Version 1, 14 August 2018

Q&A on substance identification and the potential scope of a restriction on intentional uses of 'microplastics'

Purpose

The purpose of this document is to provide further detail on the Agency's work investigating the need for a restriction on intentional use of microplastics. The document is in the form of 'frequently asked questions'. If your specific question has not been answered, please send an email to: restriction-microplastics@echa.europa.eu.

This document is based on the Q&A document originally prepared to support the Agency's 'call for evidence' on a potential restriction on intentional uses of microplastic particles in products of any kind, which was open from 01 March 2018 to 11 May 2018. This document has been revised in several aspects based on feedback from stakeholders.

The document aims provide information to stakeholders regarding the restriction investigation work currently being undertaken by ECHA. However, users are reminded that the text of the REACH and CLP Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

Submission of further information

If as a result of the publication of this Q&A you wish to send us additional information, this would be gratefully received. You can use the email address above or the following web link. If you would like to send us confidential information please use the weblink only:

https://comments.echa.europa.eu/comments_cms/documentswebform.aspx.

Content

The questions and answers have been grouped into broad categories, although some questions and answers are relevant to more than one category.

A. Restriction process
B. Substance identification and microplastics definition
C. Uses of microplastics and potential alternatives
D. Hazard and risk
E. Socio-economic analysis

A) Restriction process

Question	Answer
A.1. I thought polymers were not included in REACH. How can they be restricted?	Polymers are exempted from the registration and evaluation elements of the REACH Regulation (Article 2(9) of REACH), but as they are substances, they are covered by various other REACH provisions, such as in relation to information in the supply chain (Title IV), authorisation (Title VII), restrictions (Title VIII) and classification and labelling (C&L) (Title XI). • A polymer is a substance consisting of molecules characterised by the sequence of one or more types of monomer units (Article 3(5) of REACH). • Monomers need to be registered; their lifecycle needs to be covered in the Chemical Safety Report (CSR) (Articles 6(2) and (3) of REACH).
A.2. Are microplastic particles articles or substances?	A microplastic particle could, on a case-by-case basis, be considered as a substance on its own, a mixture or an article. However, this distinction does not matter from the perspective of a potential restriction under REACH as restriction of a substance on its own, in a mixture and/or in an article is equally possible (as described in Article 67 of REACH).
A.3. Which polymers will be included in any restriction proposed?	In principle, any polymer in a physical form consistent with the 'microplastic' concern (see Question D.1) that poses a risk to the environment or human health on an EU-wide basis could be subject to a restriction. Please refer to the 'Note on substance identification and the potential scope of a restriction on uses of microplastics' for further information on the identification of microplastics and how this links to the potential scope of a restriction.
A.4. Is my intentional use included within the scope of the	By default, actors in the supply chain that produce products that intentionally contain or release microplastic particles, irrespective of their function in products, should consider their use to be within the potential scope of a restriction. However, the 'Note on substance identification and the

Question	Answer
investigation and any potential restriction?	potential scope of a restriction on uses of microplastics' published in July 2018 describes how the working definition of microplastic has been refined on the basis of information received in the call for evidence and what information we require to refine the microplastic identification and the potential scope of a restriction further.
A.5. Is it certain that a restriction will be proposed?	No. The decision on whether to propose a restriction will depend on the conclusions of our investigation.
A.6. If a restriction is proposed, will there be a transitional period for adaptation? How long will it be?	A transitional period, or periods, may be included in any proposed restriction. The length of any proposed transitional period can be established based on various considerations, including, for example, the time and cost needed to transition to alternative substances or technologies, the time required to use existing stocks as well as the time required for other stakeholders to implement the proposed restriction (e.g., enforcement authorities). The risks that will continue to occur during any transitional period will also be a very important consideration when proposing their length.
A.7. Will there be a concentration limit for intentionally added microplastic particles in products?	Most restrictions have concentration limits to facilitate implementation, enforcement and monitoring whilst still ensuring their effectiveness. Therefore, it is likely that any proposed restriction on uses of microplastics would include a concentration limit. In general, any concentration limit proposed would be established at a level that would prevent any 'intentional' use of a substance, whilst recognising that low concentrations of substances could be present inadvertently in products, for example as a result of contamination, or that it may be necessary to take into account of the sensitivity of available analytical methods. We will assess the available information on the availability of analytical methods for detecting and quantifying microplastic particles in products as well as information on the concentration of microplastics in products are a result of 'unintentional' contamination.

Question	Answer
A.8. I have additional information that I wish to share with ECHA as a result of the publication of this Q&A (or 'Note on substance identification and the potential scope of a restriction on uses of microplastics' published in July 2018). The information that I have is confidential and business sensitive. How can I share information without affecting competiveness or anti-trust laws?	If you have additional information to send us it can be submitted using the email or the webform detailed on page 1. Confidential information will be handled in line with the provisions applicable to ECHA and EU institutions. A non-confidential overview of any confidential information received, in aggregated form where appropriate, will be included in the Annex XV report.
A.9. Will you publish the information that was received during the call for evidence?	Our current policy is that individual responses will not be published. However, we may include information received in the call for evidence in our analysis and any Annex XV report that we publish. Confidential information will be handled in line with the provisions applicable to ECHA and EU institutions. A non-confidential overview of any confidential information received, in aggregated form where appropriate, will be included in the Annex XV report.
A.10. Will you restrict the placing on the market or use of plastic pellets,	We are unlikely to propose a restriction on any use of microplastics where the particles are 'fully consumed' during the use. The 'Note on substance identification and the potential scope of a restriction on uses of microplastics' published in July 2018 provides further information on this

Question	Answer
including 'nurdles', to produce articles that do not subsequently contain microplastic particles?	scenario. The development of measures to reduce plastic pellet spillage (accidental release) is an action included in the European strategy for plastics adopted in January 2018 (http://ec.europa.eu/environment/waste/plastic_waste.htm).
A.11. Will the fashion industry be affected?	The release of microplastics from textiles is typically considered as an unintentional release (of a secondary microplastics) and is therefore outside of the scope of our investigation and a potential restriction. The examination of policy options for reducing the unintentional release of microplastics from textiles is an action included in the European strategy for plastics adopted in January 2018 (http://ec.europa.eu/environment/waste/plastic_waste.htm).
A.12. Would the use of microplastic particles in *in vitro* diagnostic analytical activities (i.e. as magnetic beads) be within the scope of a proposed restriction?	These uses are usually considered to be Scientific Research and Development (SR&D) that is outside of the scope of a REACH restriction. SR&D is any scientific experimentation, analysis or chemical research carried out under controlled conditions in quantities of less than 1 tonne per year. ECHA Guidance on scientific research and development (version 2.1, October 2017 - https://echa.europa.eu/guidance-documents/guidance-on-reach) specifically identifies the use of a substance for *in vitro* diagnostics at laboratory scale under controlled conditions as an example of an analytical activity that is consistent with the definition of SR&D. The guidance then elaborates that, in simple terms, a substance is exempt from a REACH restriction if its manufacture, use or placing on the market falls within the definition of SR&D. However, to benefit from an SR&D exemption, the microplastic particles must be present in the 'end product' used for analytical activities. If microplastic particles are used in preceding lifecycle steps but are not present in the 'end product' used for analytical activities, then their use could potentially be restricted. If you have not yet done so, please inform us if this will be the case. In

Question	Answer
	addition, the use must be under 'controlled conditions'. This can be considered to apply throughout the life-cycle of the substance, including the waste life-cycle stage.
A.13. Will the EU restrict medical and/or pharmaceutical uses of microplastic particles?	REACH restrictions can apply to substances in medicinal products and medical devices for human or veterinary use. REACH restrictions can also apply to the use of a substance in the manufacture of a medicinal product or a medical device. If you have not yet done so, please tell us about any uses of microplastic particles in medicinal products or medical devices for human or veterinary use that could be affected by a REACH restriction. Where possible, tell us about the release of microplastics to the environment from the use as well as the expected socio-economic consequences of a REACH restriction on these uses.
A.14. I am working on a new study on microplastics. Can I send it to you?	Yes. Stakeholders are welcome to submit this material, but please also indicate why you think that it is relevant. We have also undertaken our own literature review, but please tell us about ongoing research, or studies that will be published later this year (2018).

B) Substance identification and microplastic definition

Question	Answer
B.1. Has ECHA considered proceeding in two steps, first agreeing on a definition for	ECHA has launched a process with some actions taking place concurrently. ECHA proposed a working definition to facilitate data collection in its call for evidence but was explicit that this definition would be subject to refinement throughout the preparation of the Annex XV report. The 'Note on 'substance identification and the potential scope of a restriction on uses of microplastics'

Question	Answer
microplastic particles and then gathering the use data?	published in July 2018 describes how the working definition has been refined on the basis of information received in the call for evidence and what information we require to refine microplastic identification and the potential scope of a restriction further.
B.2. What is a particle?	A simple definition of a particle, according to various ISO standards (e.g. CEN ISO/TS 27687:2008 and ISO 14644-6:2007), is "*minute piece of matter with defined physical boundaries*". This can be further specified such that a "*particle has a physical boundary that can also be described as an interface and that a particle can move as a unit"*. The definition of a particle was also considered within the context of the identification of nanomaterials: • https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/towards-review-ec-recommendation-definition-term-nanomaterial-part-1-compilation-information • https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/towards-review-ec-recommendation-definition-term-nanomaterial-part-2-assessment-collected • https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/towards-review-ec-recommendation-definition-term-nanomaterial-part-3-scientific-technical
B.3. Is there a 'standard' method to establish if a particle is a 'microplastic particle'?	No. However, standardisation is being actively considered by an ISO horizontal working group, which we will follow. In addition, we are aware that various methods to detect and to characterise (e.g. particle size) microplastics and microbeads in products and environmental samples have been developed and are offered by commercial laboratories. We will investigate the availability and suitability of

Question	Answer
	analytical methods and we will consider how a potential restriction can be implemented and enforced.
B.4. Is there a minimum size for a microplastic particle? Will a minimum size be defined?	The 'Note on substance identification and the potential scope of a restriction on uses of microplastics' published in July 2018 describes how the working definition of microplastic has been refined on the basis of information received in the call for evidence and what information we require to refine microplastic identification and the potential scope of a restriction further.
B.5. How much polymer must there be in a particle for it to be captured by the scope of any proposed restriction?	The 'Note on substance identification and the potential scope of a restriction on uses of microplastics' published in July 2018 describes how the working definition has been refined on the basis of information received in the call for evidence and what information we require to refine microplastic identification and the potential scope of a restriction further.
B.6. The working definition results in the inclusion of particles/articles that are too large to be considered as microplastics, including polymer films with high surface area.	The 'Note on substance identification and the potential scope of a restriction on uses of microplastics' published in July 2018 describes how the working definition has been refined on the basis of information received in the call for evidence and what information we require to refine microplastic identification and the potential scope of a restriction further.
B.7. Will plastic fibres be included in the restriction?	The 'Note on substance identification and the potential scope of a restriction on uses of microplastics' published in July 2018 describes how the working definition has been refined on the basis of information received in the call for evidence and what information we require to refine

Question	Answer
	microplastic identification and the potential scope of a restriction further. We note that microplastic fibres in the environment may have resulted from the unintentional degradation of textiles as well as intentional uses and, in the latter case, may fall within the scope of a potential restriction.
B.8. Does particle morphology (e.g. plates, rods, flakes, fibres) affect the definition of a microplastic?	The 'Note on substance identification and the potential scope of a restriction on uses of microplastics' published in July 2018 describes how the working definition has been refined on the basis of information received in the call for evidence and what information we require to refine microplastic identification and the potential scope of a restriction further.

C) Uses of microplastic particles and potential alternatives

Question	Answer
C.1. What uses of microplastics are being investigated?	We have understood that the Commission intended us to comprehensively investigate the intentional uses of microplastics across consumer, professional and industrial workplaces (excluding intermediate uses at industrial sites).
C.2. What will happen if I have not submitted information about my specific use of	Unless you have done so already, you should tell us about uses and the implications of a restriction in order that we can take these into account in our assessment. Information on uses of microplastics including their releases to the environment, and the likely response of society to a restriction (e.g. transition to the use of alternative substances, the withdrawal of products, etc.)

Question	Answer
microplastics?	will be used to assess the costs and benefits of a potential restriction for society as a whole.
C.3. I have more information on the technical function of microplastic particles in my products, is this of use to you? How should I describe it in any further responses to you?	The process of identification and assessment of alternatives normally begins with the consideration of the function of the substance under investigation for potential action under REACH. This entails the task that the substance must perform; where and how, i.e. under what conditions, that function must be performed; the critical properties the substance has for the production process or the final product, etc. Understanding the technical function of a microplastic particle in a product is critical to understanding the technical and economic feasibility of alternatives and, thus, any impacts of a restriction on that use to society as a whole. Therefore, the technical function of a microplastic particle in a product should be described in sufficient detail for us to (a) understand why it is present in a product and (b) understand the implications of it no longer being present.
C.4. There are no alternative substances or technologies for my use.	Information on the likely response of society as a whole to a restriction (e.g. withdrawal of products with specific functions due to lack of alternatives that fully replace the technical function of microplastics, changes to product quality as a result of transitioning to potential alternatives, etc.) will be used to assess the costs of a potential restriction. Information on the technical function of microplastics in products and the relative performance of microplastic-free alternatives is an important element of our assessment.
C.5. Can microplastic particles be intentionally released even if they are not intentionally added?	Yes. Products could be designed with the knowledge that microplastic particles are intentionally released during their lifecycle. These types of products are within the scope of our investigation.

Question	Answer
Is such a use within the scope of a potential restriction?	
C.6. How can you tell if the presence of microplastics in a product is 'intentional' or not?	Intentional uses occur when a particle is deliberately added to a product to provide a function (e.g. to exfoliate, release, absorb, stabilise) or when a microplastic is deliberately released as part of the functioning of a product.

D) Hazards and risk

Question	Answer
D.1. What is the hazard/risk posed by a microplastic particle?	Microplastics could pose various types of hazards to either human health or the environment. The scientific literature describing adverse effects is growing rapidly, reporting potential effects ranging from physical hazards (clogging of feeding apparatus), inflammation or the potential for microplastics to act as 'vectors' for other environmental pollutants into organisms, including persistent organic pollutants. Importantly, effects may be associated with 'additives' within the plastic matrix (stabilisers, clarifying agents, plasticisers, anti-static agents, flame-retardants), rather than the polymers themselves. In addition, the hazard posed by a microplastic particle may be associated with its (very) long persistence in the environment combined with its potential to bioaccumulate, similar to the hazard

Question	Answer
	posed by vPvB substances, which are subject to specific regulation under REACH. In the context of our work, we have reviewed the published scientific literature on the hazard and risk of microplastics. As previously mentioned, we would very much appreciate information on any ongoing research that is not yet published but which could be relevant to our risk assessment.
D.2. Will you only investigate risks in the marine environment?	No. We will further consider risks in other compartments, including freshwater and terrestrial ecosystems (e.g. in soils).
D.3. Will you take into account exposure to humans via food?	Our analysis will be framed by a risk assessment according to Annex I of REACH that will consider both risks to the environment and human health (including human exposure via the environment). EFSA published a statement on the presence of microplastics and nanoplastics in food, with a particular focus on seafood in 2016. The statement noted that much of the toxicity and toxicokinetic information needed for a risk assessment is missing (particularly for smaller-sized particles, <150 µm), but noted that the presence of microplastics in seafood would only have a small effect on the overall exposure of additives and contaminants.

E) Socio-economic analysis (SEA)

Question	Answer
E.1. What kind of socio-economic analysis	The relevant information for socio-economic analysis for restrictions includes information on the costs of complying with the proposed restriction (imposed on society as a whole) and the benefits

Question	Answer
information are you assessing?	(to the environment or human health). Costs are often associated with the transition to the use of alternative substances or technologies, including R&D to identify alternatives, reformulation costs, purchasing of new equipment for process changes, incremental material or energy costs, market or product changes, etc. Information on benefits may include improved environmental quality or human health as a result of the phase out of a substance.
E.2. 'Intentionally added' microplastics are not the largest source of microplastics in the marine environment. How will this be taken into account?	The EU plastics strategy recognises that intentionally added microplastics are likely to represent a relatively small share of the overall microplastic pollution, particularly in the open ocean. The relative contribution of intentionally versus unintentionally used microplastics will be assessed as part of our analysis. There are several studies that examine the sources of microplastics in the environment. These will help us estimate the relative contribution of intentionally added microplastics to the overall microplastic pollution in the environment. The work the EU Commission is currently engaged in on unintentional release of microplastics to the environment will also help us put that into perspective.
E.3. There was not much time to collect information (or hire a consultant to help collate information) for the call for evidence. Can I submit additional information?	We realise that the call for evidence set out a tight timeframe. If you are in the process of generating scientific findings or other information, please contact us to discuss how this input can be provided.
E.4. Will you take into consideration the work already done from the	Yes. However, additional information may give a more complete picture, particularly for relevant sectors that did not provide information to AMEC.

Question	Answer
Commission on intentionally added microplastics by AMEC?	