Version 1, 11 April 2018

Call for evidence and information on the intentional uses of microplastic particles in products of any kind - Q&A

Purpose

The purpose of this document is to assist potential respondents to the call for evidence by elaborating on specific elements in a 'frequently asked questions' format. Some of the questions were asked during the recent online information session. If your specific question has not been answered, please send an email to: restriction-microplastics@echa.europa.eu.

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 the suitability of 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)), 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)). • Monomers need to be registered; lifecycle covered in CSR.
A.2. Are microplastic particles articles or substances?	Microplastic particles could be considered as either substances or articles. However, this distinction does not matter from the perspective of a potential restriction under REACH, as restriction of either is possible.
A.3. Is it certain that a restriction will be proposed?	No. A decision on whether to propose a restriction will depend on the conclusions of our investigation.
A.4. Is my intentional use included within the scope of the investigation and any potential restriction?	By default, actors in the supply chain that produce products that intentionally contain or release microplastic particles should considertheir use to be within the scope of a potential restriction. Please tell us how a restriction would affect your products and your business using the webform. Uses may be derogated from any proposed restriction on the basis that they do not pose an unacceptable risk or because of socio-economic considerations, but only where there is available

Question	Answer
	justification to do so.
A.5. If a restriction is proposed, will there be a transitional period for adaptation and how long will it be?	A transitional period may be included within any proposed restriction to allow stakeholders to adapt. The length of any transitional period will be determined based on various factors, including risks and socio-economic considerations, such as the availability of alternatives and the time required to transition to them. Please provide any information to us that you think would be relevant to the need for or duration of transitional arrangements.
A.6. Which polymers will be included in the restriction?	In principle, any polymer in microplastic form that poses a risk to the environment or human health on an EU-wide basis could be subject to a restriction.
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, so it is very likely that any proposed restriction would include a concentration limit for microplastic particles in products. In general, any concentration limit proposed would discourage any 'intentional' use of microplastic particles, but recognise that low concentrations of microplastic particles could be present 'unintentionally' in products. We would be interested in 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.
A.8. The information that I have is confidential and business sensitive. How can I share information	Information can be submitted confidentially during the call for evidence using the webform. We will maintain confidentially in line with the provisions for EU institutions.

Question	Answer
without affecting competiveness or anti-trust laws?	
A.9. Will you publish the information received during the call for evidence?	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 not be published in the public domain. General information about the type of information received during the call for evidence will also be included in the Annex XV report.
A.10. Will you restrict the placing on the market or use of microplastic particles, including 'nurdles', to produce plastic articles that do not contain microplastic particles?	We are unlikely to propose a restriction on any use of microplastic particles where the particles are 'fully consumed' during the use, as these uses will not pose a risk to the environment or human health. Nevertheless, please tell us about these types of uses of microplastics using the webform. Issues surrounding the accidental release of microplastic particles are being investigated under a different project of the European Commission (www.eumicroplastics.com).
A.11. Should the fashion industry respond to the call for evidence?	Some concerns of the textiles industry would likely be related to the unintentional release of microplastics during the washing of textiles. Issues surrounding the accidental release of microplastic particles are being investigated under a different project of the European Commission (www.eumicroplastics.com). However, the intentional use of microplastics in cosmetics products, certain types of paints and potentially materials found in the home, for example, are certainly within the scope of our current work. Individual industry sectors are recommended to assess the relevance of the proposed

Question	Answer
	restriction with regard to the uses they observe and provide related information, to avoid being unintentionally covered by a broad-scope restriction.
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?	Typically, no. These uses are usually considered to be Scientific Research and Development (SR&D) that is outside of the scope of a REACH restriction. Scientific research and development 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) 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.
A.13. Will you restrict medical and/or pharmaceutical uses of microplastic particles?	Pharmaceutical and/or medical uses of substances are outside of the scope of the REACH Regulation. However, REACH restrictions can apply to uses of substances in medical devices. Please report any uses of microplastic particles in medical devices that could be affected as well as the expected consequences of a REACH restriction, e.g. whether alternatives would be available or whether products would no longer be available.
A.14. I am working on a new	Yes. Stakeholders are welcome to submit this material, but please also indicate why you think that

Question	Answer
study on microplastics. Can I send it to you?	it is relevant. We will also undertake our own literature review, but please tell us about ongoing research, or studies that will be published later this year.

B) Substance identification and microplastic definition

Question	Answer
B.1. Has ECHA considered proceeding in two steps, first agreeing on a definition for microplastic particles and then gathering the use data?	It is recognised that development of a definition is an iterative process. However, given the short timeline for the preparation of an Annex XV restriction report (12 months), some actions have to take place concurrently. ECHA has proposed a working definition to facilitate data collection. The definition will be refined based on information on hazard/risks and feedback from industry on the impacts of the definition.
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:

Question	Answer
	• 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 We know that the definition of a microplastic particle is very important. We would specifically like your feedback on the proposed 'working' definition, including providing further insight into how a particle could be defined.
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 would welcome information on the availability and suitability of these methods for different types of products as we will consider how a potential restriction will be enforced.
B.4. Is there a minimum size for a microplastic particle? Will a minimum size be defined?	Our working definition of a microplastic particle does not currently establish a lower limit. However, we would consider establishing a lower limit if this would be necessary to ensure that the restriction is targeted appropriately to the risk. EFSA specifically noted that there was an absence of information on the risks posed by smaller microplastic particles (<150 um). Please provide information on what the implications of not including a lower limit would be.

Question	Answer
B.5. How much polymer must there be in a microplastic particle for it to be captured by the scope of any proposed restriction?	As soon as a polymer is present in a particle (<5 mm), the particle can be considered a 'polymer-containing particle' as described in our working definition of a microplastic, and is therefore subject to our investigation and potentially to a restriction. An example would be a polymer-coated inorganic particle.
B.6. How detailed should polymer descriptions be?	The REACH definition of a polymer should be the starting point for describing a polymer. Once it is established that a substance is a polymer under REACH, please provide us with the following information, where this is available: • polymer name/identifiers (including trade name); • the identity of the monomers used for polymerisation (including CAS#, EC#); • relevant physico-chemical properties, e.g. solubility; • potential for (bio)degradability in environmental compartments (aquatic environment and soil); • whether the polymer has a natural origin.
B.7. All my products contain polymers. How should I contribute to the call for evidence?	In such cases it may be beneficial to look at the other elements of the working definition (i.e. solid/semi-solid particles) and filter for products that fulfil these additional criteria. Stakeholders are welcome to suggest other parameters that could be used to identify polymer uses that are consistent with a microplastic concern.
B.8. The working definition results in the inclusion of	The working definition was, among other things, based on examples of national legislation that consider particles <5 mm in any dimension to be microplastics (based on a potential risk of

Question	Answer
particles/articles that are too large to be considered as microplastics, including polymer films with high surface area.	swallowing in the marine environment). We know that the definition of a microplastic particle is very important. We would specifically like your feedback on the proposed working definition, including providing further insight into the size range that should be included.
B.9. Are plastic fibres included in the definition of a microplastic particle?	Yes. Our working definition includes microplastic fibres, as we wish to understand if there are intentional uses of microplastic fibres. We acknowledge that microplastic fibres in the environment may have resulted from the unintentional degradation of textiles.
B.10. Does particle morphology (e.g. plates, rods, flakes, fibres) affect the definition of a microplastic?	All particle morphologies are intended to be captured by our working definition of a microplastic. This is because we want to encourage stakeholders to submit information on relevant morphologies and on whether morphology affects the risk to the environment or human health.

C) Uses of microplastic particles and the suitability of alternatives

Question	Answer
C.1. What will happen if I do not submit information about my specific use of microplastics?	Your use may be within the scope of any proposed restriction by default. Therefore, it is very important for us to obtain information on uses and alternatives early on in the process to avoid unintended consequences. This will help us to ensure we exclude uses from the scope of any proposed restriction where risk cannot be demonstrated or where there are no technically or economically feasible alternatives.
C.2. In how much detail should the technical function of microplastic particles be described?	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. 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 in a product. For example, we know that microplastic particles are used in cosmetic products for a range of well understood technical functions, including exfoliation, cleansing and polishing. However, we do not know much about additional technical functions in cosmetics, which could include controlling viscosity or acting as bulking/filling material. We require further information on these additional uses. Equally, microplastic particles may have different functions in different types of products, e.g. in detergents and in construction products.
C.3. There are no alternative substances or technologies for my use.	Information on the technical and economic feasibility of alternatives is very important because, when a restriction is proposed, the absence of a suitable alternative can lead to a use being excluded from the scope of the restriction or being associated with longer transitional

Question	Answer
What information should I provide to the call for evidence?	arrangements. Important information that you can provide includes the products/uses and the function of the microplastics in this product, the identity of potentially suitable alternatives and why these alternatives are perceived to be unsuitable (including information on relative technical performance against appropriate criteria). Additional information on substance volumes as well as the impact of a restriction on your business or society as a whole will also be useful. We are also interested in whether the alternatives identified in the AMEC study are suitable for your application and why not.
C.4. Can microplastic particles be intentionally released even if they are not intentionally added? Is such a use within the scope of a potential restriction?	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.
C.5. 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 or absorb, stabilise).
C.6. What is a professional or consumer use?	We have adopted a wide scope during our call for evidence. You can consider any use that is not an intermediate in an industrial location to be within the scope of our investigation.

D) Hazards and risk

Question	Answer
D.1. What is the hazard/risk posed by a microplastic particle?	Microplastics (and nanoplastics) 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, 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 posed by vPvB substances, which are subject to particular regulation under REACH. In the context of our work, we review the published scientific literature on the hazard and risk of microplastics (and nanoplastics). As mentioned above, we ask respondents to the call for evidence to draw our attention to 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. Is food that contains microplastic safe to eat?	It is premature to answer this question. It is important to know that our analysis will be framed by a risk assessment that will consider both risks to human health (potentially via food) and to 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

Question	Answer
	and toxicokinetic information needed for a risk assessment is missing (particularly for smaller-sized particles, <150 um), 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 information are you looking for?	SEA is an important tool that helps conclude on the proportionality of a proposed restriction. It compares the costs of complying with the proposed restriction (imposed on society as a whole) with the benefits (to the environment or to human health). We need your assistance with identifying the costs to industry in particular. These 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. Questions 4 and 5 of the webform provide some further guidance on potentially relevant content with regard to SEA. Any related information provided beyond the specifically named aspects will be taken into account.
E.2. 'Intentionally added' microplastics are not the largest source of microplastics in the marine environment.	The EU plastics strategy recognises that intentionally added microplastics are likely to represent a relatively small share of overall microplastic pollution. 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

Question	Answer
How will this be taken into account?	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. If you would like to see their work to date, visit: www.eumicroplastics.com.
E.3. There is not much time to collect information (or hire a consultant to help collate information). What level of SEA detail should I provide and where will I obtain the necessary information?	We realise that this is a tight timeframe. At this stage in our investigation we are looking for available information, or information that can be readily collected within the supply chain, and do not expect that stakeholders will undertake extensive research to respond to our call. Nevertheless, if you are in the process of generating scientific findings or other information that will not be concluded before the call for evidence ends, please contact us and discuss with us how this input can be provided. As mentioned in the webform, it is possible to submit confidential information, and ECHA will treat it as such. Also, it is important to know that there are other opportunities to provide input. A workshop will be held at the end of May for invited participants (more information to be published). There will also be a formal public consultation period if a restriction is proposed. However, we would like to highlight that it is very important for us to obtain information on uses and alternatives early in the process as we develop our initial analysis. This will allow us to identify the impacts and ensure that we exclude uses for which risks cannot be demonstrated or for which there are no alternatives, for example. It is most convenient for all actors (including the affected stakeholders) if issues are foreseen at the beginning of the process, to avoid unintended negative economic effects. Therefore, we advise you to take a look at our definition of microplastics, think about whether any of your products intentionally contain or release such microplastics and, at a minimum, provide us with that information. Additional information on volumes/tonnages, the function of microplastics in

Question	Answer
	the product and whether you have looked for alternatives (as well as other information in Question 4 of the webform) is also valuable.
E.4. Will you take into consideration the work already done by AMEC?	Yes. However, we hope that we will gather additional information, particularly for sectors that did not provide information to AMEC.