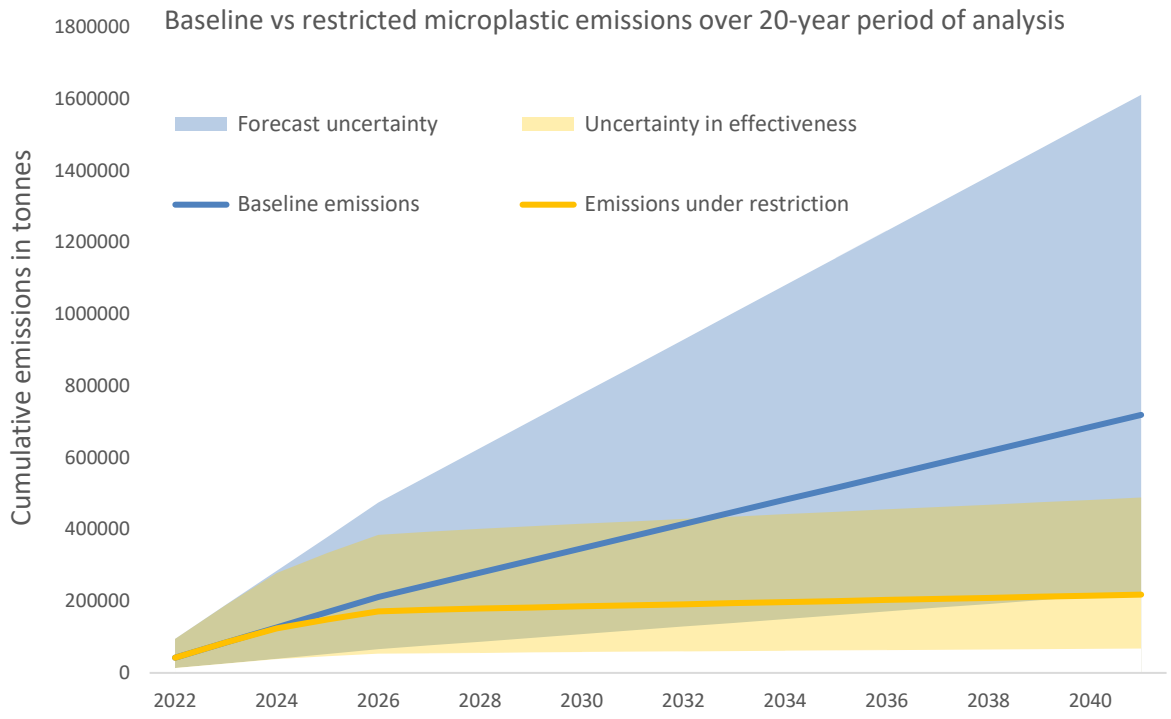


Figure 11 Effect of the proposed restriction on cumulative releases over the period of analysis

2.5 Economic and other impacts

The proposed restriction would lead to impacts primarily to end-users of microplastic-containing products and the supply chains that place these products on the EEA market. The economic costs and other impacts are anticipated to be primarily associated with compliance with the restriction on the placing on the market for selected microplastic-containing products. Costs to comply with the instructions for use and reporting requirements are minor 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 proportionality to risk of the proposed restriction. Sector-specific summaries of the underlying assumptions, description of the anticipated impacts, estimated costs and main conclusions are presented in Table 25 to Table 37. 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 €9.3 billion (€2.1bn – €18.0bn) in NPV.[81] 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 number of microplastic-containing products on the market that meet the proposed definition.

To address these and other uncertainties, sensitivity analysis is performed the results of which are presented in Table 24.

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 €200 million (€20m – €430m).[82]

2.5.3 Enforcement costs

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

[81] The impacts outlined in the main text are based on a 5 year transitional period for fragrance encapsulates. With an 8 year transitional period for fragrance encapsulates, the total reformulation/R&D costs would be €9.2 billion (€2.1 billion - €18 billion).

[82] With an 8 year transitional period for fragrance encapsulates, the total raw material costs would be €113 million (€20 million - €330 million).

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 whether products 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 €55 000 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.

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 minor 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 Cost associated with instructions for use and disposal

Paragraph 7 of the proposed restriction obliges suppliers of certain substances or mixtures that contain microplastics that are permitted to be placed on the market only by means of a derogation, to include 'instructions for use and disposal'. On this basis microplastics will continue to be placed on the market in substances and mixtures for various types of uses, including uses at industrial sites or in uses where microplastics cease to exist at the point of use (e.g. in paints and coatings as well as in certain cosmetic and household products). These instructions are permitted to be provided to users (including consumers) by various means, depending on the specific considerations of the product. See Section 2.2.1.2.

Comments submitted during the consultation on the Annex XV report provided some information on the potential costs of the proposed instructions for use and disposal requirements. The cost information not claimed confidential are summarised below. It should be noted that not all of these costs are expected to arise as some are based on misunderstandings of the instructions for use and disposal requirement. Where this is the case this has been noted below:

- According to CEPE (#2073), adding a package leaflet would be the most costly solution to implement the requirement in the paints and coatings sector as it would require an investment in filling lines, which is estimated to cost €50 000 per filling line (with an average of four filling lines per production site), CEPE states that, on an EU-wide basis, this would translate into €160 Million for the whole sector. The Dossier Submitter notes that the restriction does not oblige adding a package leaflet to be added to products containing microplastics and that alternative instructions for use (such as pictograms and links to online information) are likely to be less expensive to implement.
- Based on the results of a survey undertaken by A.I.S.E. (#2382) amongst its members in the detergents and maintenance sector, the average one-off cost of re-labelling would be €8 000/formulation with the cost ranging from €1 000 to €25 000 per formulation affected. This one-off cost includes costs associated with regulatory checks, updating the design (which may be available in different forms due to multiple product sizes) and adding the new text. Companies also said that there would be a cost associated with not using pre-printed labels. It should also be noted that A.I.S.E. argued that about 16 000 reformulations would be undertaken in the detergents and maintenance sector to avoid the instructions for use and reporting requirements. While the Dossier Submitter finds this questionable, it has undertaken a sensitivity analysis to assess the potential impacts of such reformulations. See Annex D for more information on this.

Some information on the cost of updating labels can also be found in the literature:

- RPA and Mayer Brown LLP (2018) assumed that the one-off cost of producing new labels (labelling and artwork) was between €200 and €3 000 per product.
- U.S. Environmental Protection Agency (2017) estimated that in the paints and coatings sector, costs for labelling range from $700 to $800 (approx. €610 - €700) per formulated product. This included $600 for the plate change and minimal labour cost of $100 - $200 per label.
- In the impact assessment done for the implementation of the GHS (European Commission (2006)) the average cost of redesigning and modifying labels to be compliant with CLP was assumed to be around €300 per formulation. A later study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation (European Commission (2017)), found that the weighted average cost was €388 for substances and €475 for mixtures.
- In terms of non-chemical products, the UK Food Standards Agency (2009) noted that the costs vary widely in re-labelling depending on the medium a label is printed on, the colours used and whether the label requires a plate change, amongst other factors. The report found that, on average, the cost was £1 000 (approx. €1 130) per Stock Keeping Unit (a food product with its own unique barcode).

While the Dossier Submitter has not quantified the total cost of the instructions for use and disposal requirement, it does consider that incremental costs to the proposed restriction are expected to be minor because requirements for product labelling (or updates of SDS) exist for almost all sectors under existing legislation (e.g., CLP, CPR, medicinal products regulation, etc.). These 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 (now proposed to be at least 24 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 the printing of new labels. Therefore, given the length of the transitional period proposed, any such costs associated with the instructions for use requirement would be low and unlikely to be driven by the proposed restriction.

The Dossier Submitter reiterates that the instructions for use and disposal requirement described in paragraph 7 is fundamental to the Dossier Submitter supporting the derogation of some uses from the ban on placing on the market. The costs of the instructions for use and reporting, which are acknowledged not to be trivial in all cases, will be significantly smaller than the costs that would arise from a ban on the placing on the market of the substances and mixtures that are currently proposed to be derogated.

2.5.5 Reporting requirement

The proposed restriction also includes reporting requirements for certain derogated uses (paragraph 8 of the proposed restriction). The main purpose of this requirement is to provide information for decision-makers to facilitate further action, but the requirement will also facilitate enforcement and the progressive minimisation of releases.

Comments in the consultation on the Annex XV report provided some information on the

potential costs of the reporting requirements presented in the Annex XV report. The cost information not claimed confidential are summarised below. It should be noted that not all of the costs claimed by commenters are expected to arise as some are based on misunderstandings of the reporting requirement. Where this is the case this has been clarified below:

- CEPE (#2073) estimated that there would be over 300 000 companies affected by the reporting requirement in the paints and printing inks sectors. CEPE further estimated that, when a workable reporting format would be available, each affected company would have to reserve 0.3 FTE or €20 000 per year to undertake the reporting.
- German paints and coatings associations and companies (#2044, #2117 and #2476) estimated that companies would require at least 50% of one full-time position to comply with the reporting obligation. For the 250 manufacturers expected to be impacted in Germany, the costs were estimated to be at least €6 million per year (i.e. at least €24 000 per company).
- Swedish Paint and Adhesives Manufacturers (#2154) estimated that if industrial uses at industrial sites were included, around 11 000 companies in the paint and adhesives sector in Sweden would be affected. According to this comment, if it was assumed (for sake of argument) that information on polymer type was available to the downstream users – they would need a way to track the required information in their IT-systems in order to document of amounts used per type of polymer and type of use. The comment states that this is not a functionality that is in place today and that programming will take time and resources.
- One company in the paints and coatings sector (#2148) estimated that the requirement would lead to additional costs of at least €250 000 per year, although it is not clear if substitution costs were included in the estimate.
- According to A.I.S.E. (#2382), some companies in the detergents and maintenance sector have indicated that they will first have to develop an internal IT tool or a new functionality in existing IT tools, to be able to collect the information that needs to be reported to ECHA. The development of such an IT tool can take 3-6 months. The estimates on required resources for reporting volumes of microplastics to ECHA ranged from 10 working days to 5 full-time equivalent employees. It was difficult for companies to estimate further costs, as they would need more clarity on what they need to report to ECHA and in what format. The administrative cost estimated by a few respondents were €10 000 per year but some large multinational companies noted that the administrative costs would be significantly greater as they envisaged that it would be necessary to hire additional staff. A.I.S.E. estimated that 675 companies in the detergent and maintenance sector would be affected by the reporting requirement. Similar to the instructions for use requirements, they also assumed that companies would reformulate their products to avoid the reporting requirement. See Annex D for more information on this.

While the Dossier Submitter has not quantified the total cost of the reporting requirement, it notes that the costs associated with reporting 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 once a year. The Dossier Submitter acknowledges that the latter costs are difficult to estimate as they would depend on the complexity of the

company structure and the number of products/materials for which reporting requirements hold. However, these costs are considered to be minor taking into account that the proposed instructions for use and disposal requirement will facilitate information exchange on the presence and content of microplastics throughout the supply chain.

Based on experience, the one-time costs to ECHA are unlikely to exceed €50 000, especially when considering the possibility to develop the functionality under existing tools such as REACH-IT (similar to the existing system for Article 66 downstream user notifications). Such an approach would also minimise costs for annual compiling and disseminating of the information.

It should be noted that the Dossier Submitter's proposal has been revised based on the consultation responses and envisages a relatively simple reporting mechanism. Data submission templates (such as those used for C&L notification) could be utilised where large number of submissions are required (See Section 2.2.1.2). The reporting mechanism could feasibly be further simplified to reduce costs (See Section 2.2.1.2 for a description of an alternative reporting scenario), but with a commensurate loss in information; i.e. information on uses and releases would no longer be available to decision-makers.

2.5.6 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. For leave-on cosmetics, patent costs are also estimated in the worst-case scenario. These costs are estimated to less than €2.1 billion (NPV).

2.5.7 Social costs and impacts on SMEs

Based on analysis in Annex D and summarised in Table 25 to Table 36, 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 €70 million for the study period.

The proposed restriction impacts multiple 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 instructions for use or reporting requirements which do not require substantial resources. (See also Section 2.5.3.)

The requirements that would 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. SMEs currently focusing on microplastic-free products could directly benefit from a restriction on microplastic-containing products as they already have on the market formulations that meet the requirements of the proposed restriction. Therefore, it is unclear whether on balance the impacts on EEA SMEs would be negative as a result of the proposed restriction. Consultation comments have stated that SMEs may find it challenging to conduct so many leave-on cosmetic reformulation at the same time; however, the number of reformulations estimated is the largest uncertainty in the analysis presented by the Dossier Submitter.

2.5.8 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 to comply with the restriction requirements, in particular to reformulate microplastic-containing mixtures. Therefore, while it is possible that in the worst-case scenario these impacts may materialise for microplastic-containing products, it is also likely that value-added and exports of microplastic-free products may increase. Hence, some of the negative impacts on trade and competition for microplastic-containing products may be offset by positive impacts in the markets for alternative products; with the net effect being uncertain. As any impact on exports is highly uncertain, wider economic effects are monetised only for leave-on cosmetic products. Under the worst-case assumptions they are estimated at €230 million (NPV).

2.5.9 Other impacts

Other impacts are discussed qualitatively for individual sectors and product groups in Annex D of the report and are summarised in Table 25 to Table 36 below.

2.5.10 Summary of quantified economic impacts

A detailed assessment of the anticipated socio-economic impacts of the proposed restriction on the sectors in its scope impacts is presented in Annex D to this report. Table 24 provides an overall summary of the quantified economic impacts of the proposed restriction (excl. polymeric infill material), whereas Table 25 to Table 37 summarise the expected costs per sector. The costs of a restriction on polymeric infill material were intentionally excluded from the overall summary in Table 24 as, at the time of writing, it was unclear which restriction option would be preferred by policy makers.

Table 24 Summary of quantified economic impacts of the proposed restriction (excl. polymeric infill material)

Impacts\Scenarios	**Low**	**Central**	**High**
Economic impacts			
- Material	20	197	433
- Reformulation	2 088	9 307	18 000
- Enforcement	3	3	3
- Other economic	-	-	2 073
Wider economic impacts (on employment and trade)			300
Total Restriction Costs *	2 100	9 500	20 800

Notes: NPV in €2017 million; * figures rounded. The impacts in the table are based on a 5 year transitional period for fragrance encapsulates. With an 8-year transitional period for fragrance encapsulates, the total restriction costs would be €9.3 billion (€2.1 billion - €20.6 billion).

Table 25 Summary of 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
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/nutrients to seeds - physical protection of seeds during sowing
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 [a]	6 750 (2 250-12 000)	13 500 (4 950-23 400)
Cost-effectiveness [b]: - Central-cost scenario - High-cost scenario	 €4.6/kg (€0.9-27.8/kg) €9.2/kg (€1.7-55.0/kg)	 €17.3/kg (€2.6-110.1/kg) €43.0/kg (€6.0-265.7/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		
Substitution costs [c]: - Central-cost scenario - High-cost scenario	 €31m (€11m-€63m) €62m (€21m-€124m)	 €233m (€60m-€545m) €580m (€140m-€1 315m)
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 - 95% of substitution cost attributable to FPR - Effort factor of 2 assumed for high-cost scenario Assumptions on fertilising agents: - Total substitution cost to members of Fertilizers Europe: €20m - As Fertilizers Europe presents 2/3 of producers, range estimate of €20m-100m - 95% of substitution cost attributable to FPR Effort factor of 1.5 assumed for high-cost scenario	Assumptions made on CSPs: - 40-80 reformulations - Cost per reformulation: €2m - Effort factor of 2 assumed for high-cost scenario - High-cost scenario reflects case where no R&D read-across feasible Assumptions made on seed coating: - 50-150 primary reformulations - Cost per primary reformulation: €3.4 million - 100-500 adaptations - Two thirds of cost attributable to restriction (rest to FPR) - Effort factor of 1/3 assumed for low-cost scenario
Enforcement costs	Default cost of €55 000 p.a., enforced	Default cost of €55 000 p.a., enforced

	via existing fertiliser legislation	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 [d]	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)	
Impact of scope modifications		
All dimensions < 1mm	No effect	
Change in lower limit to 100nm	Fewer practical problems with implementation	

Source: Annex D – Impact assessment for agriculture and horticulture

Notes: a) considers only fertilising products that are not regulated under the FPR; b) assumes first full year of EiF in 2022 and a 5-year transition period, ignores costs and emissions attributable to the FPR; c) based on 2018 costs attributable to REACH restriction (ignores costs attributable to the FPR); d) those relevant to proportionality.

Table 26 Summary of socio-economic impacts of the proposed restriction on construction products (fibre-reinforcement of concrete and other adhesives)

Impacts\Sectors	Fibre-reinforcement of concrete and other adhesives
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[83]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	Instructions for use and reporting requirement
Justification for action	Limited releases of microplastics are expected under specific circumstances. An instructions-for-use 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 instructions for use requirement could at least to some extent be coordinated with the regular updates to labels. The costs associated with reporting 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 once a year.
Cost-effectiveness &	Labels on products that the users are less familiar with are according to

[83] See Table 36.

Impacts\Sectors	Fibre-reinforcement of concrete and other adhesives
affordability	research more likely to be effective. While it is not known how much an instructions for use requirement may affect emissions, the 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
• Impact of change to lower limit (100 nm) or no lower limit	Not known
Main Uncertainties (impact on Proportionality conclusions)	Tonnages Emissions to the environment

Table 27 Summary of 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 + 4y	Restriction on placing on the market with TP of EiF + 6y
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 wastewater) with dimensions of < 5mm		
Function	Exfoliating or cleansing	Primarily opacifying	Various functions (see Annex D)
Tonnes used/y	107 tonnes	6 500 tonnes (2 900 – 10 000)	2 100 tonnes (1 100 – 3 000)
Proportionality			
Emissions reduced/y	Likely fully phased out by industry by 2020	3 100 tonnes (1 400 – 4 900)	600 tonnes (300 – 900)
Cost-effectiveness	n/a	€22/kg (€2-€27/kg)	€870/kg (€380 – €1 300/kg)
Affordability	No costs as industry likely to fully phase out use prior to EiF	Affordable (total restriction cost is less than 20% of profit margin)	Affordable (total restriction cost is less than 20% of profit margin)
Total restriction costs (NVP)	Negligible	€1.1bn (€50m – €2.1bn)	€7.3bn (€1.6bn – €15.5bn)
Material (NPV)	n/a	€34.4m (€15.4m – €53.4m)	€9m (€5m – €13m)
Reformulation (NPV)	n/a	€1bn (€36.3m - €2bn)	€7.3bn (€1.6bn – €13.3bn)
Enforcement	Negligible, enforced via existing CPR labelling requirement	€55 000/y, enforced primarily via existing CPR labelling requirements	€55 000/y, 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 minor
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)	- Price premium for alternatives: €650/tonne - 51 000 (11 000 – 92 000) reformulations - Cost per major reformulation: €550 000 (€63 000) 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)	- 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. Consultation comments reveal that SMEs may have difficulties conducting so many leave-on reformulations within the proposed six-year transitional period. 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 or greater than 100 nm or no lower limit	n/a	Difficult to estimate but 99% of microplastics < 1mm	Difficult to estimate but 99% of microplastics < 1mm
Excluding make-up/lip/nail products	n/a	n/a	If instructions for use requirements only for make-up/lip/nail products, cost-effectiveness changes to €460/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 y 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 (↑) - cost per reformulation (↓)	

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. Products such as make-up/lip/nail care cosmetics 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).

Table 28 Summary of socio-economic impacts of the proposed restriction on detergents and maintenance products

Impacts\Sectors	Microbeads contained in detergents and	Fragrance encapsulates	Other microplastics contained in detergents	Waxes, polishes and air care products
Proposed action/TP	Restriction on placing on the market (no TP)	Restriction on placing on the market with TP of EiF + 5/8 y	Restriction on placing on the market with TP of EiF + 5 y	Restriction on placing on the market with TP of EiF + 5 y
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. Air care products, such as air fresheners or scented candles.
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.	100 (decreasing)	400 (260 – 540)	15 200 (9 40 – 20 960)	1 300
Proportionality				
Emissions reduced over 20-year analytical period	Likely fully phased out by industry by 2020	5 year TP: 3 000 (2 000 – 4 100) 8 year TP: 2 400 (1 600 – 3 300)	115 900 (72 000 – 159 800)	8 800
Additional sector specific benefits	Increased mechanical force/motion, resulting in the need for less aggressive chemicals and cleaning time	Decreased use of perfume required (economic and environmental benefits)	Benefits include e.g. foam control and helping prevent soil from resettling on fabrics after it has been removed during washing	Benefits include e.g. rendering fibres and chipboards moisture-proof, as well as giving gloss and surface protection for various materials
Cost-effectiveness	n/a	5 year TP: €173/kg (€71 – 337/kg) 8 year TP: €128/kg (€89 – 329/kg)	€1/kg (€0.4 - 9/kg)	€1/kg (€0.1 - 2/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	5 year TP: €526.4m (€293.1m - €811.9m) 8 year TP: €312.8m (€293m - €651.8m)	€129.8m (€29.1m – €1.331bn)	€6.5m (€0.9m – €19.8m)
Material	n/a	5 year TP: €85.6m (€0 – €183.1m) 8 year TP: €1.2m (€0 – €79.5m)	€62.8m (€0 – €173.2m)	€5.4m (€0 – €10.7m)
Reformulation/R&D	n/a	5 years TP: €440.4m (€292.7m - €554.1m)	€66.6m (€43.1m – €1.059bn)	€0.7m (€0.4m – €7.9m)

		8 years TP: €311.3m (€292.7m - €521.5m)		
Enforcement	Negligible, enforced via existing labelling requirements	€413 100 (5 years TP)/ €311 000 (8 years TP), 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 €74.3m under a 5 year TP/ up to €50.5m under an 8 year TP)	Unlikely but tested for upper bound in sensitivity analysis (up to €97.9m)	Unlikely but tested for upper bound in sensitivity analysis (up to €0.7m)
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 if no alternatives: 75% (50%-100%) - Increased cost of alternatives: 50% (0-100%) - 4 500 (2 900 – 6 100) reformulations - Cost per reformulation: €40 000 (€30 000 – €50 000) - R&D premium of 12.5% - Cost of R&D: €450m (€400m - €500m) - Coordination with baseline reformulations over transitional period	- Increased cost of alternatives: 50% (0-100%) - 5 940 (3 840 – 8 040) reformulations - Cost per reformulation: €15 000 (€10 000 – €240 000) - R&D premium of 12.5% for central and lower scenario - Coordination with baseline reformulations over transitional period	- Increased cost of alternatives: 50% (0-100%) - 60 reformulations - Cost per reformulation: €15 000 (€10 000 - €240 000) - R&D premium of 12.5% for central and lower scenario - 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,	Similar impacts	The emissions reduced and costs to industry may be smaller since some of the polymers are currently present below 0.1%

		meaning that the emissions reduced and the costs to industry would be smaller.		
• Impact of change to lower limit (100 nm) or no lower limit	n/a	Could affect the tonnages and the number of affected formulations, thereby also affecting the costs	Could affect the tonnages and the number of affected formulations, thereby also affecting the costs	Could affect the tonnages and the number of affected formulations, thereby also affecting the costs
Main Uncertainties (impact on Proportionality conclusions)	n/a	Time required to develop and implement alternatives for polymeric fragrance encapsulates (different assumptions tested) Reported reformulation costs have a fairly wide range (accounted for by using lower and upper values) Whether and, if so, how many additional reformulations would be undertaken to avoid the labelling and reporting requirement (potential impact assessed in a sensitivity analysis)		

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

Table 29 Summary of socio-economic impacts of the proposed restriction on *in vitro* diagnostic devices (IVD)

Impacts\Sectors	***in vitro* diagnostic devices (IVDs)**
Use description	*In vitro* diagnostic devices could be defined as "reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood, urine and tissue donations, derived from living organisms". IVDs 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 addition to human health applications (i.e. IVD MD covered by Regulation (EU) 2017/746 (aka IVDR), IVDs are also used for veterinary health applications (e.g. pet, poultry, livestock, etc.), as well as for preventing and controlling Transboundary Animal Diseases (TADs) at borders, and in the frame of EU and national animal health programmes. IVDs are also used for research and development activities. Professional uses mainly (e.g. hospital, laboratory, and competent authorities).
Microplastics description	Microplastics (in the form of solid polymeric microspheres with dimensions < 5mm) are used in IVD applications as IVD reagents, assays and calibrator, but also analytical and purification chemistry for IVD. They allow the functioning and reproducibility of the tests carried out on the IVD instruments. During use, the microplastics are in general contained in a closed equipment or cartridge 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), or limited to a few applications where the microplastics are disposed down the drain as part of the liquid waste.
Proposed action/TP	Derogation for IVD uses conditional on including 'Instructions for use and disposal' and an annual reporting requirement. Ideally, this measure should be accompanied by 'voluntary' actions from the sector (upstream suppliers) to minimise, as much as technically and economically practically possible, the use and releases of microplastics to the environment.
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 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. The reporting requirement will help the European Commission to gather more systematic information on the use and release of microplastics. This action also sends a signal that substitution of microplastics or implementation of containment measures can be sought and encouraged without disrupting the access to IVDs. The information gathered via the reporting would reveal the effectiveness of any voluntary measures put in place by the sector to progressively reduce the release of microplastics into the environment. If low effectiveness was apparent, further regulatory action under REACH could be initiated.
Sector characteristics	
Tonnes used	Estimated: < 5 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 update label, SDS or IFU (which are revised regularly) 2) Reporting cost
Cost-effectiveness	Not calculated but the restriction proposal is estimated to be cost effective – qualitative assessment only.
Affordability	Incremental costs of the proposed restriction are considered affordable and likely able to be passed on end-users, or to be covered by the normal review and update cycles of the labelling/SDS/IFU for example.
Other SE impacts	With the proposed restriction option, IVDs remain fully available to treat patients, animals, and provide reliable diagnostic test results.
Practicality	Implementable & manageable: the proposed restriction complement the sector-specific EU regulations on IVD MD (human health applications) that will come into force in 2022. It also brings some harmonisation, consistency and clarity to all other IVD applications such as veterinary IVD, or RUO (Research Use Only) where no common EU legislation exists. 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

Impacts\Sectors	***in vitro* diagnostic devices (IVDs)**
	considered implementable and manageable for the companies placing IVDs on the market. The proposed transition period of 2 years for the 'instructions for use and disposal' requirement takes into account the transition period set in the IVDR for the human health applications: indeed some IVD MD devices, with certificates issued under the IVDD, may continue to be placed on the market until 27 May 2024 and made available until 27 May 2025. Enforceable: The possibility to perform audit and inspections at IVD MD producers/importers level is already foreseen by the sector-specific EU regulations, so the proposed restriction is enforceable for the human health application. In addition, as the same type of equipment and mixtures (reagents/assays/microsphere for calibration) would have the same requirement whatever their application domain (e.g. veterinary, RUO or other), the enforceability is expected to be feasible for inspectors.
Monitorability	For the IVD MD (human health applications), the compliance can be monitored at member state levels for example by reviewing the PSUR (Periodic Safety Update Report) of IVDs MD (administrative monitoring). In addition, the reporting requirement aims at monitoring the uses and releases to the environment that might arise both from the downstream uses, but also from the industrial uses.
Impact of scope modifications	
All dimensions < 1mm	Similar impacts (microplastics < 1mm)
Variations in lower size limit of the microplastic definition	There might be an impact: reduction of number of reagents and assays affected by the proposed restriction. It is nevertheless not possible to estimate the impact quantitatively as the Dossier Submitter does not have detailed information on the volumes of microplastics per beads size.
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, type/number of IVD 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

Source: Annex D – Impact assessment for in vitro diagnostic devices (semi-qualitative approach).

Table 30 Summary of socio-economic impacts of the proposed restriction on medical devices (MD)

Impacts\sectors	Medical devices (MD)
Use description	Medical devices (MD) are mixture (aka (substance-based) MD) or equipment (complex articles) intended generally for a medical purpose. They can be used by healthcare professionals or consumers depending on the type of application. Medical devices are regulated by the EU Regulation (EU) 2017/745 on Medical Devices (aka MDR). (substance-based) MDs: e.g. dental filling material, toothpaste, cream for topical application, sun protection, etc. Other MDs: e.g. adsorbers for blood treatment, IER (ions exchange resins) used for water treatment, ultrasound transducers
Microplastics description	Microplastics: solid polymeric microspheres with dimensions < 5mm (substance-based) MDs: microplastics have the same functions as in cosmetics formulation (i.e. emulsifiers, film forming, thickening, etc.), others would be permanently modified when the substance is used (e.g. microplastics curing in dental filling material) Other MDs: during use, the microplastics are contained in a closed equipment or cartridge without direct release to the environment (e.g. adsorbers for blood treatment, IER cartridge for water treatment, ultrasound transducers)
Proposed action/TP	Ban from placing on the market with a transition period of 6 years (similar to the one proposed for leave-on cosmetics). The microplastics that would be contained in cartridge or equipment during their life-cycle or that would lose their particulate form during use would be derogated from the ban, but subject to an instructions for use and disposal, and a reporting requirement.
Justification for action	Due to the nature of their uses (similar to wash-off and leave-on cosmetics), the releases from (substance-based) MD cannot be minimised via technical measures, therefore an EU wide action is needed. Re. the microplastics that would be contained in cartridge or equipment during their life-cycle or that would lose their particulate form, the releases to the environment are limited, and the uses have high societal value. Therefore, an appropriate restriction would entail continued use subject to specific instructions to ensure that microplastics are appropriately contained during their life-cycle and, specifically, that waste containing microplastics is not discarded to the environment. Such an approach would minimise further the releases, whilst ensuring continued socio-economic benefits of the use.
Sector characteristics	
Tonnes used	Not known for the (substance-based) MD. Estimated to 10 tpa for the other types of MD.
Alternatives	Similar to alternatives for cosmetics applications
Proportionality	
Risk reduction capacity	Not known.
Costs	(substance-based) MDs: reformulation costs including MD market application costs Other MDs (if the microplastics is contained): 1) Cost to update label, SDS or IFU (which are revised regularly) 2) Reporting cost
Cost-effectiveness	Qualitative assessment only
Affordability	Incremental costs of the proposed restriction are considered affordable, especially if a transition period is granted, and likely able to be passed on end-users.
Other SE impacts	With the proposed risk management option and the transition period, MDs remains available to treat patients and provide reliable diagnostic test results. Re. (substance-based) MD, sufficient time is given to industry to transition to alternatives.
Practicality	Implementable & manageable: the proposed restriction complement the sector-specific EU regulations on MD that will come into force in 2020. Given the uncertainty related to the uses and availability of alternatives, the proposed restriction accompanied by a transition period similar to leave-on cosmetics is a practical proposal as this sector could benefit from the reformulation made in other sector for similar type of products. Hence, the practicality for industry actor should be feasible. The proposed restriction is also allowing sufficient time to update the instructions for use, 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 on the market. Enforceable: The possibility to perform audit and inspections at MD producers/importers level is foreseen by the sector-specific EU regulations, but would have to be confirmed for end-user site inspections (e.g. in hospitals) during the consultation.
Monitorability	The compliance can be monitored at member state levels for example by reviewing the PSUR (Periodic Safety Update Report) of MD (administrative monitoring).

Impacts\sectors	Medical devices (MD)
Impact of scope modifications	
All dimensions < 1mm	Similar impacts
Variations in lower size limit of the microplastic definition	Limited impact expected on the SB-MD based on the assessment made for the leave-on cosmetic products
Film forming in scope	Some (substance-based) MD might be affected (but no detailed information received)
Microplastic concentration in mixture > 0.1%	Similar impacts
Main Uncertainties (impact on Proportionality conclusions)	
	Tonnages and type/number of MD (including SB-MD) affected Enforceability at end-user sites (e.g. hospitals, laboratories)

Source: Annex D – Impact assessment for medical devices (qualitative approach).

Table 31 Summary of socio-economic impacts of the proposed restriction on medicinal products

Impacts\Sectors	Solid dosage forms (matrix and film diffusion)	Ion exchange based controlled release	Osmotic systems
Use description	In medicines for human health and veterinary uses, microplastics are essentially used for their Controlled Release (CR) and taste masking functions essentially in solid dosage form (tablets and capsules). In addition, microplastics can be used as binder, disintegrant, diluent, lubricant (in solid dosage form formulation). Microplastics play a key role in controlled-release formulations, and offer many advantages for the patients (better safety profile, better observance due to less frequent medicine intake etc…). Microplastics are used either as excipient or API (Active Product Ingredient) in medicinal formulations. . 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 in the medicine formulation: • Microplastic at formulation stage • Microplastic if the medicine placed on the market has core/granule/tablet dimensions ≤ 5 mm (aka 'mini-tablets' or pellets)[84] If the solid polymer has any other function (e.g. taste masking, binder, disintegrant, diluent, lubricant function): • Microplastic at formulation stage • Microplastic when the medicine is placed on the market	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 if the medicine/osmotic system is ≤ 5 mm in all dimensions[85]
Proposed action/TP	1) Reporting requirement 2) Instructions for use and disposal requirement to provide sufficient instructions in the Package Leaflet (PL) on how to dispose unused medicines containing microplastics. The 'Instructions for use and disposal' should follow the specifications from the EMA templates, guidance and standard phrases to be used on SmPC and packaging leaflet.		
Justification for action	Microplastics are 100% excreted from the body and released to the environment either as a microplastic or secondary microplastic. In addition, a proportion of microplastics can be released to the environment because of disposal of unused medicines down the drain. As these releases could potentially be further minimised through targeted measures, there is a need for an EU wide 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.		

[84] 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').

[85] 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	Solid dosage forms (matrix and film diffusion)	Ion exchange based controlled release	Osmotic systems
	Meanwhile, to address the issue of microplastics that can be released to the environment because of disposal of unused medicines down the drain, it is proposed to complement the existing provisions under the medicinal product regulations (and in particular the SmPC), hence instructions for use and disposal 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. Nevertheless, other medicines (without CR function, but which might which might contain other microplastics as binder), or other formulations (e.g. parenteral etc) of the same medicine, might 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)	Alternative substance: none readily available Nevertheless alternative medicines seems to exist for most of the therapeutic area using IER.	Alternative substance: none readily available. But alternative medicines seems to exist for most of the therapeutic area using osmotic systems
Proportionality			
Risk reduction capacity	Limited for the moment as only an instructions for use requirement is proposed.	Limited for the moment as only an instructions for use requirement is proposed.	Limited.
Costs	1) Reporting cost: estimated to be manageable - the pharmaceutical sector is already well-organised to report regularly information to the relevant authorities. This is part of the routine 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) 3) SmPC and PL update cost: estimated to be negligible as they are revised regularly already. Some respondents indicated that the instructions for disposal are already part of the PL, and would therefore not need to take additional action with regard to the instructions for use requirement.		
Other SE impacts	Medicinal products have a high societal value. With the proposed restriction option, medicinal products remain fully available to treat patients, and animals.		
Practicality	The 'Instructions for use and disposal' requirement complement the existing medicinal product regulations with the obligation to indicate on the package leaflet (PL) of the medicines, sufficient instructions for the patients to dispose properly the unused medicines (as instructed in EMA QRD templates, and associated guidances). The potential issue of retrospective changes of approved PL or packaging could be dealt with by way of derogation for previously approved medicines for example. The reporting requirement is considered implementable and manageable for the pharmaceutical sector as long as a central/common receiving system is put in place on the authority side. The transition period would allow industry to handle the update of instructions for use (if necessary) within the normal product re-labelling/repacking life cycle.		

Impacts\Sectors	Solid dosage forms (matrix and film diffusion)	Ion exchange based controlled release	Osmotic systems
Monitorability	Monitorability of the instructions for use implementation (change of PL) could be done via a monitorability of the SmPC update.		
Impact of scope modifications			
All dimensions < 1mm	Tablets, core or granules containing microplastics with a film coating function only would be excluded from the scope if their dimensions are >1mm	Same impacts (microplastics < 1mm)	Would be out of scope
Variations in lower size limit of the microplastic definition	Same impact	Same impact	Same impact
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 / solubility 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 32 Summary of socio-economic impacts of the proposed restriction on food additives (in food supplements and medical food)

Impacts\Sectors	Food additives
Use description	Microplastics used as food additives have similar technical functions, and benefits, to the microplastics used as excipients in medicinal products: i.e. film coating, binder, filler, disintegrant, taste masking, controlled released. They are used in the solid formulation (tablets, granules, cores) of food supplements (e.g. vitamins), and food for special medical purposes (aka 'medical food').
Microplastics description	If the solid polymer has a film coating function in the formulation: • Microplastic at formulation stage • Microplastic if the formulation placed on the market has core/granule/tablet dimensions ≤ 5 mm (aka 'mini-tablets' or pellets) If the solid polymer has any other function (e.g. taste masking, binder, disintegrant, diluent, lubricant function): • Microplastic at formulation stage • Microplastic when the formulation is placed on the market Microplastics are authorised as food additives under the EU Regulation (1333/2008) for use in solid food supplements.
Proposed action/TP	1) Reporting requirement 2) Instructions for use and disposal requirement to provide sufficient instructions in the Package Leaflet (PL) on how to dispose unused products containing microplastics. Alternatively, microplastics authorised as food additives could be re-evaluated within the frame of recital 14 to EU Regulation (EC) No 1333/2008 (food additives Regulation).
Justification for action	Microplastics are 100% excreted from the body and released to the environment either as a microplastic or secondary microplastic. In addition, a proportion of microplastics can be released to the environment because of disposal of unused food supplements or medical food down the drain. As these releases could potentially be further minimised through targeted measures, there is a need for an EU wide action. Food additives are already regulated under other sector specific EU regulation for the HH aspects, nevertheless there is no harmonised practice in Europe nor within the same Member State regarding the authorisation of a product as a food supplement, medical food or medicine. As there is a risk of market-distortion, food additives should be restricted in the same manner as microplastic excipients in medicinal products.
Sector characteristics	
Tonnes used	Not known (only scarce information received). Assumed to be similar to the medicinal products tonnage (worst case).
Alternatives	Similar to alternatives for medicinal products applications.
Proportionality	
Risk reduction capacity	Not known.
Costs	1) Cost to update label, SDS or IFU (which are revised regularly) 2) Reporting cost
Practicality	The reporting requirement is considered implementable and manageable as long as a central/common system is put in place. The instructions for us requirement is considered practical if a sufficient transition period is granted to the sector.
Monitorability	The reporting requirement aims at monitoring the uses and releases to the environment that might arise both from the downstream uses, but also from the industrial uses.
Impact of scope modifications	
	Cf. medicinal products (Table 31)
Main Uncertainties (impact on Proportionality conclusions)	
	Polymers that would fall under the microplastic definition / (bio)degradability / solubility of polymers. Tonnages. Availability of alternatives.

Source: Annex D – Impact assessment for additives in food supplements and medical food (qualitative approach).

Table 33 Summary of socio-economic impacts of the proposed restriction on paints and coatings

Impacts\Sectors	Paints and coatings
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	Instructions for use 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. An instructions for use 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	
Risk reduction capacity	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, an instructions for use requirement is expected to reduce these emissions to the environment. It is not known how effective the instructions for use requirement will be. However, the reporting requirement will help to assess changes to emissions. The emissions could be reduced by up to 48 100 tonnes for consumer products. If professional paints are included, the emission reduction could be up to 93 300 tonnes.
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 instructions for use requirement could at least to some extent be coordinated with the regular updates to labels. The costs associated with reporting 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 once a year.
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 instructions for use 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 instructions for use 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
• Impact of change to lower limit (100 nm) or no lower limit	Not known
Main Uncertainties (impact on Proportionality	How much emissions would be reduced as a result of the instructions for use requirement.

Impacts\Sectors	Paints and coatings
conclusions)	

Source: Annex D – Impact assessment for paints and coatings (qualitative approach).

Table 34 Summary of socio-economic impacts of the proposed restriction on 3D printing

Impacts\Sectors	Description
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	Instructions for use and reporting requirement
Justification for action	Limited releases of microplastics are expected. An instructions for use 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 instructions for use requirement could at least to some extent be coordinated with the regular updates to labels. The costs associated with reporting 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 once a year
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 an instructions for use requirement may affect emissions, the instructions for use 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

Impacts\Sectors	Description
• Impact of change to lower limit (100 nm) or no lower limit	Not known
Main Uncertainties (impact on Proportionality conclusions)	Tonnages Availability of alternatives Emissions to the environment

Source: Annex D – Impact assessment for 3D printing (qualitative approach).

Table 35 Summary of socio-economic impacts of the proposed restriction on toners and printing inks

Impacts\Sectors	Toners and 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. Printing inks are used in printing and consist of a pigment or pigments of the required colour mixed with oil or varnish.
Microplastics description	According to #2027 and 2235, toners consist for 100% of microplastics while some printing inks contain microplastics. In general the microplastic concentration in printing inks is above 1% to be effective (#2027 and 2077). According to #2040, 2216 and 2467, printing inks may contain up to 80% of microplastics. 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. According to #2077, particles with a size above 5 mm cannot be used in the toner. 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 may be expected primarily in the maintenance of printing machines. However, according to #2077, the majority of toner cartridge used is sold for professional use, and maintenance is normally performed by trained professional operators who address the potential risks associated with this operation effectively.
Proposed action/TP	Instructions for use and reporting requirement
Justification for action	Limited releases of microplastics are expected under specific circumstances. An instructions for use requirement is intended to inform users about how to minimise the releases, where possible.
Sector characteristics	
Tonnes used p.a.	No information available on total tonnage but one printing ink manufacturer (#2467) said to use no less than 500 tonnes of microplastics per year.
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 instructions for use requirement could at least to some extent be coordinated with the regular updates to labels. The costs associated with reporting 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 once a year
Cost-effectiveness & affordability	While it is not known how much an instructions for use requirement may affect emissions, the 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.

Impacts\Sectors	Toners and printing inks
• Film forming in scope	N/A
• Impact of change to lower limit (100 nm) or no lower limit	Unlikely to have an impact
Main Uncertainties (impact on Proportionality conclusions)	Tonnages Availability of alternatives Emissions to the environment

Source: Annex D – Impact assessment for toners and printing inks (qualitative approach).

Table 36 Summary of socio-economic impacts of the proposed restriction on oil & gas

Impacts\Sectors	Oil & gas
Proposed action	Reporting & instructions for use / 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 (qualitative).Notes: 2017 values, assumed entry into force (EiF) in 2022, annual data.

Table 37 Summary of socio-economic impacts of the proposed restriction on polymeric infill material

Impacts\Sectors	Polymeric infill material
Proposed action	The Dossier Submitter has analysed several restriction options and finds two options to be proportional: RO2 – full ban on placing on the market entering into effect 6y after EiF; RO4 – set of technical measures to prevent emissions to be implemented 3y after EiF. In Annex D, the Dossier Submitter presents arguments for and against each of both restriction options noting that the final choice is left to the decision maker.
Justification for action	Infill material is currently lost in considerable quantities (currently around 16 kilotonnes p.a.) from synthetic turf pitches (incl. so-called mini-pitches) throughout the EU, whilst infill and non-infill alternatives become increasingly available.
Sector characteristics	
Use description	Polymeric infill material is widely used as infill material for synthetic turf pitches, especially football pitches. Currently around 100 kilotonnes of virgin and recycled (from end-of-life tyres) polymeric infill material are used for replenishing existing pitches.
Tonnes used	100 (15 – 185) kilotonnes
Alternatives	Several non-polymeric infill materials can be produced from organic alternatives such as cork, coconut husk and timber granulates; moreover some biodegradable polymeric infill materials based on sugar beet have been developed. Finally, non-infill turf systems become increasingly available. This said, the availability of alternatives is not yet sufficient to immediately replace the current demand for infill material, and many of the existing pitch systems cannot use non-polymeric infill material.
Effectiveness & Proportionality	
Targeted at risk/ capable to reduce risk (or risk reduction capacity)	Based on current information, emissions are estimated at 16 kilotonnes per year. Under both restriction options these emissions would be reduced by more than 75% over the analytical period.
Cost-effectiveness & affordability	Both restriction options imply compliance costs which have been estimated at €1.3bn and €9.6bn (NPV) over the analytical period for RO4 and RO2, respectively. Per pitch this correspond to incremental costs of €40k to €300k over the 20y-period for RO4 and RO2 period, respectively. The corresponding cost-effectiveness ratios are €4.5 and €33.3 per kg of emission avoided. It is important to note that the cost for RO4 may be substantially lower if alternative infill material or non-infill systems become less expensive over time. In turn this would improve the cost-effectiveness ratio.
Practicality	Both options are considered practical by the Dossier Submitter.
Monitorability	Both options are considered monitorable by the Dossier Submitter.
Impact of scope modifications	
Change in the lower limit value	No specific assessment has been made but given the concentration limit it is not foreseeable that a different lower limit value would have any impact on the restriction.
Main Uncertainties (impact on conclusions)	No major uncertainties.

Source: Annex D – Impact assessment for polymeric infill material.

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 stepwise 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 Step 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. As a part of the restriction proposal, Dossier Submitter has outlined reporting requirements which are intended to ensure that there is sufficient information in the supply chain which will enable formulators to assess whether or not the starting materials they use are or contain microplastics. If the formulation process is such that it can be concluded that chemical reactions do not take place (e.g. microplastics are not formed as a part of formulation process) information from the starting material can be sufficient to conclude that microplastics are not present in the product. If there are chemical reactions during the formulation (for example coating of inorganic particles with polymers), the information from the manufacturing process can be used as part of the assessment.

If the product is imported into European Union area, the reporting requirements in the supply chain do not apply. However, it is the responsibility of the importer which places the product in the market to ensure that sufficient information on the composition of the product is available. Sector specific labelling requirements, such as INCI labelling for cosmetics, may help in identifying 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 Step 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 specific limitations which need to be taken into account when selecting the measurement technique depending on the sample to be analysed.

In addition to spectroscopic methods, several analytical methods for characterising microplastics are available based on gas chromatographic coupled with mass spectrometry (GC-MS) principles. For instance, in pyrolysis GC-MS (pyro GC-MS) microplastics are decomposed by pyrolysis and then the resulting 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 a next step these products are thermally desorbed, chromatographically separated and in a final step identified with mass spectrometry. The advantage of TED GC-MS over 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 microplastics especially the molecular distribution of the constituents which is based on the size of the analytes.

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

As noted above, the type of product will ultimately determine the most suitable techniques to be used to obtain meaningful results. Suppliers are ultimately best placed to decide which set of analyses would be most applicable on a case-by-case basis. Independently of the kind of analysis performed it is the responsibility of the supplier to have the proper documentation available to ensure that a 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 an enforcement authority, upon request.

Prior knowledge of the nature and complexity of a product (i.e. identity and number of other substances present) will depend on product type and will influence both the appropriate analytical strategy and the potential for analytical limitations to prevent either the identification or quantification of microplastics . Analytical limitations are likely for certain products and may pose enforcement challenges, particularly if there is limited information on the composition of a product. However, it should be emphasised that the scenarios where there would be a need to analyse a sample(s) from which there is no prior information available are rare. For example, information available from the ingredients can normally be used to decide which sample preparation techniques and analytical methods could be employed. Furthermore it should also be emphasized that the use of insufficient/unsuitable analytical method(s) with which the presence of the microplastics cannot be confirmed in a certain product is not a reason to avoid restriction obligations.

To confirm the presence and identity of microplastics in a product might not always be

straight forward, especially if the product is complex and contains many 'similar' objects (e.g. oil droplets, other solid particles etc.) that are comparable to microplastic particles. This might lead to false outcomes from the analysis. The Dossier Submitter is aware of this fact that is also further supported by Schwaferts et al. (2019) as well as by the comments received in the consultation. The information provided describes current limitations in the analytical techniques that are capable of identifying microplastic particles, morphology and particle size distribution below the micrometre range. However, Schwaferts et al. (2019) also discusses which analytical techniques from nanomaterials analysis might be adapted to overcome the problem of measuring below that range. Another important element to obtain meaningful and comparable results across different laboratories is a protocol that describes unified sample collection, treatment and analysis.

It is worth mentioning that separation techniques such as field flow fractionation, chromatography and electrophoresis are available and rapidly developing. Similarly, there are multiple, viable methods for characterisation of particle size and morphology based on light scattering or imaging techniques. In addition to know more about the chemical identity of the microplastics that are intentionally added to the product, techniques based on spectroscopy or chromatography are available options. Especially chromatography coupled with mass spectrometry is able to deliver results below the micrometre range.

It is inevitable that the amount of R&D that is put into the continuous development of the above analytical techniques is significant and, thus, it will provide more and more reliable results in the micro- and nanosize range. The transition period(s) allowed in the restriction will give the opportunity to stakeholders/enforcement bodies to adapt and use the most appropriate method(s) for the given product.

In addition, there are also notable work done to identify nanomaterials using suitable methods. A report by Rauscher et al. (2019) has recently been published that elaborates more on reference measurement system, sample preparation and identification of nanomaterial using suitable measurement techniques.

From a practical point of view, Steps 1 and 2 could be translated into a decision tree (cf. Figure 12) that presents key questions to be arranged across three tiers, which need to be answered to identify if a substance or a mixture placed on the market contains microplastic and would therefore be subject to the proposed restriction. It is possible to leave the assessment at each of the tiers as it will be possible to conclude that a substance or mixture is not a microplastic in many cases without additional assessment.

There is no hierarchy in the various elements of the microplastic definition set in the restriction proposal. Nevertheless, it is advised to start with simple checks, such as for the presence of solid particles or polymers in the substance or mixture placed on the market. The absence of either of these, or the presence below the proposed concentration limit of 0.01% w/w, will lead to a conclusion that the substance or mixture will not be affected by the proposed restriction.

Importantly, the decision trees below present one way to interpret the microplastic definition in a stepwise way. However, it is likely to be equally valid to approach the definition from different starting points and this may be more appropriate for particular substances to mixtures depending on the prior knowledge available.

More details on the key questions are presented in:

- Figure 13: Microplastic decision tree - Tier 1a – relevant solid particles
- Figure 14: Microplastic decision tree - Tier 1b – relevant polymers
- Figure 15: Microplastic decision tree - Tier 2 –Particle
- Figure 16: Microplastic decision tree - Tier 3 – concentration considerations

Note that both of the elements in Tier 1 (i.e. 1a and 1b) have to be fulfilled to progress to tier 2, and can be assessed independently. In some cases, e.g. when information is available on a label or via the supply chain or other prior knowledge, it will be easier to start with criteria 1b rather than 1a.

At any step in the decision tree, if the answers to the criteria questions lead you to the conclusion that there is “no microplastics in the substance/mixture placed on the market” (as indicted in the green shapes), then no further assessment is needed, and the restriction does not apply to the substance or mixture placed on the market. For example, if criterion 1a is not met there is no need to assess criteria 1b, and *visa-versa*.

Figure 12: Microplastics definition decision tree overview

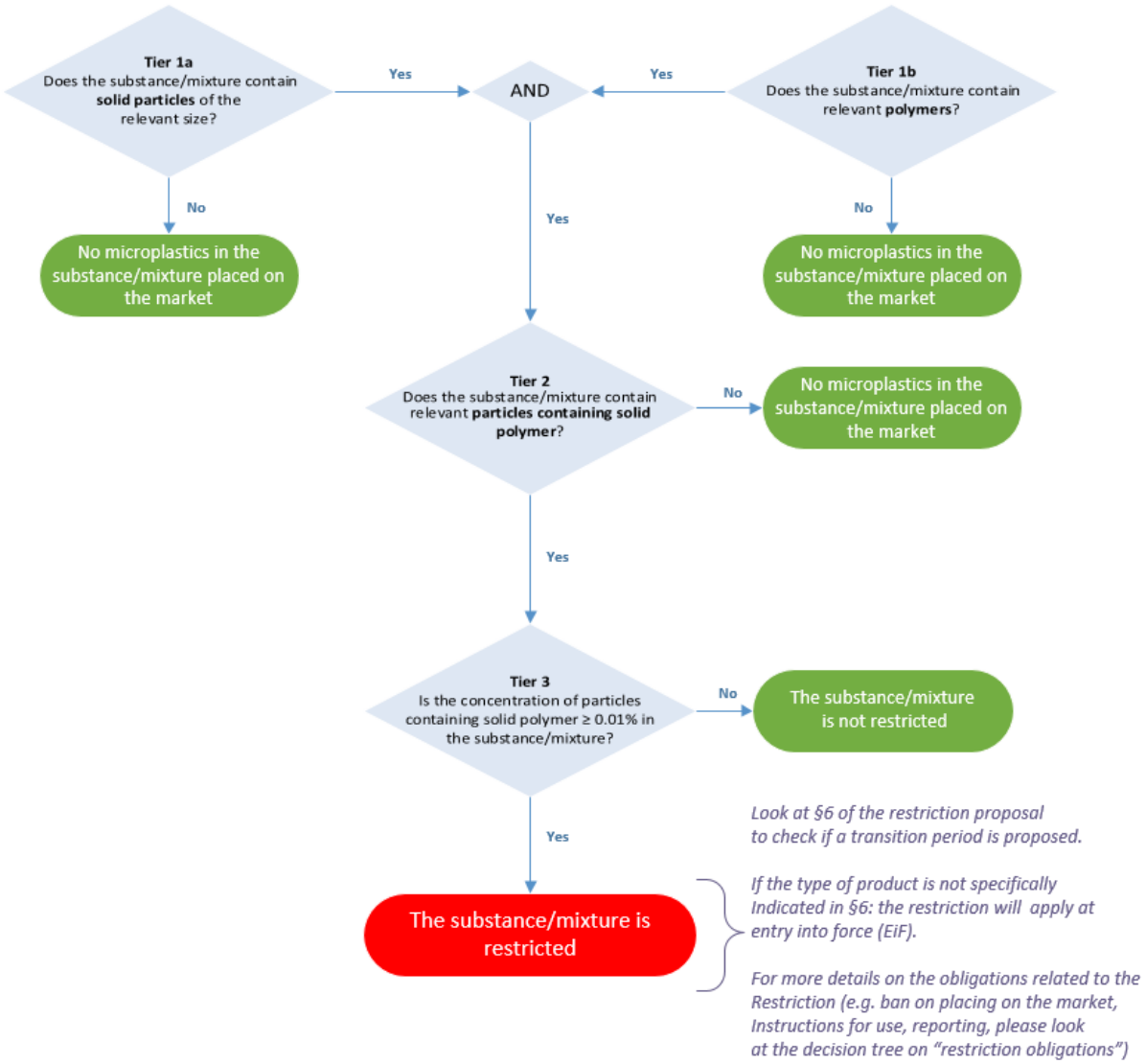


Figure 13: Microplastic decision tree - Tier 1a – relevant solid particles

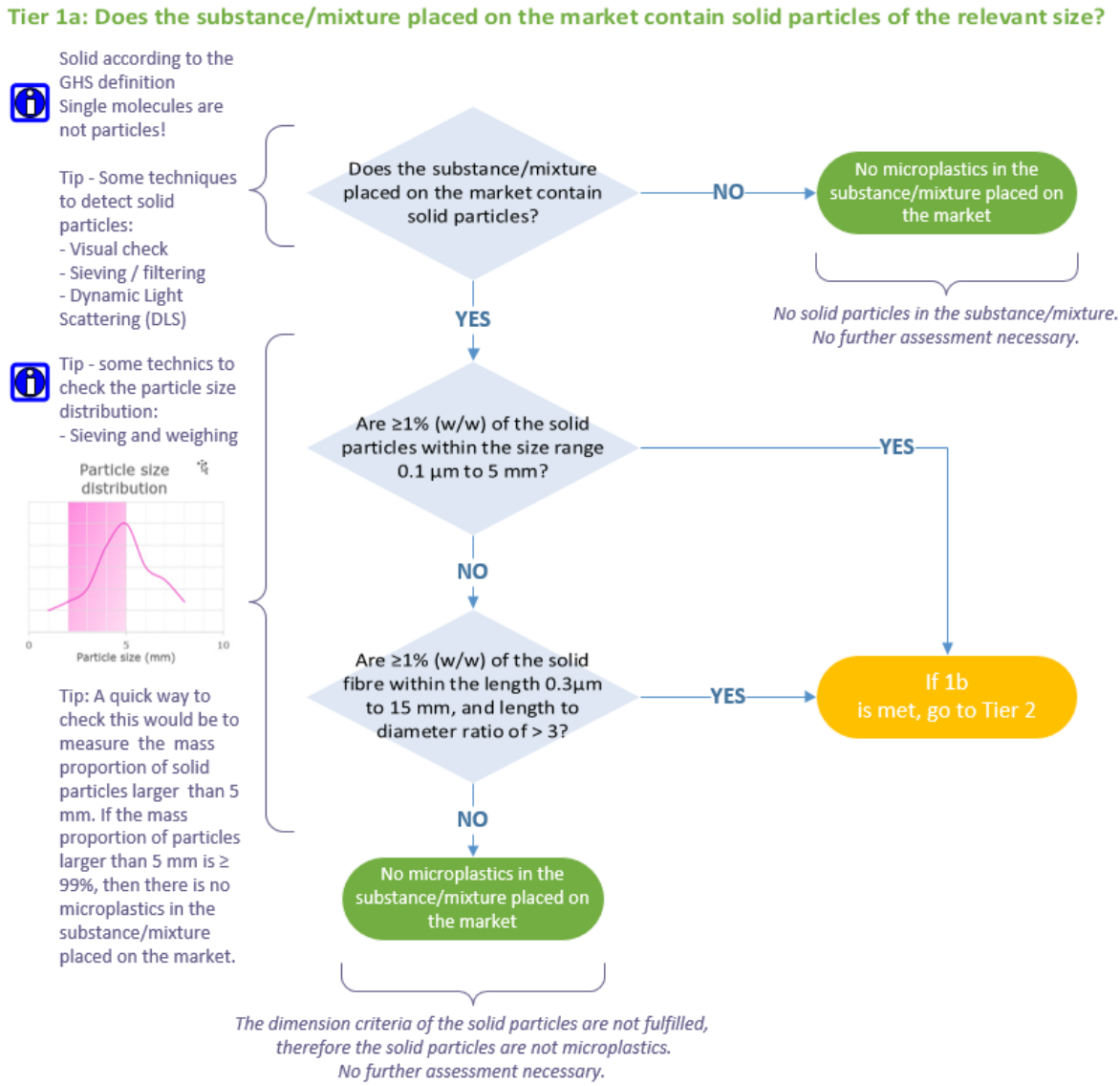


Figure 14: Microplastic decision tree - Tier 1b – relevant polymers

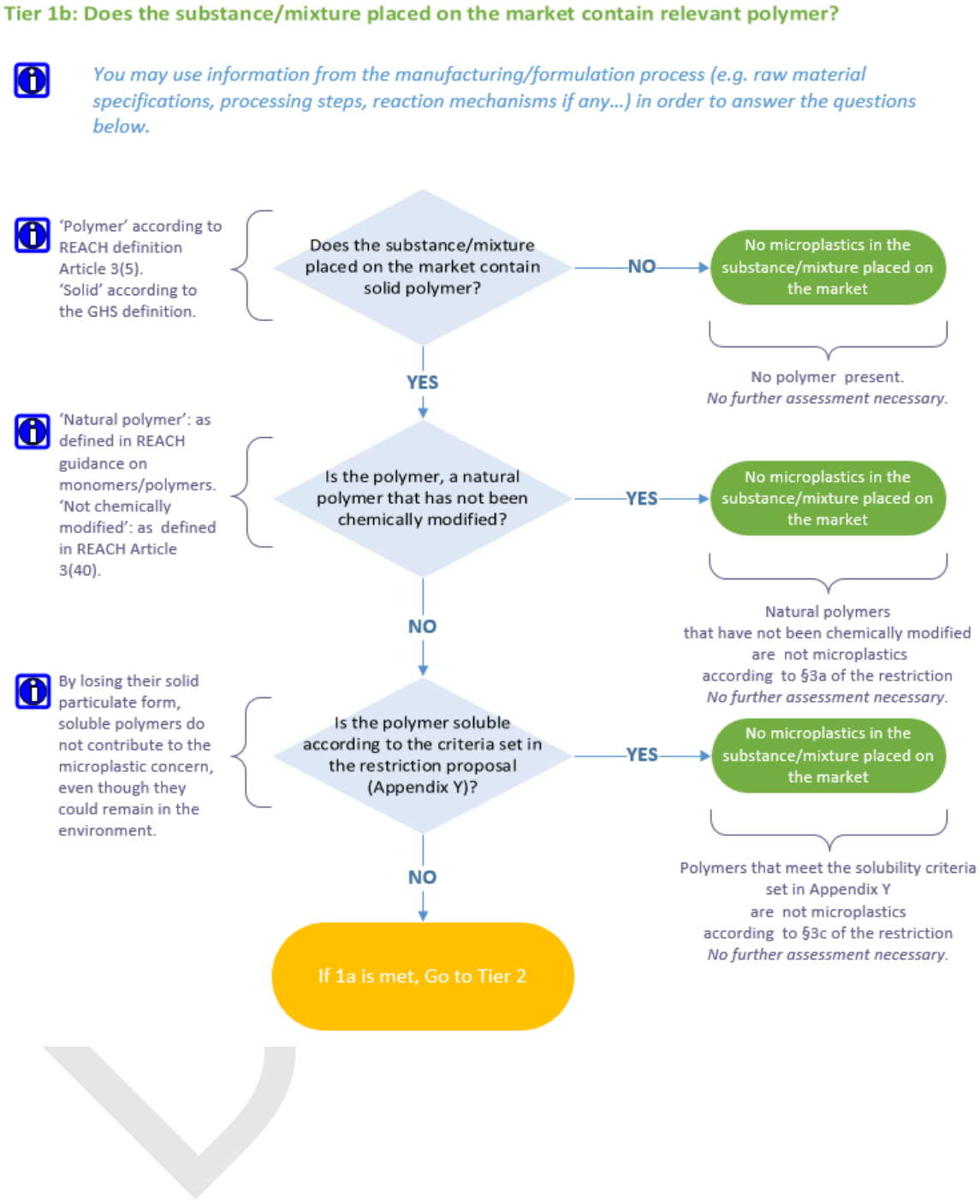


Figure 15: Microplastic decision tree - Tier 2 –Particle containing solid polymer

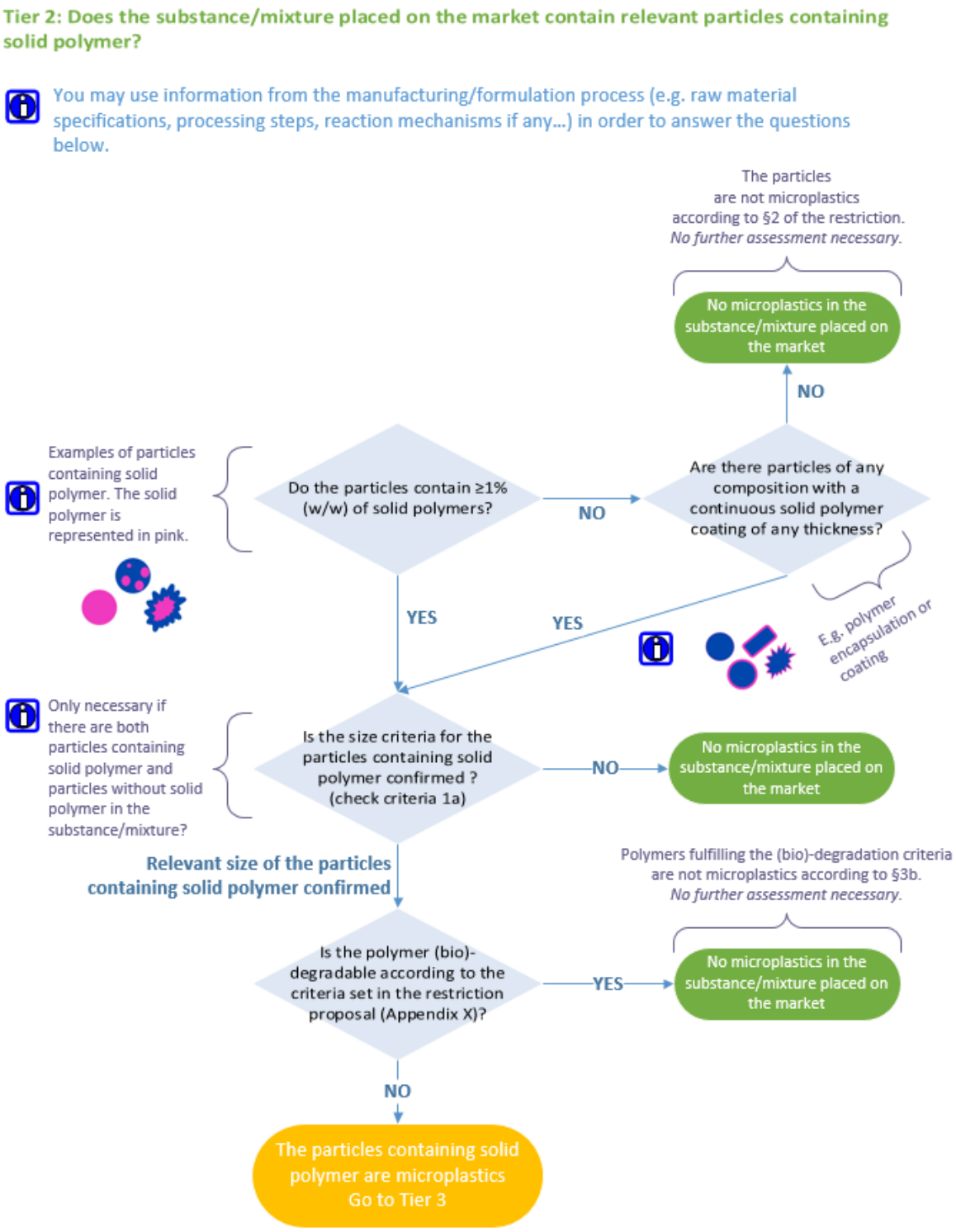
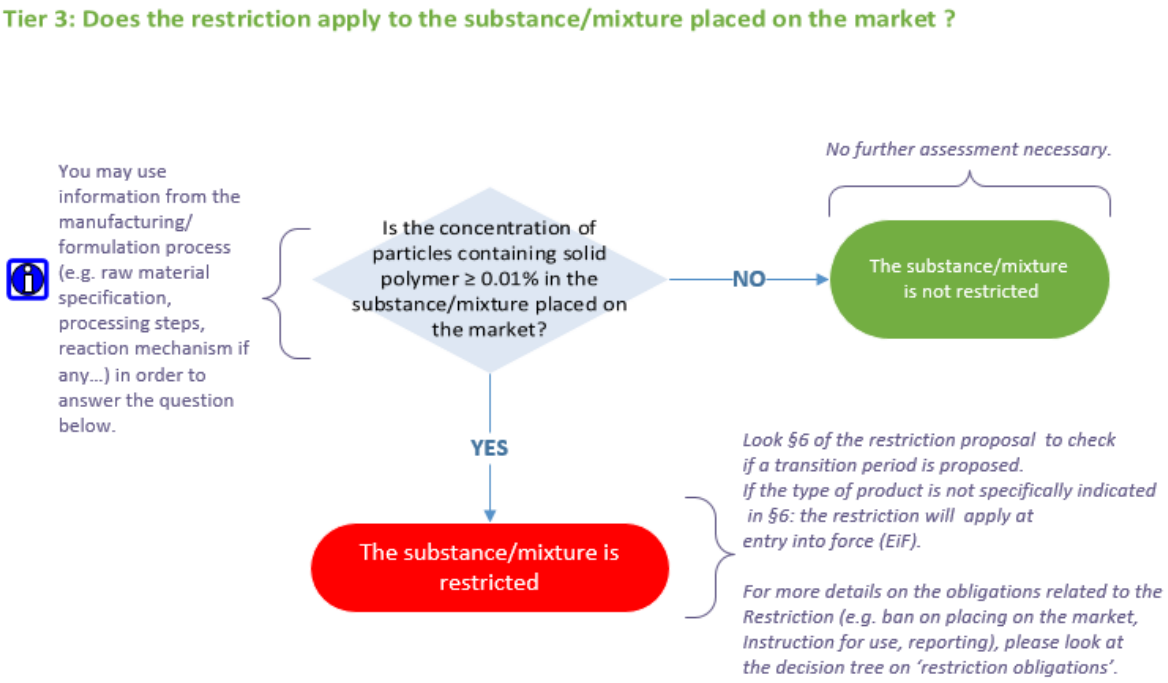


Figure 16: Microplastic decision tree - Tier 3 – concentration considerations



2.6.1.3 Step 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 natural 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 during film forming), the product may be derogated. It is expected that when products containing microplastics are placed on the market on the basis of a derogation the manufacturer/importer of the product would fully document and justify compliance with the conditions of the derogation and provide this to enforcement authorities, on request.

Methods for the enforcement of bans on microbeads in cosmetics is already available (Canada: Microbeads in toiletries Method 445)[86].

The figures below may assist in concluding whether the use is derogated or placing on the market can continue after fulfilling the proposed 'reporting' and 'instructions for use and disposal' requirements.

Figure 17, Figure 18, and Figure 19, are an attempt to represent in a simplified way the obligations arising from the restriction at different levels of the supply chain.

The different boxes outline the obligations for suppliers (manufacturers, importers, distributors and downstream users according to REACH definition), and downstream users at industrial sites, that will arise from the proposed restriction when placing a

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

substance or mixture on the market containing a microplastic, or when using it (downstream users at industrial sites).

Each box is relevant to a particular actor/role in the supply chain, and includes the questions that the actor/role should ask themselves to identify its obligations:

- Box 1 represents the obligations of **an EU manufacturer of substances**, or an **importer of substance or mixture** (cf. Figure 17)
- Box 2 represents the obligations of **downstream users**[87] (**industrial activities**) **benefiting from the derogation 4a (use at industrial site)** (cf. Figure 18)
- Box 3 and Box4 identify the different types of products, and the associated obligations of the importer or downstream user when placing on the market, for **consumer or professional**, substance or mixture containing microplastics. It identifies in particular the obligations of suppliers 'placing for the first time'[88] microplastics on the market for an end use allowed on the basis of paragraphs 4(b), 4(d), 4(e), or 5. (cf. Figure 19).

The obligations (in term of reporting, 'instruction for use and disposal', placing on the market…) of each actor in the supply chain (except distributors) are identified in orange, magenta and salmon-pink coloured shapes.

It should be kept in mind that the definition of 'use' is broad in REACH and is defined in REACH Article 3(24) as 'any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation'.

Therefore a company in the supply chain might have multiple different roles under REACH: for example a REACH manufacturer can also be a REACH downstream user of the microplastics they are manufacturing. In this case, the company will have to fulfil all obligations associated with the different roles.

Distributors[89], are not considered as downstream users, and would have to comply only with the 'instruction for use and disposal' obligations and pass down the supply chain relevant information necessary to enable appropriate use and disposal of the substance or mixture containing microplastic.

The green shapes indicate that there is no microplastic concern, or that no restriction applies ('full' derogation).

The red shape indicates that the substance or mixture cannot be placed on the market after the restrictions enters into force (EiF) or after the transitional period specified in

[87] More information on downstream users and end-users is available here: https://echa.europa.eu/regulations/reach/downstream-users/about-downstream-users/who-is-a-downstream-user. End users use substances or mixtures but do not supply them further downstream. Examples include users of adhesives, coatings and inks, lubricants, cleaning agents, solvents and chemical reagents like bleaching products. This includes producers of articles.

[88] 'Placing on the market for the first time' means the first natural or legal person who supplies or makes available substances, mixtures or articles on the market in the EU. The first placing on the market in the EU will either be by the manufacturer or the importer of the substance, mixture or article concerned.

[89] Distributor: Actor who only stores and places on the market substances, on their own or in a mixture. This is not a downstream user according to REACH definition in Article 3(13 and 14).

paragraph 6 of the restriction proposal.

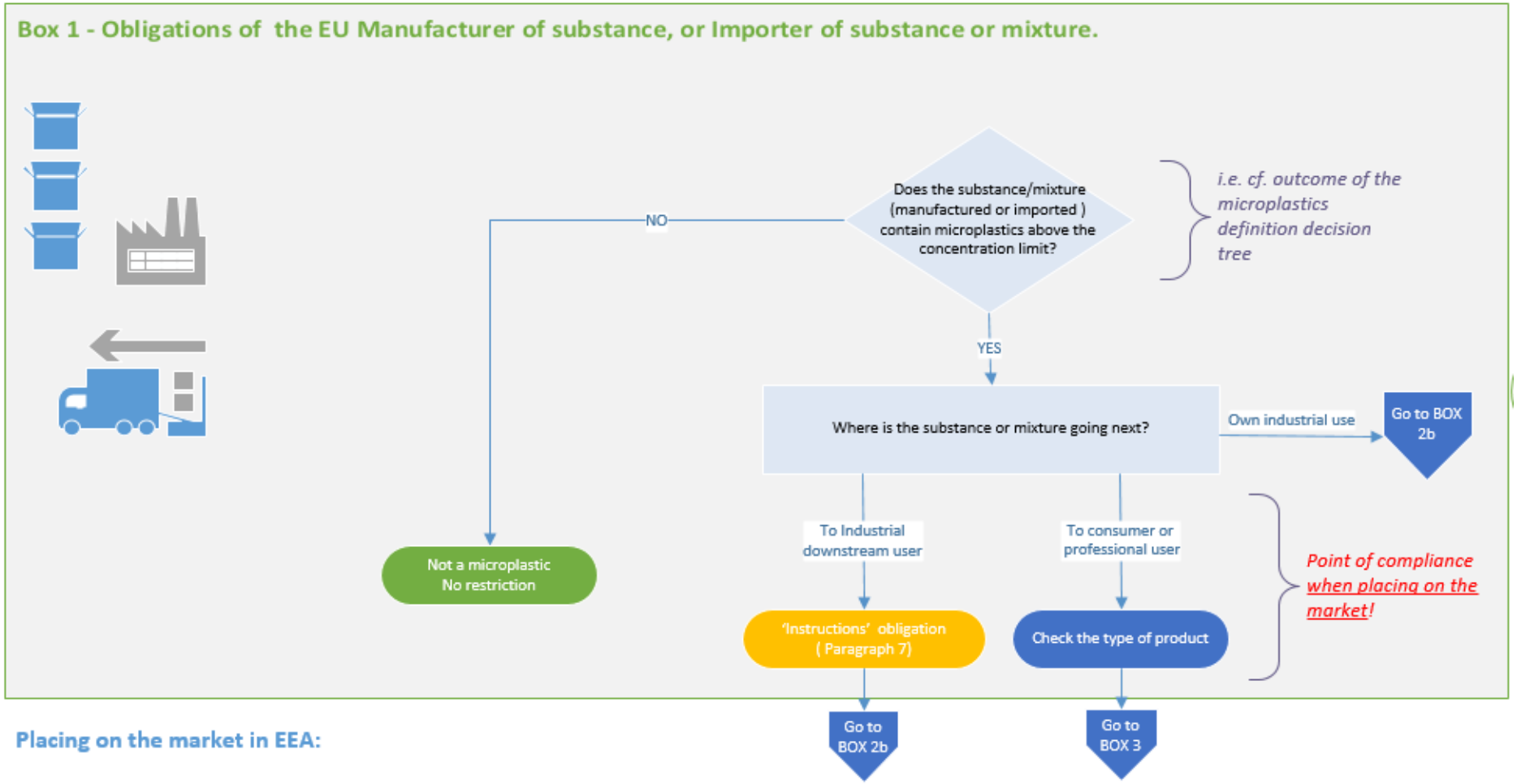


Figure 17: Obligations of the EU manufacturer of substance, or importer of substance or mixture

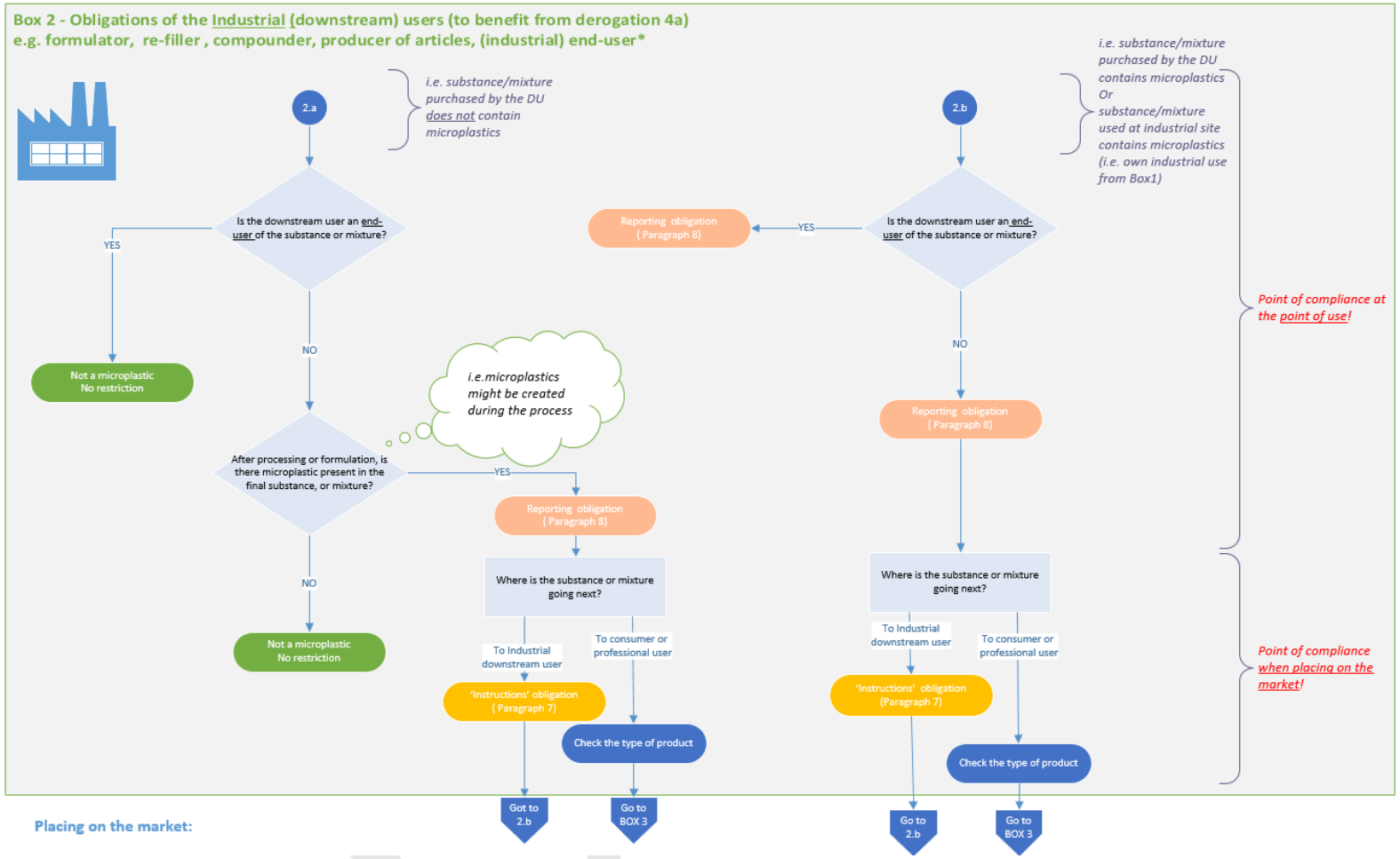


Figure 18: Obligations of downstream users (industrial activities)[90]

[90] *: End users use substances or mixtures but do not supply them further downstream. Examples include users of adhesives, coatings and inks, lubricants, cleaning agents, solvents and chemical reagents like bleaching products. This includes producers of articles.

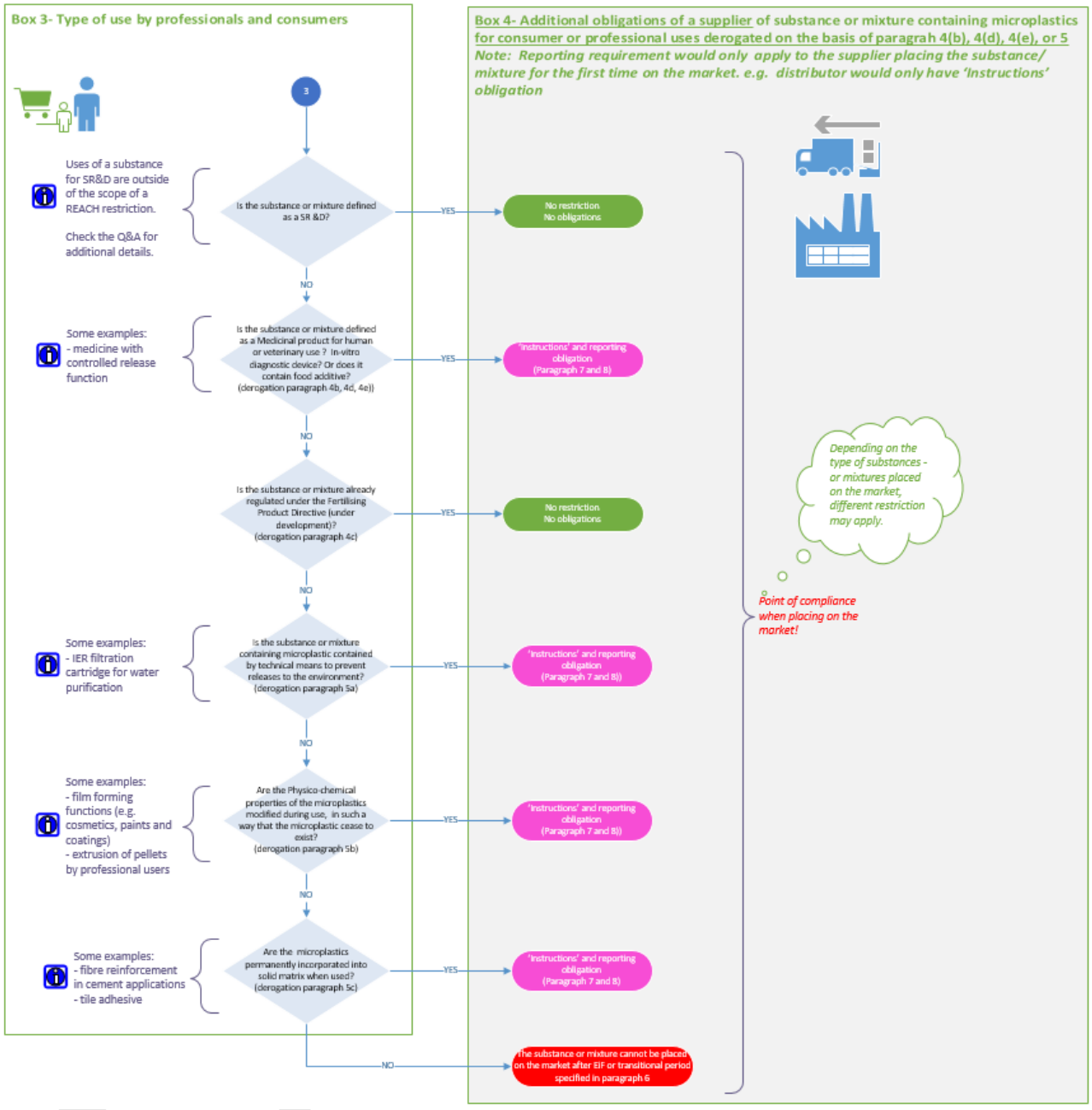


Figure 19: Obligations when placing on the market for consumers or professionals

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 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

Specific 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 five 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 by an estimated 42 kilotonnes (lower bound: 13 kilotonnes; upper bound: 95 kilotonnes) annually for thirteen product groups where the available information allowed quantification of emissions to the environment.[91] The proposed restriction is expected to avoid 70% of these emissions over a 20 year period 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 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-benefit

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

considerations. The affordability of the proposed restriction is also demonstrated below.

One important remark pertains to the proportionality considerations for polymeric infill material. Indeed, extensive information on the use of polymeric infill material was received in the consultation of the Annex XV report. Based on this information the Dossier Submitter updated its original restriction proposal and provided a new Annex D.13 in which various restriction options for the particular use of polymeric infill are discussed. However, as the infill material constitutes an important contributor to both the release of intentionally added microplastics and the costs of restricting such releases, and as the different restriction options have their own costs and release projections, this information has not been used to update summary graphs or tables in Section 2.7, where this would have come at the cost of analytical tractability.

2.7.1 Affordability considerations

As shown in Section 2.5, reformulations are expected to constitute the largest economic impact of the proposed restriction, requiring considerable time and other resource investments. Aligning the transitional periods of the proposed restriction with the reformulation time required by industry would help minimising the economic, but also social and distributional impacts of the restriction. However, considerations for the determination of the length of transitional periods have to be balanced against the goal of minimising emissions to the environment, as each additional transitional year of the restriction would lead to further releases of microplastics, thus increasing the environmental pressure from the rising pollution stock in the environment.

As demonstrated in Annex D and summarised in Table 38, the proposed restriction is expected to lead to a relatively small cost per kilogram of microplastics used. In particular, Table 38 suggests that the costs per kg used are the highest for the proposed action on leave-on cosmetics. Therefore, overall, the proposed restriction is an affordable regulatory action to curb microplastic emissions to the environment.

Table 38 Indicative restriction costs in € per kilogram of microplastics used

Sectors/ Scenarios	Low	Central	High
Control release fertilisers & fertiliser additives	1	7	42
Coated seeds & Capsule suspension PPPs	4	30	188
Other rinse-off cosmetics	1	12	15
Leave-on cosmetics	107	257	367
Fragrance encapsulates	5y TP: 75 8y TP: 94	5y TP: 88 8y TP: 110	5y TP: 100 8y TP: 125
Other microplastics contained in detergents	<1	1	4
Waxes, polishes and air care products	<1	<1	1
Polymeric infill material*	RO2: 5 RO4: <1	RO2: 5 RO4: <1	RO2: 5 RO4: <1

Source: Annex D. *At the time of writing, it was unclear which of two restriction options would be preferable to policy makers, RO2 (ban 6y after EiF) or RO4 (technical measures 3y after EiF), see Table 37 and Annex D.13.

2.7.2 Abatement cost (cost-effectiveness) considerations

Table 39 shows that the overall cost-effectiveness of the restriction is about €19/kg (€2/kg - €133/kg), taking into account information on the uses, emissions and costs where those could be quantitatively estimated.[92]

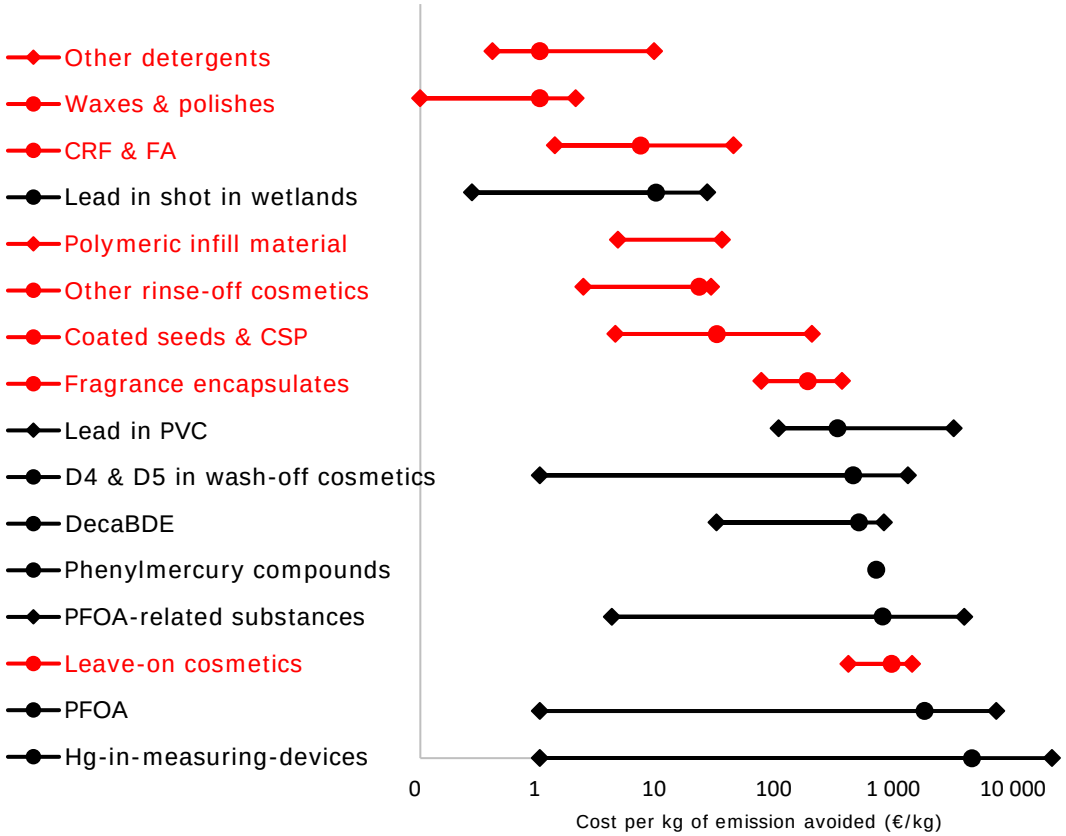
Table 39 Summary of cost-effectiveness of proposed restriction on placing on the market

Sectors / Scenarios	Low	Central	High
Control release fertilisers & fertiliser additives	1	7	42
Coated seeds & Capsule suspension PPPs	4	30	188
Other rinse-off cosmetics	2	22	27
Leave-on cosmetics	380	870	1 300
Fragrance encapsulates	5y TP: 71 8y TP: 89	5y TP: 173 8y TP: 128	5yTP: 337 8y TP 329
Other microplastics contained in detergents	<1	1	9
Waxes, polishes and air care products	<1	1	2
Polymeric infill material*	RO2: 33 RO4: 4	RO2: 33 RO4: 4	RO2: 33 RO4: 4
Overall cost-effectiveness (€/kg)**	**2**	**19**	**133**

Source: Annex D. *At the time of writing, it was unclear which of two restriction options would be preferable to policy makers, RO2 (ban 6y after EiF) or RO4 (technical measures 3y after EiF), see Table 37 and Annex D.13.
** The overall cost-effectiveness estimates do not include the cost-effectiveness of a possible restriction on polymeric infill material since it is unclear which restriction option would be chosen for polymeric infill material.

In order to allow decision-makers to select the optimal risk reduction strategy, separate cost-effectiveness values are presented for the main use sectors of microplastics. Table 39 shows that these range from less than €1/kg to up to €870/kg in the central case. Figure 20 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, the available evidence suggested that measures costing less than €1 000 per kilogram of emission reduction would usually not be rejected for reasons of disproportionate costs, whereas for measures with costs above €50 000 per kilogram PBT such a rejection is likely (Oosterhuis et al., 2017).

[92] Depending on the effectiveness of the proposed instructions for use 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 in Table 39. CRF & FA – Controlled release fertilisers and fertiliser additives. CSP – capsule suspension 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 20 Comparison of the cost-effectiveness of the proposed restriction measures on microplastic uses with previous regulatory actions of PBT/vPvB or similar substances

As shown in Figure 21, the average costs of restricting the uses in agriculture & horticulture, microbeads, other detergents, waxes, polishes and air care products are low. It slightly increases with further extending the restriction scope to include other rinse-off cosmetics and fragrance encapsulates. The addition of leave-on cosmetics in the restriction scope significantly increases the average restriction costs per kilogramme emissions reduced. With €870/kg the cost-effectiveness of restricting this use is the lowest, although still comparable with previously adopted restrictions addressing similar environmental concern (see Figure 20).

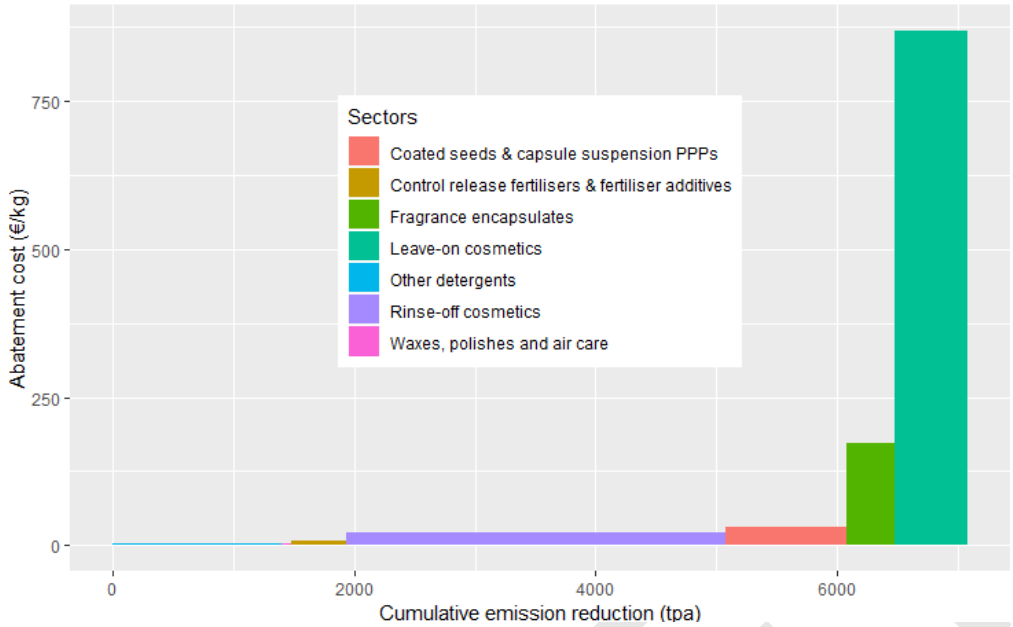


Figure 21 Average restriction cost per kilogramme emissions reduced

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 3.3% of the emissions anticipated to be reduced as a result of the proposed restriction, see Figure 22 and Figure 23.[93]

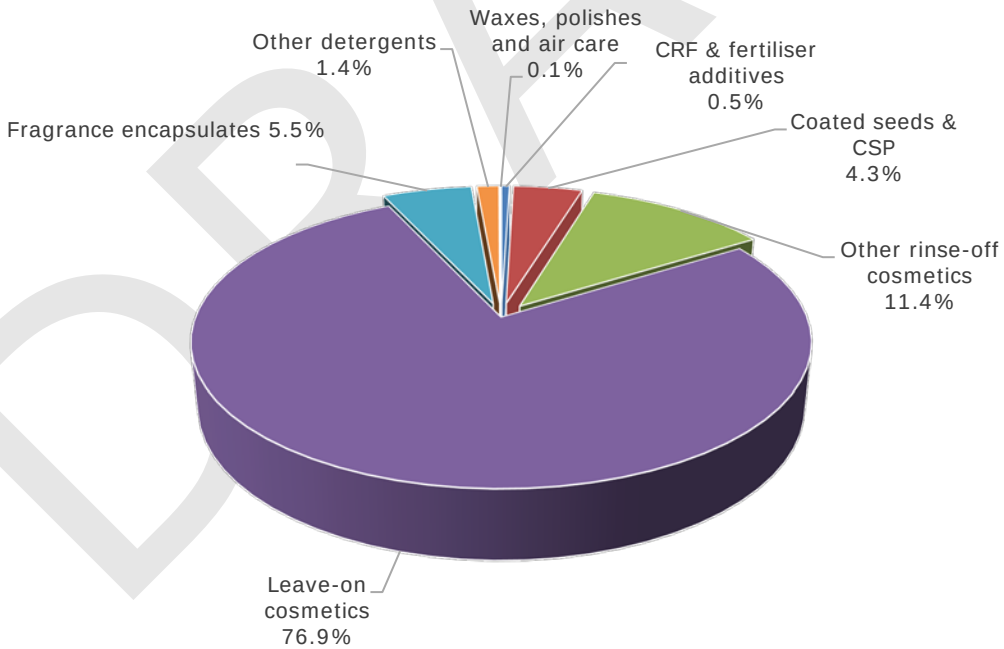


Figure 22 Share of total restriction costs (central cost scenario)

[93] 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 instructions for use 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).

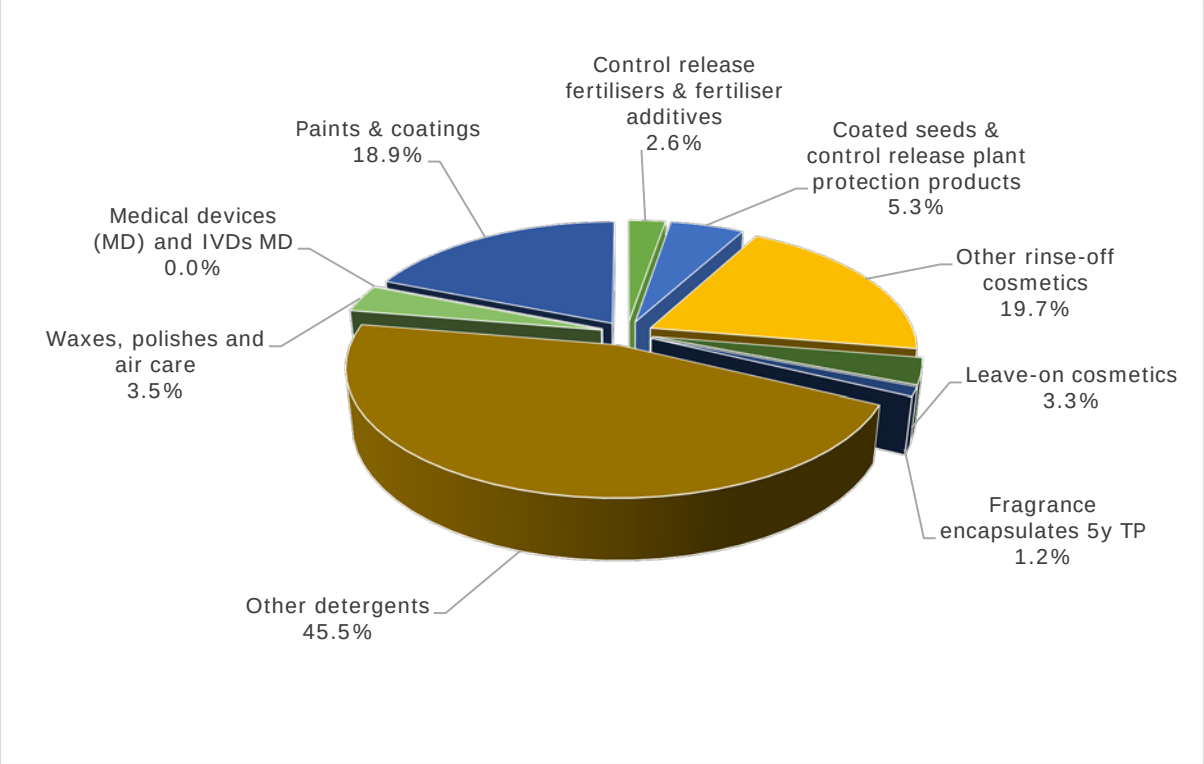


Figure 23 Share of total emissions (central emission scenario)

Figure 21 to Figure 23 do not include information on infill material since including this information would have made the graphs incomprehensible. Instead, the reader is pointed to Table 37 for a summary of the socio-economic impacts of the proposed restriction options on polymeric infill material. It is however clear from Table 39 and Figure 20 that the cost-effectiveness of the proposed options is in the same order of magnitude than those gauged for the other sectors and hence any conclusion on the proportionality of the proposed restriction on those sectors would carry over to the restriction proposed on the polymeric infill material.

2.7.3 Cost-benefit considerations

In addition to the considerations above, a link can be made to the option value theory in resource economics.[94] 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.

[94] 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.

There are also several 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 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 emission 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 500 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 ~70% of average annual emissions to the environment of intentionally added microplastic over the 20 year analytical period. Once in full effect, this is an emission abatement in excess of 30 000 tonnes per year which given the persistent nature of microplastics would otherwise accumulate in the environment. This corresponds to an abatement effectiveness of >90% at the end of the analytical period of 20 years.

- 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 is the paucity of hazard data for terrestrial species and for nanoplastics, in general. The non-threshold 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, in order to minimise the likelihood of adverse effects arising as a consequence of increasing exposure concentrations if the use of intentionally added microplastics were to be continued. 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 500 thousand tonnes of microplastics over the 20-year period following its entry into force (a reduction of 70%[95] 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 €9.5 billion (NPV). The cost-effectiveness of avoided emissions, for sectors where those have been quantified, ranges from less than €1/kg to €870/kg per year in the central scenario. The costs of the instructions for use and disposal requirements could not be quantified, but are considered to be minor in comparison to the other estimated costs.

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 the aim to minimise costs to society, without unnecessary delay in emissions reduction. In this manner industry will have sufficient time to develop and

[95] The actual effectiveness of the proposal depends on both the length of transitional periods and the effectiveness of instructions for use requirements and scenario assumptions. After all transitional periods have expired >90% of emissions are prevented.

transition to suitable alternatives, including biodegradable polymers where this is appropriate;

- Instructions for use and disposal 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 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 5-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 are to be synchronised with those for (bio)degradable polymers foreseen in the EU Fertilising Products Regulation (EC) No 2019/1009.
- 'Microbeads' contained in detergents: 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.
- Fragrance encapsulates: a transitional arrangement of either 5 or 8 years is proposed. An 8-years transition period would make it more likely that alternatives could be developed and implemented before entry into effect, thereby reducing the costs. On the other hand, there would be microplastic releases for three additional years. If industry did not have enough time to develop feasible alternative encapsulates within the end of the transitional period, companies would be forced to remove the polymeric encapsulates and reformulate products to increase the amount of perfume contained in them. The Dossier Submitter

considers the proposed restriction proportional for this product category both under a 5 and an 8-year transitional period. Ultimately, the decision on what transition period is given depends on how much weight is given to the reduction of microplastic releases to the environment as compared to the associated societal costs.

- Other microplastics contained in detergents, waxes, polishes and air care products: a transitional arrangement of five years is considered appropriate to give industry sufficient time to substitute microplastics.
- 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 8 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) and to start reapproval processes for PPPs.
- Medical devices as defined in Directive 93/42/EEC or in the classification rule 21 set in Annex VIII to Regulation (EU) 2017/: The measure is justified with reference to the cost effectiveness of previous restrictions for substances with similar concerns
- Polymeric infill material: The measures identified are justified with reference to the cost-effectiveness of previous restrictions for substances with similar concerns. Continued use of existing pitches is guaranteed.

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 5 mm, or fibres with length <15 mm. 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 methods 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 wastewater 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 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 of 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 five 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 impacts of microplastics on the environment and human health.

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