QUESTIONS AND ANSWERS ON THE RESTRICTION PROPOSAL ON INTENTIONALLY ADDED MICROPLASTICS

VERSION NUMBER: 1.0

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PURPOSE:

The purpose of this document is to clarify aspects of the proposed restriction on intentionally added microplastics. It is presented in the form of 'questions and answers'. It does not address generic restriction issues, or other aspects of REACH, which are addressed on the ECHA website[1].

The document is intended to support respondents to the public consultation on the proposal, which is open from 20 March 2019 until 20 September 2019: https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/22921/term

This document is complementary to the ECHA webinar that was organised on 3 April 2019. The webinar can be viewed via the following link: https://youtu.be/QrirqfFe2PI

This document is based on questions received from stakeholders before, during and after the webinar. It replaces the Q&A document published to support the call for evidence held during the preparation of the proposal. This document might be revised based on feedback, or if additional questions are received from stakeholders.

If you need further clarification, or if a specific question has not been answered, please contact the ECHA helpdesk[2].

Readers are reminded that the text of the REACH and CLP Regulation is the only authentic legal reference and that the information in this Q&A document does not constitute legal advice.

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. Use of the information in this document remains the sole responsibility of the reader.

[1] https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Restrictions

[2] https://echa.europa.eu/contact/other

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1. REACH Restriction proposal

1.1. REACH Restriction process

#	Question	Answer
1.1	When implementing the restriction, can Member States make their national legislation stricter than the proposed restriction?	In general, this would not be possible as REACH is a single market Regulation directly applicable in all EU/EEA Member States.
1.2	When will the (bio)degradability criteria (detailed in Table 21 of the Annex XV report) be discussed in the ECHA's Committees.	The scope and hazard, including the (bio)degradability criteria, will be discussed by RAC (Risk Assessment Committee) during its second plenary meeting, which is scheduled for September 2019. In addition to the plenary session, an evening working group will discuss the criteria. Stakeholders that are interested in this aspect of the proposal are encouraged to submit comments to the public consultation as early as possible prior to the September meeting (ideally at least 4 weeks prior to the meeting). Subsequent plenary meetings of RAC may also address the (bio)degradability criteria, particularly if relevant comments are received later in the public consultation.
1.3	What is the expected Entry Into Force (EIF) date of the restriction?	The RAC and SEAC opinions on this restriction proposal are scheduled to be adopted in December 2019 and March 2020, respectively. SEAC's draft opinion is scheduled to be adopted in December 2019 and is subject to a 60 day public consultation. The decision on any restriction (including its scope) will then be taken in the EU REACH Committee, comprised of Member States and chaired by the European Commission. As this stage is likely to take some time, it could be expected that the Entry Into Force (EIF) of the restriction, if adopted, will be some time in 2021. The impact assessment presented in the Annex XV restriction proposal report assumes that the first full year of the restriction is 2022. As indicated in paragraph 6 of the restriction proposal, some sectors and/or uses are associated with transitional periods during which the conditions of the restriction will not apply (e.g. EiF + 5 years for detergents). These periods are proposed to allow supply chains to adapt to the conditions of the restriction e.g. by undertaking the reformulation of products using alternatives to

#	Question	Answer
		microplastics. It is important to note that any use of microplastics that is not specifically identified in paragraph 6 will be subject to the conditions of the restriction from the initial EIF date.

1.2. Public consultation

#	Question	Answer
1.4	How can I participate in the public consultation?	Interested parties can submit their comments via the webform on the ECHA website: https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/22921/term The public consultation is open until 20 September 2019. Please familiarise yourself with the proposed restriction and the supporting documents before sending your comments.
1.5	Do I have to reply to all of the general and specific questions?	No, it is not compulsory to answer all the questions. However, a minimum amount of compulsory information is requested. This information is marked with an asterisk in the public consultation webform.
1.6	I have confidential business information that I wish to share with ECHA. How can I share this without breaking competiveness or anti-trust laws?	It is possible to attach confidential documents to a consultation submission. Confidential information will only be used by ECHA (including its Committees), Member State competent authorities and by the European Commission. Only non-confidential comments are published on the ECHA website.
1.7	Could the information submitted in the public consultation influence the transitional (phase out) period recommended for a specific use or sector?	Yes. Information provided during the public consultation may have an influence on the transitional periods for certain uses or sectors, particularly where arguments are well supported with evidence e.g. timelines requires for the identification of alternatives and reformulation. Please refer to the guidance on public consultations on restriction proposals for further details on what type of information should be provided in the public consultation.
1.8	Will you publish the comments received during	Yes. Non-confidential comments are published a regular intervals (typically monthly) throughout the consultation period. After the consultation has

#	Question	Answer
	the public consultation?	concluded the responses to them by the Dossier Submitter (in this case ECHA) and the RAC/SEAC Committee Rapporteurs will be published on the ECHA website.
1.9	I already submitted information during the 2018 'call for evidence' hosted by ECHA. Shall I resubmit the same information, or will this already be taken into account by the committees?	If considered to be relevant by the Dossier Submitter, the information provided during the call for evidence was included in the restriction proposal. However, if you feel that the information you provided was not or insufficiently taken up, then you might want to resubmit the information during the public consultation.
1.10	We noticed that the Annex XV report has been edited since January. Could ECHA inform stakeholders where updates were made (ideally indicating which parts have been changed) given the length of the dossier?	Version 1.0 of the Annex XV report and annexes were published on the ECHA website in January 2019, just after its formal submission. Version 1.1 of the Annex XV report and annexes were published on the ECHA website on 30 March to coincide with the start of the public consultation. Only minor modifications to version 1.0 were made in version 1.1, essentially to clarify certain aspects of the proposal and to correct spelling mistakes. Respondents to the public consultation should check that they have the most recent version of the Annex XV report and annexes (currently version 1.1).
1.11	What kind of information can I submit on the topic of 'baseline'?	You are welcome to submit any information that you consider will help ECHA and the Committees to better understand the current use of microplastics in your sector. Please refer to specific question 5 in the public consultation webform for the type of information that should be submitted.
1.12	With respect to the public consultation, would relevant information submitted after the first deadline (20 May 2019) though still within 6 months be considered by RAC and SEAC in forming the final opinion?	Yes. As set out in the background note to the consultation, information on the scope of the proposal, hazard of the substance(s) and the costs of the proposal is likely to be most useful if it is submitted by 20 May 2019. However, information submitted after this date will still be considered by the Committees as they develop their opinions. This timing takes into account that stakeholders have access to the dossier much earlier than in the past, as it is published two weeks after submission or more than six weeks in advance of the start of the public consultation. It is possible to submit more than one consultation response during the six

#	Question	Answer
		month period so please take this into account when deciding when to submit information.
1.13	Is the use of an *In vitro* diagnostic (IVD) medical device considered as scientific research and development (SR&D) and therefore outside of the scope of REACH restriction?	Uses of substances in scientific research and development (SR&D) are always outside of the scope of REACH restrictions (Article 67(1)). ECHA Guidance on scientific research and development (version 2.1, October 2017) specifically identifies the use of a substance for *in vitro* diagnostics (IVD) at laboratory scale under controlled conditions as an example of an analytical activity that is consistent with the definition of scientific research and development (SR&D) under REACH. In addition to IVD devices for human health purposes, the exemption covers IVD for animal health purposes. However, it should be noted that SR&D is defined under REACH (Article 3(23)) as any scientific experimentation, analysis or chemical research carried out under **controlled conditions** in quantities of less than 1 tonne per year. As there is currently no agreement with Member States on what would constitute controlled conditions for uses of microplastics the derogation under paragraph 5a was proposed to give regulatory certainty to uses of microplastics in IVD medical devices. In addition, substances must be present in the 'end products' used for analytical activities to be considered as SR&D. If substances are used in preceding lifecycle steps but are not present in the 'end product' used for analytical activities, then the use of the substance is not scientific research and development.
1.14	In relation to question 4 of the public consultation, are 'Research Use Only/Lab Use Only' devices within the scope of the derogation described in paragraph 6b of the proposal?	'Research Use Only/Lab Use Only' devices are only within the scope of paragraph 6b if they comply with the definitions of a Medical Device or an In Vitro Medical Device as set in regulations (EC) 2017/745 or (EC) 2017/746.
1.15	I am working on a new study investigating the (eco)toxicity or risks of microplastics. Can I send it to you?	Yes. Stakeholders are welcome to submit this material via the public consultation webform, but please also indicate why you think that it is relevant in relation to the assessment of the hazard and risks of microplastics presented in the Annex XV report.

2. Microplastic definition

2.1. Decision tree (definition)

The decision tree on the microplastics definition (Figure 1) presents the key questions, arranged across three tiers, which need to be answered to identify if a substance or a mixture placed on the market contains microplastics 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 Tiers 1a, 1b, 2 and 3 are presented in:

- Figure 2: Tier 1a – are relevant solid particles present?
- Figure 3: Tier 1b – are relevant polymers present?
- Figure 4: Tier 2 – are polymer-containing particles present?
- Figure 5: Tier 3 – is the concentration limit exceeded?

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.

Additional decision trees are included in Section 3. They can assist in concluding whether the use is derogated or placing on the market can continue after fulfilling the proposed ‘reporting’ and ‘information on conditions of use’ requirements.

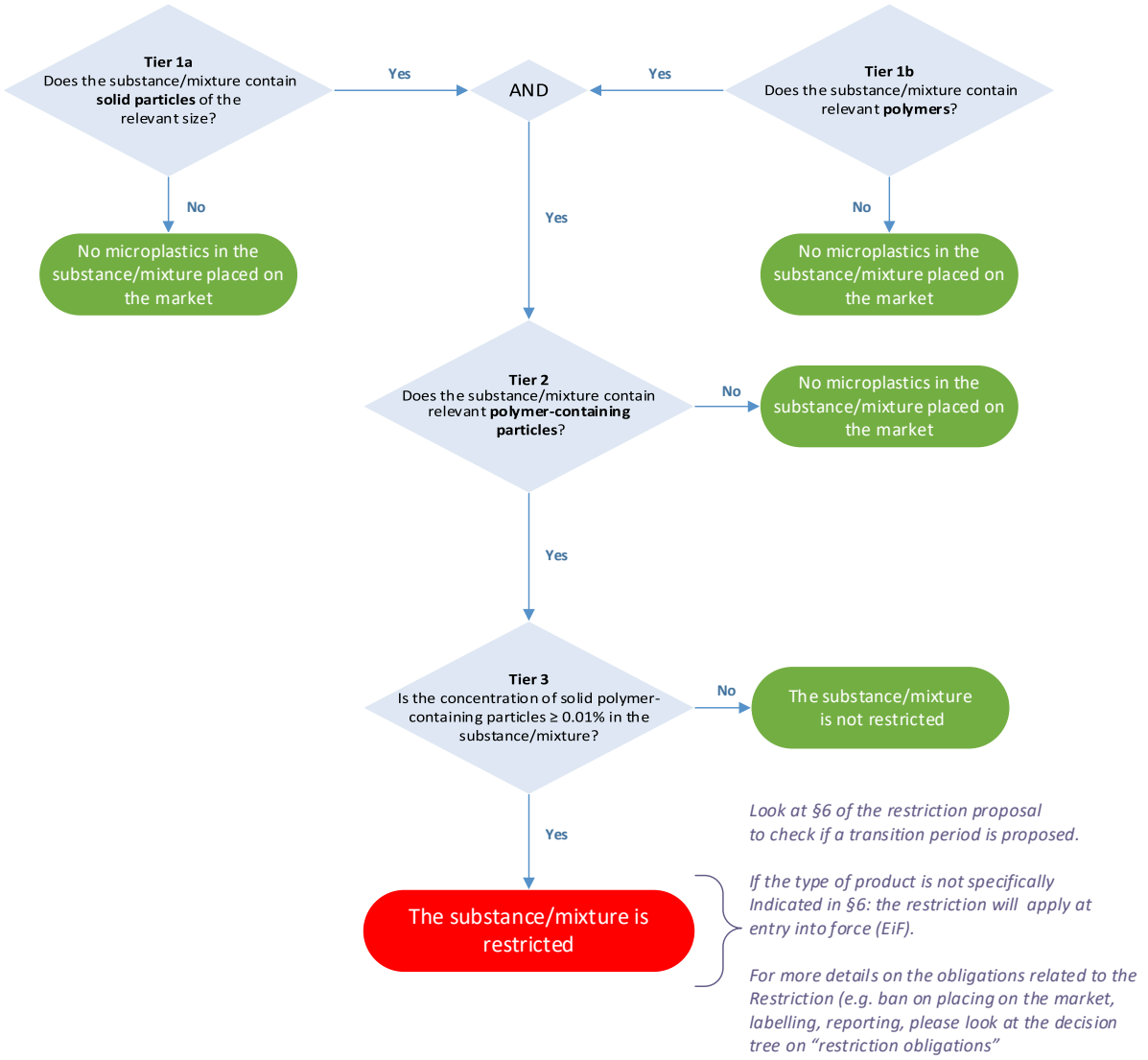


Figure 1 Microplastics definition decision tree overview

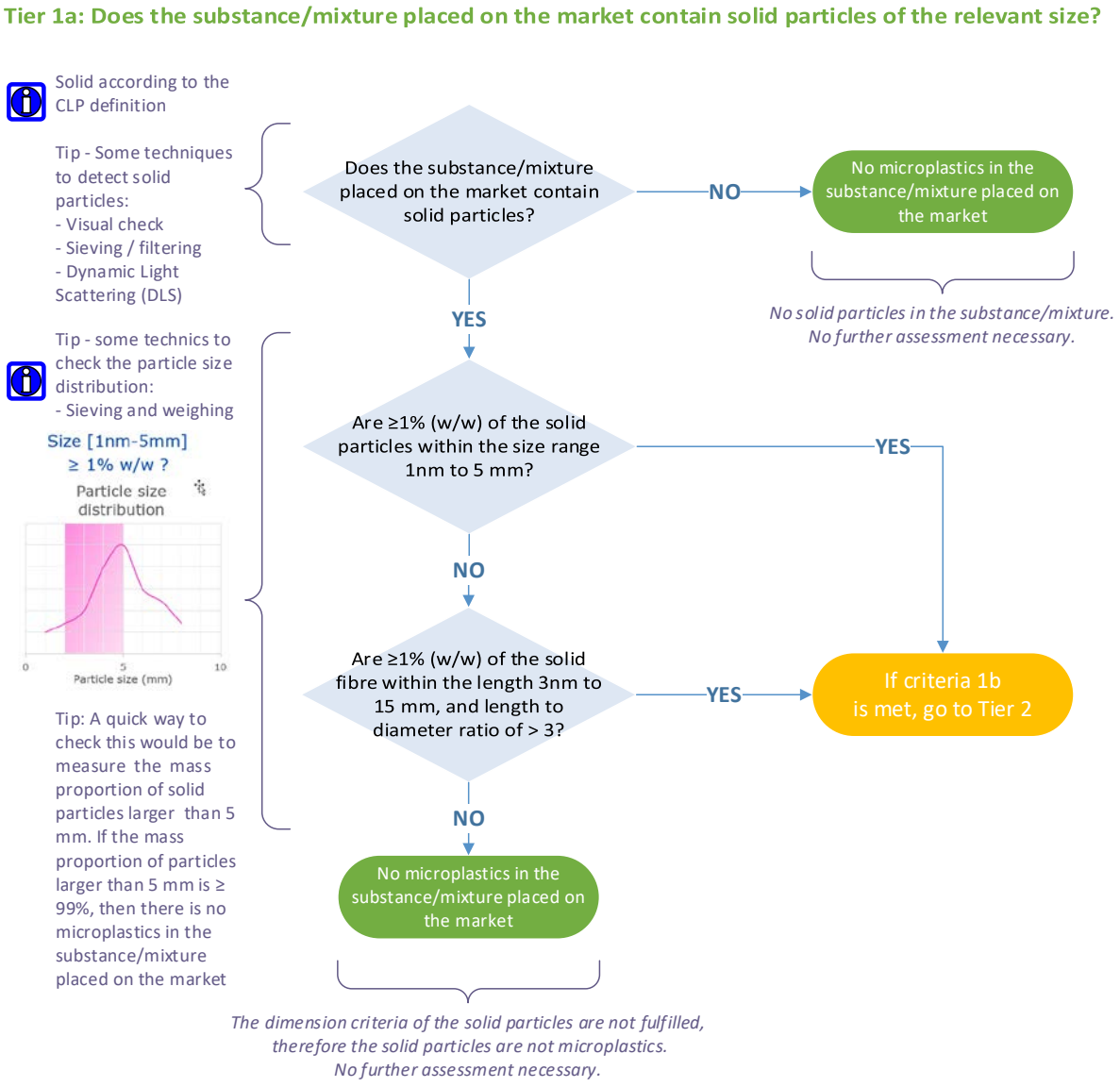


Figure 2 Microplastic decision tree - Tier 1a – relevant solid particles

Tier 1b: Does the substance/mixture placed on the market contain relevant polymer?

You may use information from the manufacturing/formulation process (e.g. raw material specifications, processing steps, reaction mechanisms if any…) in order to answer the questions below.

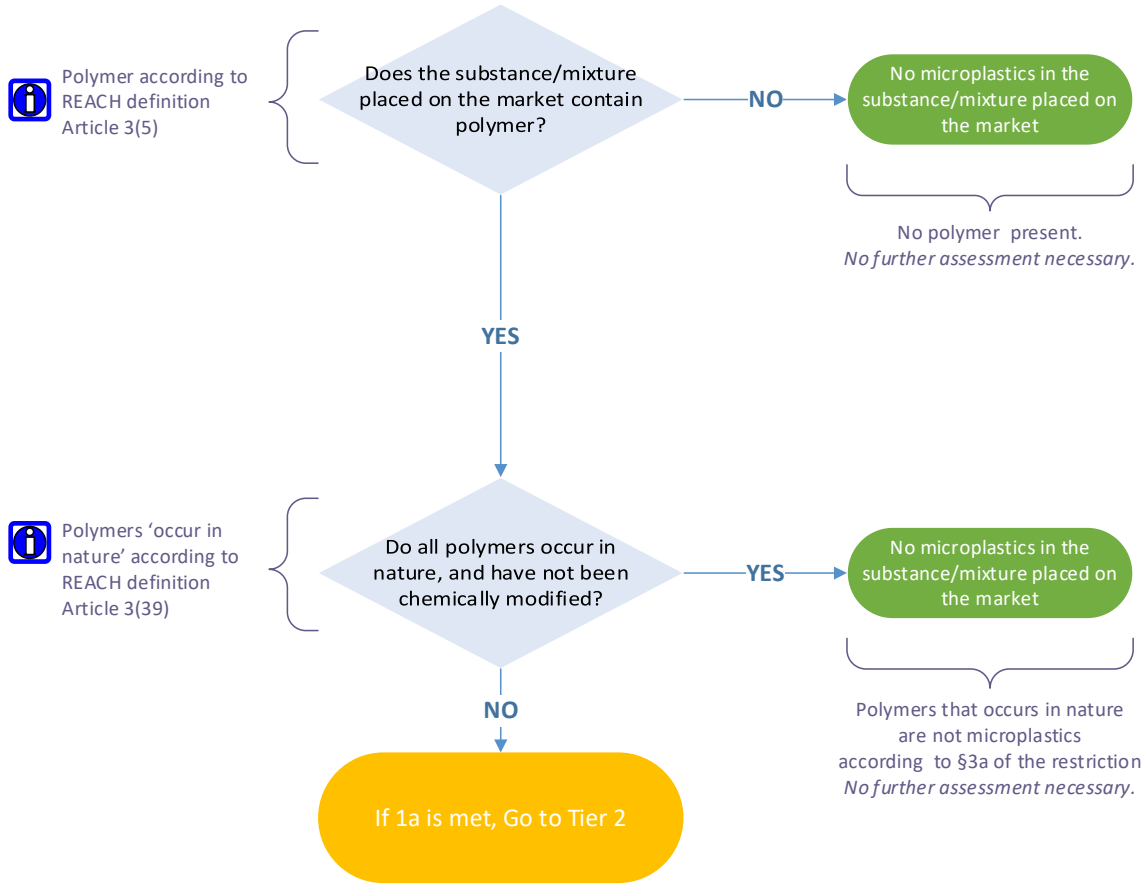


Figure 3 Microplastic decision tree - Tier 1b – relevant polymers

Tier 2: Does the substance/mixture placed on the market contain relevant polymer-containing particles?

You may use information from the manufacturing/formulation process (e.g. raw material specifications, processing steps, reaction mechanisms if any…) in order to answer the questions below.

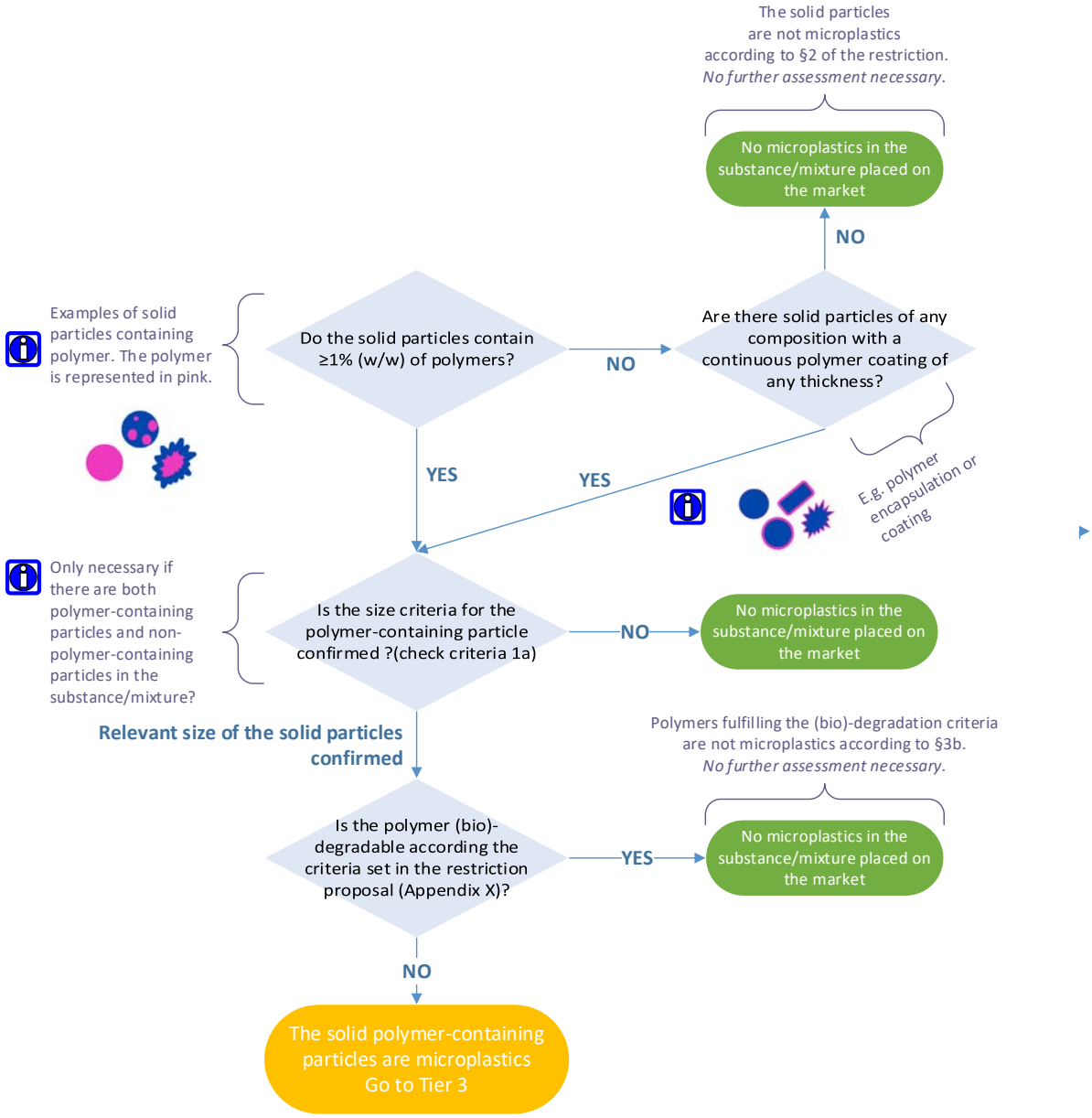


Figure 4 Microplastic decision tree - Tier 2 – polymer-containing particle

Tier 3: Does the restriction apply to the substance/mixture placed on the market ?

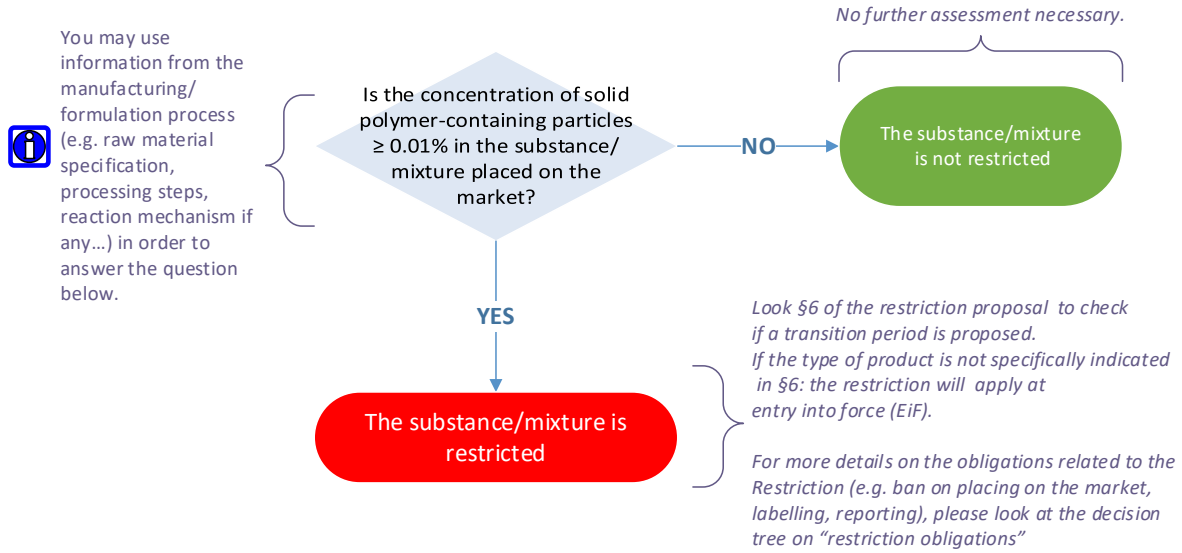


Figure 5 Microplastic decision tree - Tier 3 – concentration considerations

2.2. General questions

#	Question	Answer
2.1	Is the definition of microplastic harmonised across all EU?	No. There is currently no harmonised definition of a microplastic in the EU or internationally. The proposed restriction will harmonise the definition of microplastic under the REACH regulation. Other organisations may develop other definitions that would be appropriate for their specific purposes.
2.2	Microbeads as understood in common language have uses different from the defined term, e.g. in order to improve flow. Does that mean some uses of microbeads will have different transitional periods before the proposed restriction would enter into effect?	In a similar way as the term 'microplastic', there is no harmonised definition of the term 'microbead' neither in EU/EEA countries or elsewhere in the world. This is why the Annex XV report proposes to define 'microbeads' as microplastics used in a mixture as an abrasive i.e. to exfoliate, polish or clean. Other uses of microplastics, e.g. to improve flow, are referred to in the Annex XV proposal simply as uses of 'microplastics'. According to information provided by stakeholders, industry is on course to fully phase out the use microbeads (as defined by the restriction proposal) in cosmetics and household products before the entry into force or the restriction. Therefore, no transitional period is proposed for this use and microbeads (as defined by the restriction proposal) must not be placed on the market once the restriction enters into force, unless for a derogated use e.g. use for abrasive blasting at industrial sites (see paragraph 4a). Other uses of microplastics, including some uses of what could commonly be referred to as microbeads, will have different transitional periods. These are outlined in paragraph 6 of the proposed conditions of the restriction.
2.3	What is the hierarchy of applying the criteria of the definition of a microplastic?	There is no hierarchy for the criteria. All criteria of the definition must be met to be considered as a microplastic: polymer, solid particle/fibre, dimensions, concentration limit, non (bio)-degradability.

2.3. Polymers

#	Question	Answer
2.4	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 other REACH provisions, such as in relation to information in the supply chain (Title IV), authorisation (Title VII), restrictions (Title VIII). • 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).
2.5	How do I assess whether my substance is or is not a polymer under REACH?	You need to know the chemical composition of the polymer together with information on the relevant manufacturing process (polymer-forming reaction) in detail in order to identify all polymeric and non-polymeric molecules that are present in the substance composition. In addition, you also need to know the molecular weight distribution of the above molecules in the substance composition. A polymer is a substance consisting of molecules characterised by the sequence of one or more types of monomer unit. Such molecules must be distributed over a range of molecular weights. Differences in the molecular weight are primarily attributable to differences in the number of monomer units. In accordance with REACH (Article 3(5)), a polymer is defined as a substance meeting the following criteria: (a) Over 50 percent of the weight for that substance consists of polymer molecules; and, (b) The amount of polymer molecules presenting the same molecular weight must be less than 50 weight percent of the substance.

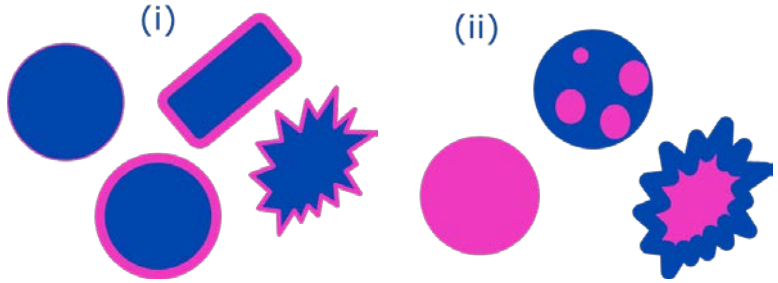
#	Question	Answer
		A "polymer molecule" is a molecule that contains a sequence of at least 3 monomer units, which are covalently bound to at least one other monomer unit or other reactant. It should be noted that, for example, a well-defined mono-constituent substance cannot be a polymer since the substance needs to consists of polymer molecules with certain molecular weight distribution. See more detail in the "Guidance for monomers and polymers" available at ECHA webpage.
2.6	Are all polymers microplastics?	No. Only synthetic polymers whose properties in a substance/mixture fulfil **all** of the criteria described in paragraph 2a of the proposal are 'microplastics' i.e. synthetic, solid, in the form of particles, within appropriate dimensions. Equally, polymers that occur in nature, or that meet the criteria for (bio)degradability included in the restriction proposal (cf Table 21 in the Annex XV report) are not microplastics.
2.7	If a substance is already registered under REACH, and is by definition not a polymer, can I consider it as being out of the scope of the proposed restriction?	Yes. It is true that a registered substance should not fulfil the REACH polymer definition. However, please note that the fact that a substance has been registered does not automatically mean that it is not a polymer. Some registered substances have been found to be polymers after review and their registrations annulled. Please also note that it is the responsibility of the Registrant to correctly identify whether their substance fulfils the polymer definition or not.
2.8	Are acrylic emulsions microplastics?	No. On the basis that the term 'emulsion' refers to a liquid-liquid mixture. If the acrylic polymer is not present as a solid particle then it is not a microplastic. Where polymer containing particles are solid then they could be microplastics, depending on whether the other elements of the definition are also met. Please refer to the decision trees in this document.
2.9	Are the polymers listed in Table 46 in the Annex already regarded as microplastics?	No. The polymers listed in Table 46 in the Annex are known to be commonly used in cosmetics but, based on the information available to the Dossier

#	Question	Answer
		Submitter, it was not fully clear which would be considered as microplastics. These and other polymers listed in Table 88 were used as an appropriate basis for estimating the 'high scenario' of the socio-economic impacts arising from the proposed restriction on cosmetic products, which is likely to have overestimated impacts, as not all polymer uses would fall within the scope of the proposed restriction. If you have any information whether these polymers are/ or are not microplastics, please provide this information in the public consultation (specifically in response to question 6).
2.10	Polysilicone-15 is a liquid. Why is it mentioned in Table 46 of the Annex to the restriction proposal?	The polymers listed in Table 46 in the Annex are known to be commonly used in cosmetics but, based on the information available to the Dossier Submitter, it was not fully clear which would be considered as microplastics, as defined in the proposal. This would depend on the physical state of the polymer, its morphology and size. These and other polymers listed in Table 88 we used as an appropriate basis for estimating the 'high scenario' of the socio-economic impacts arising from the proposed restriction on cosmetic products, which is likely to have overestimated impacts, as not all polymer uses would fall within the scope of the proposed restriction. Polysilicone-15 is an INCI name used in cosmetics. It does not refer to a specific polymer. If the substance referred to as 'polysilicone-15' is not present in a form of a solid particle, then this would not fulfil the definition of a microplastic and would not be covered by the proposed restriction. However, any synthetic polymer, including polysilicone, which would fulfil the definition, will be included in the proposed scope. If you have any information whether these polymers are/ or are not microplastics, please provide this information in the public consultation (specifically question 6).
2.11	Are natural cellulose fibres, polyethylene glycols and polyamines microplastics?	All naturally occurring polymers are not microplastics. For synthetic polymers, such as polyethylene glycols and polyamines, other criteria should be considered, e.g. it should be considered if the substance

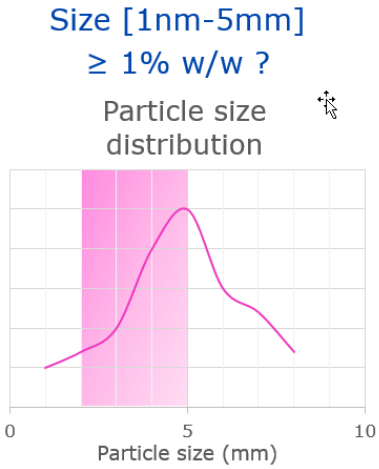
#	Question	Answer
		meets the other relevant criteria for a microplastic. Please refer to the decision trees in Section 2 of this document.
2.12	If a synthetic polymer also occurs in nature, is it derogated?	No. Under REACH a naturally occurring substance is defined based on the origin of the substance (Article 3(39)).
2.13	If polymer 'A' is chemically modified to obtain polymer 'B' (which occurs in nature), would polymer 'B' be a microplastic?	Yes, but only if all of the other relevant criteria for the polymer are met. Please refer to the decision trees in Section 2 of this document. Under REACH, a naturally occurring substance is defined based on the origin of the substance (Article 3(39)).
2.14	Would polymers obtained from polylactic acid be considered as a microplastic?	Polymer-containing particles should be evaluated as to whether or not the criteria described in the proposal for a microplastic are met, e.g. is the polymer present in a solid particle within the specific dimensions. Please refer to the decision trees in Section 2 of this document.
2.15	If a polymer is dissolved in oil, is it a microplastic?	The restriction proposal focuses on presence of polymer-containing particles in the product(s) placed on market. If the polymer is not in form of a solid particle it would not fall within the proposed definition of a microplastic. The type of solvent is not an element of the definition.
2.16	Does a polymer falls within the scope if it is not added as a microplastic but during the use of the substance/mixture becomes a "microplastic"?	No. Spontaneous formation of microplastics at the 'point of use/disposal' is not included in the scope of the proposal.
2.17	Will amorphous polymers with a glass transition temperature below 20 degrees celsius be included in the microplastic definition? Are they solid or liquid?	Glass transition temperature is not proposed as one of the criteria for a microplastic. Specifically, you should consider whether or not the polymer-containing particle meets the definition of solid as defined in the CLP Regulation (which is used for the proposed restriction).
2.18	Will there be a list available with CAS-numbers of the polymers that are potentially microplastics?	It is not possible, for various reasons, to provide an exhaustive list of the identifiers for the polymers that would fulfil the microplastic definition proposed the Annex XV dossier. For example, a single polymer may exist in several forms, some of which would be considered as microplastic whilst others would not. Nevertheless, non-exhaustive lists of polymers that typically meet the

#	Question	Answer
		definition of a microplastic could be provided by ECHA, or other stakeholders, in the future once there was greater practical experience of the definition. These lists could be used to aid the workability and enforceability of the proposal. Additional information would become available progressively by means of the proposed reporting requirements for derogated uses.

2.4. Particles and polymer-containing particles (including particle size)

#	Question	Answer
2.19	What is meant by a 'polymer containing particle'?	Polymer-containing particle means either (i) a particle of any composition with a continuous polymer surface coating of any thickness or (ii) a particle of any composition with a polymer content of ≥ 1% w/w.  Note: the pink colour represents the polymer The reason to distinguish particle type (i) from particle type (ii) stems from the fact that the amount of polymer used in encapsulation applications may be <1% w/w, relative to the overall mass of the particle whilst these uses are a key focus of the restriction. A threshold of 1% for particle type (ii) was chosen on the basis that this is the established standard for reporting the composition of a well described substance under REACH.
2.20	Are particles coated or encapsulated with	Yes, these would be type (i) polymer containing particles and would be considered as microplastics as long as the other elements of the definition are

#	Question	Answer
	polymers considered to be microplastics?	met.
2.21	How should the fact that synthetic polymers in a solution might behave differently with respect to their particulate form at different stages during life cycle be considered, i.e. formulation of cosmetic products, in the cosmetic product placed on the market and during the use of the product.	The microplastic criteria should always be considered at the point of placing a substance or mixture on the market e.g. after formulation or in case of import. Various obligations would exist for providing 'instructions for use' and/or reporting depending on the actor involved and the type of product. Please refer to the decision trees in this document for further information. In addition, the state of the microplastic at the point of end use by a consumer or professional is relevant for determining if the restriction on placing on the market can be derogated according to the conditions described in paragraphs 5(b) e.g. when a cosmetic product is applied to the skin or hair by a consumer or when a paint is applied to a wall. Please refer to Section 3 of the Q&A for further details of the obligations that will arise under the proposed restriction at different levels of the supply chain of microplastics.
2.22	How do we prove that a polymer substance in a size range between 1 nm and 100 nm is solid when it might be the size of the polymer substance itself	Single molecules are not considered to be particles. The size of the polymer itself is not being questioned. The question is whether or not the potential particles consist of polymers as defined under REACH and whether or not these particles are in solid form as defined in the CLP Regulation, and whether or not other parameters such as percentage of polymer molecules in the particles with the appropriate dimensions are met.
2.23	How should particle size be measured?	A particle is defined as a 'minute piece of matter with defined physical boundaries'. This can be further specified as: 'a particle has a physical boundary that can also be described as an interface and that a particle can move as a unit'. Particle size can be measured according to various ISO standards e.g. CEN ISO/TS 27687:2008 (ISO, 2008) and ISO 14644-6:2007 (ISO, 2007). In addition, techniques used for the characterisation of nanomaterials could be useful for very small particles, e.g. dynamic light scattering (DLS) or field flow fractionation (FFF). In relation to the particle size criteria a particle size distribution needs to be considered. In any given test sample, the particle size measured will have a

#	Question	Answer
		distribution and there may be particles present with sizes both above and below the size cut-off for a microplastic. Note that it is the weight distribution rather than the number distribution that is the key parameter to be measured. To assess the distribution we suggest to use a mean value obtained from several batches over time. 
2.24	Establishing 1 nm as a lower limit of the microplastic definition could already include a single polymer molecule. Does that mean that single molecules fall under the microplastic definition?	Single molecules are not considered to be particles. The size of polymer itself is not under question as long as the substance itself considering all polymeric molecules that are present in fulfil the polymer definition as defined in Article 3(5) of REACH. When considering if the substance is a microplastic or not the total substance composition needs to be taken into account. The question further relates to whether or not the potential particles comprises of polymers as defined under REACH and whether or not these particles are in solid form as defined in the CLP Regulation and whether or not other parameters such as percentage of polymer molecules in the particles with the appropriate dimensions are met.

#	Question	Answer
2.25	What about larger particles, for example 20 mm size, with a small amount of abraded dust in the µm or nm range? Determining a number or size distribution in this kind of situation if challenging.	The current proposal refers to weight average particle size distribution, not to a number size distribution. In general, it should be more straightforward to determine the weight size average distribution for such substances rather than the number size distribution.
2.26	Are 'swellable' polymer particles included in the scope of the proposed restriction e.g. gels, microgels or absorbing gels?	If the swellable polymer containing particle retains its solid particulate form during use (and remains <5mm in size), then these are still considered as microplastics. Further to the particulate state, a 'particle' means a minute piece of matter with defined physical boundaries. Defined physical boundaries means if it can be distinguished from the surrounding matter. There must be a continuous boundary that indicates where the particle 'ends'. The term 'interface' can be used to describe this boundary. Should a swellable polymer cease to have an interface during use then it would cease to be a microplastic. Please tell us about your experience with interfaces and swellable polymers in the public consultation.

2.5. Particle state (solid, semi-solid and liquid)

#	Question	Answer
2.27	Are semi-solid particles included in the scope of the proposed restriction?	The term 'semi-solid' was considered during the development of the restriction proposal (e.g. call for evidence stage), but was ultimately not used in the microplastic definition in the submitted proposal. Therefore, the term 'semi-solid' is not a relevant parameter. The restriction proposal considers solid polymer-containing particles as microplastics (assuming they are within the relevant size range). Solid is defined as per the CLP regulation. On this basis, any material which is not considered to be a liquid or a gas is considered to be a solid. Certain polymer materials that could be considered to be 'semi-solid' would be considered to be solid according to the CLP regulation definition.

#	Question	Answer
2.28	According to Annex XV page 184, the definition for semi-solids refers to the glass transition temperature (Tg). However, Tg is a range and the value depends largely on the measurement conditions, so making Tg part of a definition does not seem to be robust.	The term 'semi-solid' was considered during the development of the restriction proposal (e.g. call for evidence stage), but was ultimately not used in the microplastic definition. Therefore, the term 'semi-solid' is not a relevant parameter. The state of a polymer consistent with a microplastic in the proposal is based solely on the definition of solid in the CLP regulation. Therefore, Tg is not required when determining if a polymer meets the definition of a microplastic.
2.29	Are polymers synthesised by emulsion polymerisation and dispersed in an aqueous solution microplastics?	Possibly. The process of polymerisation is not a determining factor in the proposed definition of a microplastic. The definition refers to a presence of solid particles with the relevant physical parameters (dimension, polymer concentrations etc.).
2.30	Are 'antifoam' particles considered to be microplastics? i.e. ions of silica nanoparticles and polydimethylsiloxane? These droplets are ~4 microns in size and since these emulsions are not stable upon mechanical shear they are not considered as solid particles.	Where there are no solid particles present in a substance or mixture then any polymers present would not be considered as a microplastic as defined in the restriction proposal. In addition, where a substances ceases to be a polymer-containing particle at the point of use (e.g. on the basis of mechanical sheer) it would cease to be a microplastic and would be derogated from the restriction on the basis of paragraph 5b.

2.6. Solubility

#	Question	Answer
2.31	Why is solubility not included as a parameter in the microplastic definition? Are water-soluble polymers exempted from restriction?	The term solubility has been used in several of the available definitions of microplastic used for regulatory and non-regulatory purposes and was initially considered as an element of the restriction definition (as outlined in the Annex XV report and its Annexes). The relevance of a 'solubility' consideration to the microplastics concern is acknowledged. Soluble materials would not contribute to the microplastics concern as they would not be present as particles (single molecules are not considered to be particles). However, on a theoretical and empirical level, the understanding of polymer

#	Question	Answer
		'solubility' it is not straightforward. Polymer 'solubility' can be understood differently depending on the context and, as such, was not considered to be a suitable element in the definition of 'microplastic'. Therefore, as an alternative, the terms 'solid and 'particle' were used to capture the concept that a polymer has to retain its state and morphology in the medium into which it is placed to be considered as a microplastic. The derogation proposed under paragraph 5b, where microplastics that lose their particulate form at the point of use (i.e. exist as single molecules) are derogated, is considered to achieve the same outcome as would occur by derogating 'soluble' polymers, but with fewer theoretical and practical difficulties.

2.7. (Bio)degradability

#	Question	Answer
2.32	The proposed legal text does not say at which point in the life cycle the (bio)degradability criteria must be considered.	The criteria for biodegradability apply throughout the life-cycle and is considered as intrinsic property of the polymer-containing particle. The purpose of the criteria is to provide a means to demonstrate that microplastic would not accumulate in the environment. This can be demonstrated either by screening methods or higher tier methods.
2.33	Biodegradable polymers are 'excluded' from the microplastics definition on p 23 of the proposal. On other locations in the text, they are 'derogated'. Which of the two is it: excluded or derogated?	Polymer-containing particles that fulfil the criteria for (bio)degradability set out in Appendix X are not considered to be microplastics and are derogated from the proposed restriction with no obligations for providing 'instructions for use' or 'reporting'.
2.34	Can data from GLP-certified labs be used to assess biodegradability (instead of ISO 17025 certified labs)? How will ECHA check that biodegradability data used have well been obtained in quality certified labs?	Data on the (bio)degradability of polymers used to satisfy the derogation proposed in paragraph 3b must be obtained from reliable, quality assured, studies. The enforcement of REACH restrictions is performed by competent national enforcement authorities, not ECHA. They will check if the scope and criteria set in the restrictions are fulfilled by the companies placing substances

#	Question	Answer
		and mixtures on the market. This is the key reason why the test methods and pass/fail criteria are prescriptive and require appropriate quality assurance. Equally, this is the reason that 'weight of evidence' approaches to compliance with this element of the restriction have been ruled out. The required competence to assess weight of evidence approaches cannot be assumed to be available within Member States, and may be interpreted different in different Member States. As proposed, only data from laboratories with ISO 17025 certification would be acceptable to demonstrate that (bio)degradation criteria have been achieved. This may be expanded during the opinion making phase if other quality assurance schemes are considered to result in a similar reliability i.e. to include GLP certification.
2.35	Does a biodegradation screening test have to be specifically listed in order to be accepted as a valid test? For example, certain test methods accepted under OSPAR are not included in the list of potential test protocols.	The acceptable standard test methods with the corresponding pass/fail criteria are detailed in the Annex XV report and are proposed to be listed in an Appendix to the REACH Annex XVII entry in order that they can be readily updated in response to technical progress. The Annex XV report refers to this Appendix as 'Appendix X'. You are encouraged, via the public consultation, to provide proposals on other suitable standard methods which, in your opinion, could be used to demonstrate the (bio)degradability of microplastics. In any comments submitted you may want to consider the applicability of the test guideline to poorly soluble particles such as microplastic, the reliability of the methods in predicting the degradability and added value against those already provided. We invite the stakeholders to provide additional information on the feasibility and availability of testing methods via the specific question 1 in the public consultation.
2.36	How will inorganic polymers be regarded with respect to (bio)degradability? Acc. to REACH this is not an applicable information requirement for inorganics.	Inorganic polymers are not likely to be (bio)degradable, but could be assessed according to the methods and pass/fail criteria set our in the restriction proposal. You are encouraged via the public consultation to provide proposals on other

#	Question	Answer
		suitable standard methods which, in your opinion, could be used to demonstrate the (bio)degradability of microplastics. In any comments submitted you may want to consider the applicability of the test guideline to poorly soluble particles such as microplastic, the reliability of the methods in predicting the degradability and added value against those already provided. We invite the stakeholders to provide additional information on the feasibility and availability of testing methods via the specific question 1 in the public consultation.
2.37	Is it possible to use different methodologies or approaches (i.e. weight of evidence) when assessing if the derogation in paragraph 3b on (bio)degradability is satisfied?	No. The proposed methods and pass/fail criteria are prescriptive and cannot be modified, even if considered more realistic. This is on the basis that enforcement is undertaken by Member State Competent Authorities. You may propose alternative standard methods and pass/fail criteria to be used in the public consultation (see specific question 1). You must provide robust justification as to why the proposed method would demonstrate a level of (bio)degradation to prevent accumulation in the environment.
2.38	Is it possible that other (bio)degradable test methods will be added to Appendix X?	Yes. You may propose alternative standard methods and pass/fail criteria to be used in the public consultation (see specific question 1). You must provide robust justification as to why the proposed method would demonstrate a level of (bio)degradation to prevent accumulation in the environment. Once the methods and criteria set out in Appendix X and agreed it will not be possible to deviate from these, unless Appendix X is formally updated with respect to scientific and technical progress.
2.39	Does the evaluation of biodegradation take into account the marine environment?	Yes. The criteria set for biodegradability also cover the marine environment. For example, the higher tier assessment criteria specify thresholds for the degradation half-life in marine water and sediment. Similar to other aspects of REACH (e.g. PBT assessment), the early tiers of the assessment framework proposed use rapid 'screening methods' that are independent of specific environmental compartments but which have very stringent pass/fail criteria. It is considered that where a screening test is passed then (bio)degradation will occur in the environment in the event that a

#	Question	Answer
		material is released. These criteria are no less stringent than for chemicals in general.

3. Obligations arising from the restriction at different levels of the supply chain

The boxes below outline the obligations for manufacturers, imports and downstream users that will arise from the proposed restriction when placing a substance or mixture on the market containing a microplastic i.e. under the various derogations.

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:

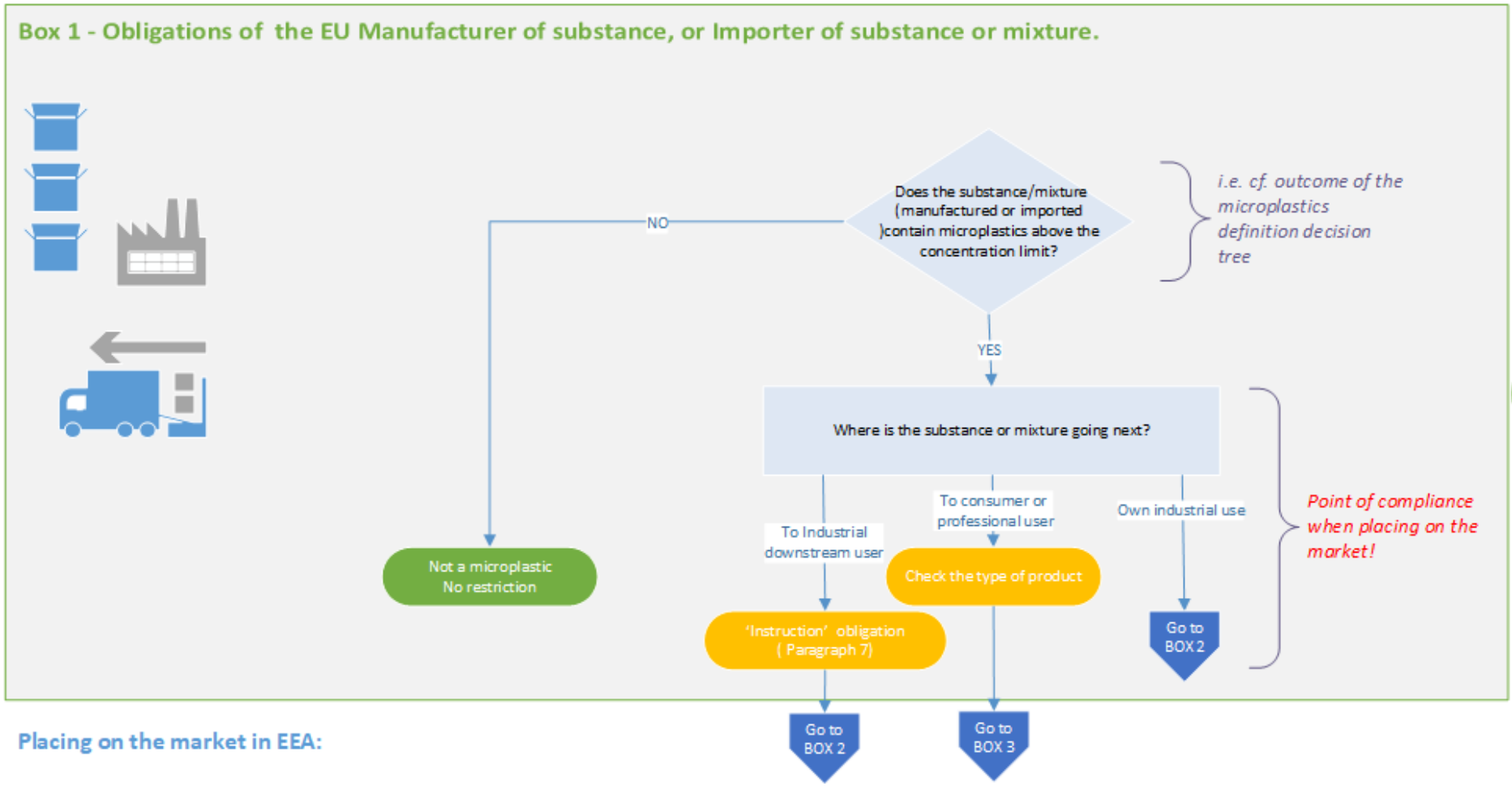
- Box 1 represents the obligations of an **EU manufacturer of substances**, or an **importer of substance or mixture**
- Box 2 represents the obligations of **industrial downstream users**[3]
- Box 3 identifies the different types of products, and the associated obligations of the importer or downstream user when placing on the market, **for consumer or professional**, substance or mixture containing microplastics.

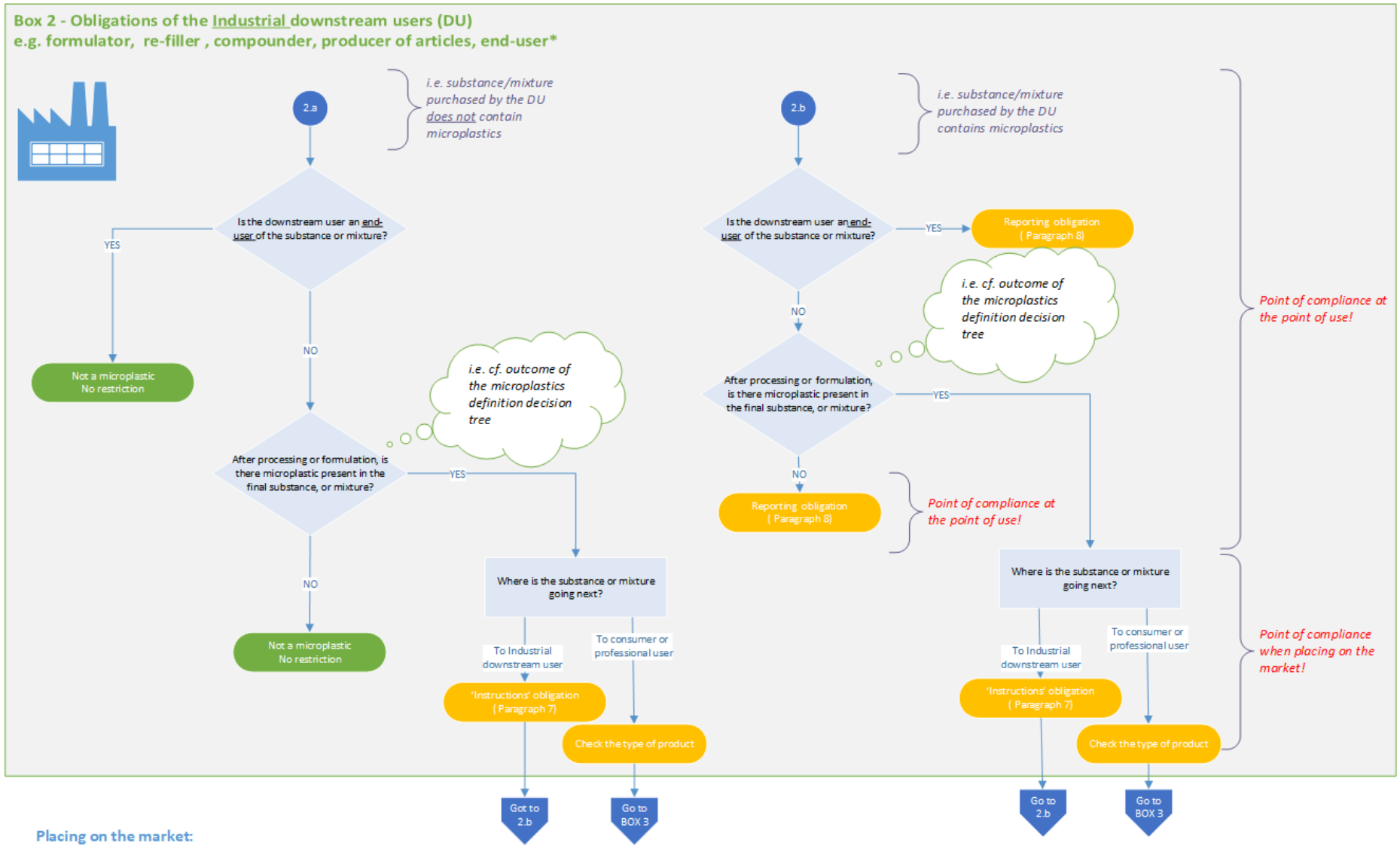
The obligations (in term of reporting, 'instruction of use', placing on the market…) of each actor in the supply chain are identified in orange or red shapes.

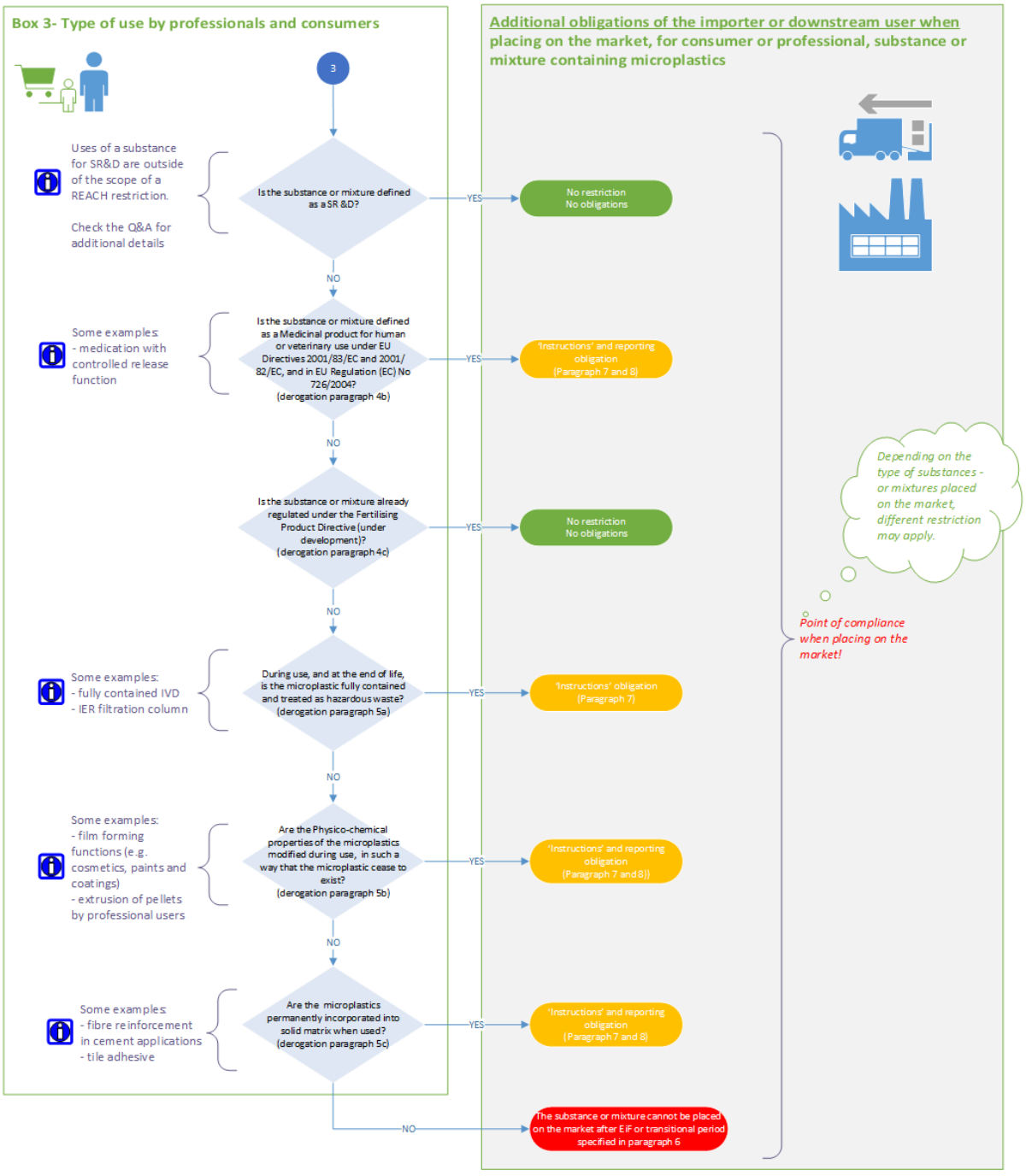
The green shapes indicate that there is no microplastic concern, or that no restriction applies ('full' derogation).

[3] *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.


Box 1 - Obligations of the EU Manufacturer of substance, or Importer of substance or mixture.
Does the substance/mixture (manufactured or imported)contain microplastics above the concentration limit?
NO
YES
i.e. cf. outcome of the microplastics definition decision tree
Where is the substance or mixture going next?
To Industrial downstream user
To consumer or professional user
Own industrial use
Point of compliance when placing on the market!
Not a microplastic No restriction
Check the type of product
'Instruction' obligation (Paragraph 7)
Go to BOX 2
Go to BOX 3
Go to BOX 2
Placing on the market in EEA:


Box 2 - Obligations of the Industrial downstream users (DU)
e.g. formulator, re-filler , compounder, producer of articles, end-user*
2.a
i.e. substance/mixture purchased by the DU does not contain microplastics
Is the downstream user an end-user of the substance or mixture?
YES
Not a microplastic
No restriction
NO
After processing or formulation, is there microplastic present in the final substance, or mixture?
i.e. cf. outcome of the microplastics definition decision tree
YES
NO
Not a microplastic
No restriction
Where is the substance or mixture going next?
To Industrial downstream user
To consumer or professional user
'Instructions' obligation (Paragraph 7)
Check the type of product
Got to 2.b
Go to BOX 3
2.b
i.e. substance/mixture purchased by the DU contains microplastics
Is the downstream user an end-user of the substance or mixture?
YES
Reporting obligation (Paragraph 8)
NO
i.e. cf. outcome of the microplastics definition decision tree
After processing or formulation, is there microplastic present in the final substance, or mixture?
YES
NO
Reporting obligation (Paragraph 8)
Point of compliance at the point of use!
Point of compliance at the point of use!
Where is the substance or mixture going next?
To Industrial downstream user
To consumer or professional user
'Instructions' obligation (Paragraph 7)
Check the type of product
Go to 2.b
Go to BOX 3
Point of compliance when placing on the market!
Placing on the market:


Box 3- Type of use by professionals and consumers
3
Uses of a substance for SR&D are outside of the scope of a REACH restriction.
Check the Q&A for additional details
Is the substance or mixture defined as a SR &D?
YES
No restriction
No obligations
NO
Some examples:
- medication with controlled release function
Is the substance or mixture defined as a Medicinal product for human or veterinary use under EU Directives 2001/83/EC and 2001/82/EC, and in EU Regulation (EC) No 726/2004?
(derogation paragraph 4b)
YES
'Instructions' and reporting obligation
(Paragraph 7 and 8)
NO
Is the substance or mixture already regulated under the Fertilising Product Directive (under development)?
(derogation paragraph 4c)
YES
No restriction
No obligations
NO
Some examples:
- fully contained IVD
- IER filtration column
During use, and at the end of life, is the microplastic fully contained and treated as hazardous waste?
(derogation paragraph 5a)
YES
'Instructions' obligation
(Paragraph 7)
NO
Some examples:
- film forming functions (e.g. cosmetics, paints and coatings)
- extrusion of pellets by professional users
Are the Physico-chemical properties of the microplastics modified during use, in such a way that the microplastic cease to exist?
(derogation paragraph 5b)
YES
'Instructions' and reporting obligation
(Paragraph 7 and 8))
NO
Some examples:
- fibre reinforcement in cement applications
- tile adhesive
Are the microplastics permanently incorporated into solid matrix when used?
(derogation paragraph 5c)
YES
'Instructions' and reporting obligation
(Paragraph 7 and 8)
NO
The substance or mixture cannot be placed on the market after EiF or transitional period specified in paragraph 6
Additional obligations of the importer or downstream user when placing on the market, for consumer or professional, substance or mixture containing microplastics
Depending on the type of substances - or mixtures placed on the market, different restriction may apply.
Point of compliance when placing on the market!

4. Derogations

4.1. General questions

#	Question	Answer
4.1	I don't think my use should be restricted. How can I ask for an exemption?	In order to consider an exemption for a specific use a clear justification, including detailed supporting information, must be provided in the Public Consultation. Guidance on the information that should be submitted during the public consultation on a restriction proposal is available on the ECHA website: https://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf Specifically, respondents must demonstrate that an inclusion would be disproportionate or generate undesirable indirect effects that would not contribute to overall risk reduction. Other relevant information may be considered.

4.2. Derogation for use at industrial sites (paragraph 4a)

#	Question	Answer
4.2	What is the definition of 'industrial sites' under the REACH regulation?	The REACH legal text refers to industrial and professional use [activity] in the definitions in Articles 3(13), 3(25) and 3(35), as well as section 6 of Annex VI. In Annex XVII the terms 'industrial installation' and activity of a 'professional outside industrial installations' are used. Guidance R.12 on Use description (ECHA, 2015) provides a non-exhaustive list of characteristics associated with industrial sites.
4.3	ECHA R.12 Guidance does not fully clarify what an 'industrial site' is. Would onshore and sub-sea wells (offshore oil and gas) be considered as industrial sites?	ECHA R.12 Guidance covers various REACH-related considerations. The intention of the Dossier Submitter (in this case ECHA) was that the term 'for use at industrial sites' included in Paragraph 4a of the proposal would apply to **all industrial uses** of microplastics, including onshore and offshore oil and gas sites.

#	Question	Answer
4.4	Would a recycling plant be considered to be an industrial site? Hence, do recyclers have to report to ECHA according to Paragraph 4a?	ECHA R.12 Guidance covers various REACH-related considerations. The intention of the Dossier Submitter was that the term 'for use at industrial sites' included in Paragraph 4a of the proposal would apply to **all industrial uses** of microplastics, including recycling facilities. The interface between waste legislation and REACH can be complex. Nevertheless, the Dossier Submitter considers that where a recycling plant manufactures microplastics (e.g. pellets of recycled plastic) and places these on the market (for further use by a downstream user), then the requirements outlined in paragraph 7 to provide information on appropriate conditions of use to minimise releases to the environment (which may be on a label, on an SDS or similar) would apply. Where a recycling plant manufactures microplastics (e.g. pellets of recycled plastic) and uses them to produce articles at the same location (aka an 'integrated recycler'), then the reporting requirements outlined in paragraph 8 would apply to the recycling plant, but not those outlined in paragraph 7.
4.5	Our understanding is that only mixtures containing microplastics that have their end use at industrial sites would be subject to reporting and labelling criteria set out in paragraphs 7 and 8, and not raw materials used at industrial sites higher up the supply chain. Can you confirm this?	The purpose of paragraph 7 is to ensure that relevant information on conditions of use to minimise releases of microplastics to the environment (which may be on a label, on an SDS or similar)) is available throughout the supply chain. Therefore, the paragraph 7 requirement applies any time a substance or mixture containing microplastics is placed on the market irrespective of the recipient of the substance or mixture e.g. industrial site, professional or consumer. The purpose of the reporting requirement outlined in paragraph 8 is to understand where residual releases of (derogated uses) of microplastics may occur, in order that the effectiveness of restriction can be assessed over time. It would therefore apply to industrial end use (e.g. use of coatings containing microplastics at industrial site, or use of pellets to produce articles), but also where a substance or mixture containing microplastics is further processed at an industrial site (e.g. formulation) before being supplied further down in the supply chain either to another industrial site or a consumer. Section 3 of this documents sets out the obligations arising from the proposed

#	Question	Answer
		restrict for different actors.

4.3. Derogation for containment and disposal as hazardous waste (paragraph 5a)

#	Question	Answer
4.6	Are ion exchange resins used for water treatment microplastics?	According to the information provided during the call for evidence, Ion exchange resins (IER) used for water treatment would fall under the definition of microplastics. If used at an industrial site, IER for water treatment would be derogated according to paragraph 4a. In other cases (professional and consumer uses), IER for water treatment could be derogated according to paragraph 5a as long as IER is both (i) contained by technical means throughout their whole lifecycle to prevent releases to the environment (including any recycling) and (ii) any microplastic containing wastes arising are incinerated or disposed of as hazardous waste. In all the above situations, the requirement (paragraph 7) to provide information about conditions of use to minimise releases to the environment (which may be on a label, on an SDS or similar) and reporting would apply as well.
4.7	What is the definition of 'contained by technical means'? (in paragraph 5a)	Paragraph 5a aims at derogating from the restriction uses of microplastics where a specific technical design is implemented to prevent, by technical means, the release of microplastics to the environment during their use. 'Contained by technical means' could be, for example, when microplastics are contained during their use in a cartridge or column with no potential for release. An analogy could be the concept of 'rigorous containment' introduced in REACH when considering the registration of substances used as intermediates under 'strictly controlled conditions'.
4.8	Are microplastics contained in an article out of the scope of the restriction?	Microplastics contained within an article throughout their whole lifecycle to prevent releases to the environment would benefit (i) either from the derogation under paragraph 5a if the microplastic containing wastes arising are

#	Question	Answer
		incinerated or disposed of as hazardous waste, or (ii) from the derogation under paragraph 5c if the microplastic are permanently 'contained' at the point of use and permanently incorporated into a solid matrix when used. The derogation is intended to work together with the requirement (paragraph 7) to provide information about conditions of use to minimise releases to the environment (which may be on a label, on an SDS or similar) and reporting elements of the proposal (paragraph 8).

4.4. Derogation for loss of microplastic form at point of use (paragraph 5b)

#	Question	Answer
4.9	Paragraph 5b of the proposed restriction provides a derogation for 'substances and mixtures where the physical properties are permanently modified when the substance is used'. The Annex XV report 2.2.1.2. indicates that this applies when 'the particle ceases to exist'. Can this concept be further clarified.	This derogation is indeed intended to address the issue where microplastics are present in a substance or mixture placed on the market, but these are 'consumed' or otherwise cease to exist in the form of microplastics at the point of use. This mainly corresponds to the loss of the particulate nature of the microplastic through various physico-chemical processes or chemical reactions. e.g. • Coalescence of film-forming particles (e.g. polymer binders in paints and coatings) when applied to a surface. • Water 'soluble' polymers, including the disassociation of polymers from the surfaces of inorganic particles • Use of pre-production pellets or powders to manufacture articles though an extrusion or similar process (if not at an industrial site). Section 2.2.1.2 of the dossier simply recognises that the presence of a 'particle' is one of the key diagnostic properties of a microplastic. Any of the properties, e.g. state, could be substituted for particle. The derogation is intended to work together with the requirements (paragraph 7) to provide information about conditions of use to minimise releases to the environment (which may be on a label, on an SDS or similar) and reporting

#	Question	Answer
		elements (paragraph 8).
4.10	Regarding swelling polymers, the Annex XV report uses super absorber polymer as an example for when derogation 5b would apply. How about a polymer-based thickener for cosmetic use where the polymers swell in the cosmetic formulation	The determining factor is whether or not the thickener loses its solid particulate form in the product. If the particulate form is lost in the product that is placed on the market then these substances would no longer fulfil the regulatory definition of a microplastic. In this case derogation 5b would not be required to place the product on the market, and no additional obligations would apply to these products (e.g. instructions for use / reporting). If the particulate form is retained in the product that is placed on the market, but this form is lost at the point that the product is used, then the product could be placed on the market on the basis of paragraph 5b, but reporting (paragraph 8) and the requirement (paragraph 7) to provide information about conditions of use to minimise releases to the environment (which may be on a label, on an SDS or similar) would apply.
4.11	Regarding 'film forming', does it only refer to leave-on cosmetic products or to rinse-off products, e.g. all conditioning polymers form a film on the hair.	The derogation proposed in paragraph 5b is not limited by the type of product and could apply to a rinse-off cosmetic product.
4.12	Are all waxes and polishes covered? If a wax contains solid glittering polymers, is it still covered by the derogation scope?	The intention is that the film-forming elements of a formulation would be derogated, but that other components, if they would remain microplastics, would not unless they are **permanently** incorporated into a solid matrix – i.e. derogation 5(c).
4.13	Why are microplastics that form films excluded? Don't they break down into microplastics over time and are released into the environment.	The proposed restriction relates to intentionally added microplastics. Any secondary microplastics that are formed during the service life of a film are not covered by the current restriction proposal as they are not intentionally added to the product.
4.14	How could a manufacturers or downstream user placing a microplastic on the market demonstrate that microplastics are permanently modified when used (exemption 5b)	Enforcement is the responsibility of Member States. Downstream users should consider collating relevant evidence that supports their conclusion that the derogation would apply for their product, that could include the results of experimental studies e.g. on the presence of solid particles, and make this available to enforcement on request.

5. Supply chain information / communicating instructions for use (paragraph 7)

#	Question	Answer
5.1	How do you suggest 'microplastic content' information is passed down the supply chain to the end user placing on the market?	The requirement specified in paragraph 7 of the proposed restriction is intended to inform downstream users and consumers about appropriate conditions of use to minimise releases of microplastics to the environment. It does not require that products are labelled as 'contains microplastics'. Although this requirement is referred to, for brevity, in sections of the Annex XV report as the 'labelling' requirement, it should be correctly understood as a requirement for actors placing microplastics on the market (for derogated uses) to provide instructions for how to use or dispose of the product in the most appropriate way. This information could be included e.g. on a label, in a product leaflet or as part of the SDS. 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/mixture is subject to the conditions of use prescribed in 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.
5.2	Why do we need labelling/reporting for derogated substances like pharmaceuticals?	The purpose of the paragraph 7 requirement is to influence how the products are used and disposed of in a way that minimises the negative impacts on the environment. For pharmaceuticals, this could for example instruct users not to dispose of the unused products down the drain. The paragraph 8 reporting requirement will help to monitor residual release of microplastics and to assess whether there is a need for further regulatory action on the derogated uses in the future.
5.3	Does a biodegradable microplastic need labelling?	Polymers that are biodegradable (as set out in the criteria in Appendix X in the restriction dossier) are not considered microplastics. Therefore, paragraph 7 requirement also does not apply to them.

#	Question	Answer
5.4	What will be the requirements of labelling, because most polymers are not classified as hazardous, and as such their identity does not need to be detailed on the SDS.	According to Article 32 of REACH, 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 these case, actors placing substances/mixtures on the market should identify that a substance/mixture is subject to the conditions of use prescribed in 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.
5.5	Will a product SDS have to disclose the chemical identity of the microplastic? How can proprietary information be maintain?	If the substance/mixture is classified or if the substance is persistent, bioaccumulating and toxic (PBT) or if it is, based on other hazards, included in the Candidate list of substances of very high concern under REACH then the substance must be identified in accordance with the rules outlined in sections 1 and 3.1 (or 3.2 for a mixture) of the SDS. If the mixture is not classified and the substance does not fulfil the conditions of REACH Article 31(3) then there is no requirement for an SDS. In this case an SDS can be provided on a voluntary basis. In these cases, actors placing substances/mixtures on the market should identify that a substance/mixture is subject to the conditions of use prescribed in 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.

6. Reporting requirement (paragraph 8)

#	Question	Answer
6.1	If a polymer particle or polymer containing particles meets the microplastic specification and falls under some of the derogations, a reporting	The reporting requirement (paragraph 8) and the requirement (paragraph 7) to provide information about conditions of use to minimise releases to the environment (which may be on a label, on an SDS or similar) expire when the

#	Question	Answer
	and labelling obligation arises. If in the further course it is or contains no more microplastics, when will this reporting and labelling obligation be expired? Or in other words, once it is a microplastic, will it remain a reportable microplastic for all time?	use no longer requires the derogation to continue.
6.2	There are examples of materials which if they enter the environment they effectively cease to be microplastics (e.g. they swell). As such they cannot contribute to microplastic loadings in the environment and cannot contribute to any risk. How is the need to label or report justified here?	The reporting requirement will help to monitor residual release of microplastics and to assess whether there is a need for further regulatory action on the derogated uses in the future. We may revise the reporting mechanism to ensure that it performs as intended. Please tell us about this in the public consultation.
6.3	Can you explain the reporting responsibilities for industrial users again please? does, and as such their identity does not need to be detailed on the SDS. The polymer identity may be CBI, and disclosing this to industrial Downstream Users would be an issue.	The reporting obligations for industrial users are detailed in Section 3 of this document. The reporting requirement will help to monitor residual release of microplastics and to assess whether there is a need for further regulatory action on the derogated uses in the future. We may revise the reporting mechanism to ensure that it performs as intended, including in relation to the transfer of CBI within supply chains. Please tell us about this in the public consultation.
6.4	Confidentiality of polymers in case of reporting: What if my upper suppliers refuse to disclose information (the identify of polymers) to us even under NDA? Would there be any flexible ways of reporting?	The reporting requirement will help to monitor residual release of microplastics and to assess whether there is a need for further regulatory action on the derogated uses in the future. We may revise the reporting mechanism to ensure that it performs as intended, including in relation to the transfer of CBI within supply chains. Please tell us about this in the public consultation.
6.5	The quantities of microplastics in mixtures of chemicals are often commercial sensitive information. There are cases that end-users have no access to detailed percentage or full disclosure of mixtures, only content ranges are available.	The reporting requirement will help to monitor residual release of microplastics and to assess whether there is a need for further regulatory action on the derogated uses in the future. We may revise the reporting mechanism to ensure that it performs as intended,

#	Question	Answer
	How can paragraph 8 obligations be met in these cases?	including in relation to the transfer of CBI within supply chains. Please tell us about this in the public consultation.
6.6	How can one quantify the release of microplastics to the environment either estimated or measured?	The standard methodologies for exposure assessment of chemicals, e.g. those outlined in relevant REACH Guidance, are expected to be sufficient to satisfy the reporting requirements outlined in the proposed restriction, including the use of default values i.e. those established for ERCs or in OECD emission scenario documents In addition, refined default-based approaches for specific uses/sectors, such as those used to derive spERCs, are envisaged to be usefully applied to meet the reporting obligation. Please refer to the ECHA website for more information https://echa.europa.eu/csr-es-roadmap/use-maps/concept
6.7	Related to reporting requirement, paragraph 8, it says any downstream user using a microplastic, Does it include upstream polymer producers using polymer as their pre production? i.e. do upstream producers also have reporting requirement?	The purpose of the reporting requirement outlined in paragraph 8 is to understand where residual releases of (derogated uses) of microplastics may occur, in order that the effectiveness of restriction can be assessed over time. It would therefore apply to industrial end use (e.g. use of coatings containing microplastics at industrial site, or 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 another industrial site or a consumer. Section 3 of this documents sets out the obligations arising from the proposed restrict for different actors.

7. Socio-economic aspects of the restriction proposal

#	Question	Answer
7.1	'Capsule Suspension' formulation can reduce the amount of active substance required in a plant protection product. Can the environmental benefits of uses of microplastics be compared to	The Dossier Submitter acknowledges that microencapsulation can provide environmental benefits, especially in agricultural uses (reduction of pesticides and fertilisers used, reduced run-off, etc.).

#	Question	Answer
	the potential risks of microplastic emissions?	Therefore, the proposal suggests that the transition to biodegradable polymers is closely monitored after the implementation of the proposal and, where socioeconomically valuable applications appear likely to be lost to society despite efforts to substitute, a review of the implementation timetable of the restriction may be needed. The restriction is intended to lead to an overall reduction in risk. The environmental benefits of microencapsulation, as well as availability of alternatives, will be considered by RAC and SEAC as they develop their opinions. ECHA welcomes concrete evidence to substantiate and quantify the benefits (e.g. environmental, worker protection, consumer exposure) of microencapsulation.
7.2	How is proportionality assessed in the restriction?	Proportionality of the proposed restriction is assessed on a per-sector basis (and where information permits even on a product group level). Thereby the costs incurred per sector are compared to their microplastic emission potential. A detailed description of the approach taken can be found in Chapter 2.3 of the restriction report.
7.3	What information do you need on alternatives in the public consultation?	For the assessment of the technical and economic feasibility of an alternative it is particularly important to understand: - where the alternative does and does not work (i.e. its performance compared to the use of microplastics); - how much (more) it costs per specified unit to use this alternative rather than using microplastics (i.e. price differences); - How many products would need to be reformulated, and how much would this cost; - how quickly the alternative could be implemented in a company or even a sector, e.g. the time necessary to develop alternatives and reformulate products; - whether alternatives are available in sufficient quantities on the market or the time necessary for that; - Information on hazard and risk of alternatives as well as indirect effects (e.g. need for increased used of other chemicals);

#	Question	Answer
		- Other relevant information.

8. Sector specific questions

8.1. Agrochemicals

#	Question	Answer
8.1	The timelines required for the substitution of microplastics in capsule suspension formulations of plant protection products is likely to be longer than the 5 years proposed in the Annex XV report. Is there a possibility for an extension?	A request for a longer transitional period than currently foreseen may be made. Importantly, such a request should be supported by well-substantiated information and argumentation of timelines to transition and why you believe the currently foreseen transition period would be too short. For example those arguments may include justification for the technical and economic (in-)feasibility of alternatives, time necessary to identify and transition to suitable alternatives, the need to review the authorisation because of changes in the microencapsulation material, etc.
8.2	In the assessment of agrochemicals in the Annex XV report, reference is made to biodegradation criteria that may be set under Article 42(6) of the new fertilising products regulation (EU 2019/1009). As these criteria have not yet been set (and may not be set until at least 2024) how can they be used for assessing the biodegradability of microplastics?	The new fertilising products regulation sets an obligation for the Commission to assess biodegradation criteria for polymers used in coating agents and to increase the water retention capacity or wettability of the EU fertilising products by 16 July 2024. Where appropriate, based on this assessment, biodegradation criteria shall be set provided that they comply with the requirements listed in Article 42(6) of this Regulation. In the absence of these criteria, the criteria outlined in Table 21 of the restriction proposal (Appendix X) *for 'demonstrating (bio)degradability if microplastics are deliberately applied to soil or foliage'* can be used to asses the (bio)degradability of microplastics in agrochemicals.
8.3	Will the restriction also apply to the application of biosolids (e.g. treated sewage sludge) to agriculture land?	If biosolids containing microplastics (as defined by this restriction proposal) are placed on the EU market then the restriction, as proposed, will apply to them from the entry into force date.

8.2. Infill material for synthetic turf

#	Question	Answer
8.4	Will you elaborate the term 'in fill material'? What is it?	Infill material are the granules of synthetic polymeric material that are used in many types of artificial sports turf. The infill material supports individual blades of synthetic grass so that they remain upright. Infill material also gives artificial turf its cushioned feel, or bounce. Infill material may be produced from end-of-life tyres (ELT) or other synthetic elastomeric materials. They are likely to be an intentionally added microplastic.
8.5	Is artificial turf infill exempted from the restriction if it is demonstrated that its dispersion into the environment is prevented by the use of appropriate 'technical means'?	No, not as proposed. The derogation proposed under 5a of the restriction proposal for containment by technical means is not considered to be applicable to the use of infill material for synthetic turf. Further information is needed in order to assess the implications that the restriction would have for granular infill material used in synthetic turf and to assess the possible need for a derogation. We encourage you to submit information on artificial turf infill via the public consultation, specifically by responding to question 2.

8.3. Cosmetic products

#	Question	Answer
8.6	Should the restriction be adopted, who would be responsible for ensuring that a microplastic placed on the market falls within the scope of a derogation? Would it be the raw materials manufacturers or the finished cosmetic product manufacturer?	In general, it is the responsibility of the actor who is putting a product on the EU market to ensure that it complies with EU regulation. The requirements detailed in paragraph 7 of the proposal for actors placing microplastics on the market to include appropriate instructions for use on a label and/or SDS should help downstream users to comply with their obligations under the proposed restriction.
8.7	If a polymer used in cosmetic products and mentioned in the Annex (Table 88) to the Restriction Proposal is liquid, do we still have to	The polymers listed in Table 88 may or may not fall in the scope of the proposed restriction. ECHA acknowledges that simply by looking at the INCI name of an ingredient it would not be possible to conclude if a polymer would be a

#	Question	Answer
	provide information on it during public consultation?	microplastic or not. Further information on which polymers could be impacted by the proposed restriction is requested via Specific question 6. Liquid polymers would not fall under the definition of a microplastic. In case some polymers listed in Table 88 would be liquid polymer, or would not fall under the microplastic definition, we encourage you to submit this information via the public consultation with a justification. It should be noted that a polymer dispersed in a liquid might be considered as a microplastic should solid polymer-containing particles be present.
8.8	Microbeads contained in rinse-off products are not covered by transitional agreements. Will the restriction consequently enter into force directly after adoption? Or, in other words, is the date of adoption the date of entry into force?	Yes. It is proposed that the restriction on the placing on the market of 'microbeads' (as defined in the proposal) in cosmetic products or other mixtures would apply from the entry into force date of the restriction. No transitional period is proposed for the use of microbeads.
8.9	Does the CosmEthics database provide information on alternative ingredients or only alternative products?	CosmEthics, Que Choisir and the Danish Forbrugerrådet Tænk are all sources of information on the ingredients used in cosmetic products placed on the EU market. These data were used by ECHA to analyse the availability of cosmetic products on the EU market that were not likely to contain microplastics in different product categories. Alternative ingredients, per se, were not identified. The information collated by CosmEthics, Que Choisir and the Danish Forbrugerrådet Tænk were collected independently. The analysis of data from different sources lead to comparable results.

8.4. Inks and printing

#	Question	Answer
8.10	What are the grounds for considering printing inks as derogated i.e. labelling and reporting requirement, no ban on use).	Microplastics in printing inks form a film when used and are therefore derogated in accordance with paragraph 5(b) of the restriction proposal. The releases from printing inks are mainly expected to come during the maintenance of the machines. Since these releases are not inevitable, the

#	Question	Answer
		requirement to provide information about conditions of use is expected to minimise releases to the environment. This information can be included on a label, as a package insert, or an SDS or similar.
8.11	Are printing inks in the scope of microplastics? Toners seem to be in the scope, but what about inkjet printing liquid inks?	Yes. Any substance or mixture placed on the market that contains microplastics is within the scope of the proposed restriction, unless derogated. Therefore, printing inks containing microplastics (including inkjet printing liquid inks) would be included the scope of the restriction. If these microplastics form films during use then paragraph 7 (instruction on use) and 8 (reporting) requirements would apply to them, but not the ban on the placing on the market (described in paragraph 1).

8.5. Packaging

#	Question	Answer
8.12	Are food-contact materials included within the proposed restriction?	If by 'food-contact materials', it is meant the packaging of food within the meaning of Regulation (EC) No 1935/2004. Then this is outside the scope of the proposed restriction as packaging would not fall within the relevant size limits of the microplastic definition. In case, by 'food-contact materials', it is meant a specific application that would be within the relevant size criterion, please inform us about this via the public consultation.
8.13	Is the primary packaging used for medicines for human or veterinary use within the scope of the proposed restriction?	No. The primary packaging of medicines for human and veterinary products (e.g. blister, pill box, etc.) would not fall within the relevant size limits of the microplastic definition. Nevertheless, the paragraph 7 and 8 requirements would apply to the master-batches/pellets used to produce the primary packaging. It should be noted that the paragraph 7 requirement to provide information about conditions of use to minimise releases to the environment (which may be on a label, on an SDS or similar) and the reporting requirements (paragraph

#	Question	Answer
		8) apply to microplastics used in human and veterinary medicines.

8.6. Paints and coatings

#	Question	Answer
8.14	If I make a raw material for paints that contains microplastics as per the definition and send to company B for formulation into a final paint, who is responsible for labelling/reporting?	The requirement to provide information about conditions of use to minimise releases to the environment (which may be on a label, on an SDS or similar) applies to both you and company B as it concerns 'any manufacturer, importer or downstream user responsible for the placing on the market'. The reporting requirement only applies to company B (as long as company A is not a downstream user itself, e.g. if it does some form of pre-formulation, in which case it would apply to them as well), as a downstream user of the raw material.
8.15	Would microplastics in artist's paint that are film-forming be derogated from the proposed restriction?	Paints, including artist paints, are derogated from the ban on the placing on the market (derogation 5b). However, the requirement (paragraph 7) to provide information about conditions of use to minimise releases to the environment (which may be on a label, on an SDS or similar) and the reporting requirements apply to them.
8.16	Would the derogation for paints be applicable to the use of those paints by consumers?	Yes. The proposed restriction is on the placing on the market of microplastics, rather than their use. The proposed derogation for placing microplastics on the market that are film-forming (derogation 5b) applies to paints and coatings for industrial, professional and consumer uses. However, microplastics may be placed on the market only where the conditions specified in paragraph 7 to provide information about conditions of use to minimise releases to the environment (which may be on a label, on an SDS or similar) and in paragraph 8 on reporting are satisfied. Therefore, while the restriction does not introduce any legal obligations for consumers, the label requirements will ensure that consumers are provided with relevant instructions for use, for example in relation to the correct disposal of wastes arising from brushes/rollers.

8.7. Pharmaceuticals

#	Question	Answer
8.17	Is our understanding correct that Pharmaceutical applications (e.g. polymer coatings to allow lower Active Pharmaceutical Ingredient concentrations in medicine, pills, etc.) are out of scope of this restriction?	Partially. The proposed restriction is that microplastics in human and veterinary medicines (as defined in EU Directives 2001/83/EC and 2001/82/EC, and in EU Regulation (EC) No 726/2004) are derogated from the ban on the placing on the market but that the paragraph 7 (instruction on use) and paragraph 8 (reporting) requirements apply.

8.8. Feed and food

#	Question	Answer
8.18	What is the rule regarding the inclusion of substances that are authorised under sectorial legislation, such as food additives and food and feed applications?	A REACH Restriction can apply, irrespective of the existence of other sectoral legislation, especially if a different risk is being managed - i.e. in this specific case the environmental risk is not addressed under the food regulation.
8.19	Are feed and food applications within the scope of the proposal even though these are regulated under other sectoral legislation? If so, are wax-like materials (polymers) used for coating feed/food that are digested within the scope?	Yes. Uses of microplastic in feed and food are in within the scope of the proposed restriction if all elements of the microplastic definition are met e.g. dimensions, solid particles etc. The digestion of polymers after ingestion could be analogous to the derogation outlined in paragraph 5b of the proposal. The derogation for (bio)degradable or natural occurring polymers may also be applicable.
8.20	If food fortified with ingredients using microplastics is manufactured and distributed from Europe for consumption in Africa, does the restriction apply?	The direct export outside of the EU/EEA of food supplements containing microplastics manufactured in Europe would still be possible under the proposed restriction, but only where not placed on the EU/EEA market first.

8.9. Pre-production plastic pellets (nurdles) and plastic compounding

#	Question	Answer
8.21	Are pre-production pellets and masterbatches outside of the scope of the proposed restriction?	Partially. Placing microplastics on the market for use at industrial sites is derogated from the restriction, but paragraph 7 (instruction on uses) and paragraph 8 (reporting) requirements would apply. The derogation described in paragraph 5b for permanent modification would also apply if placing on the market for use outside of an industrial site. In this case the paragraph 7 (instruction on uses) and paragraph 8 (reporting) requirements would also apply.
8.22	Company A ships microplastic particles to Company B within the EU. Company B produces an article whereby the microplastic particles are 'consumed' in accordance with derogation 5.b. What are the obligations of Company A and Company B?	From the question, we understand that: - both company A and B are industrial sites - company A is producing microplastic particles and placing them on the market - company B is using a microplastic to produce articles during which the microplastic particles are permanently modified 'consumed'. The articles are then placed on the EU/EEA market. The paragraph 7 (instruction on use) requirement applies to company A only as it concerns 'any manufacturer, importer or downstream user responsible for the placing on the market, substance or mixture containing microplastics'. The reporting requirement only applies to company B, as a downstream user of the microplastic. Please refer to Section 3 of this document for further information on the obligations that arise at different levels of the supply chain from the proposed restriction.
8.23	Does an electrical cable (with polymer insulation material) fall within the scope of this restriction?	No. An electrical cable would be very unlikely to fulfil the definition of microplastic as it would typically exceed the maximum size criterion of either 5mm (for non-fibres) or 15mm (for fibres).
8.24	What about pellet losses during transportation by exporters outside of the EU/EEA? Are exporters	Not as currently proposed.

#	Question	Answer
	from the EU/EEA required to report losses?	

8.10. Other sectors

#	Question	Answer
8.25	Are biocidal products excluded from the proposed restriction?	Biocidal products are within in the scope of the proposed restriction, as are plant protection products. In this specific case, the risk posed by the presence of microplastics in Biocidal products is not addressed by the existing Biocidal Products Regulation and it would be covered by the REACH restriction.

9. Miscellaneous questions

#	Question	Answer
9.1	Will there be a guidance developed by ECHA to support the interpretation of the provisions in the restriction?	If the restriction is adopted, the Commission may consider whether additional guidelines are appropriate.
9.2	Will there be R&D and/or low-volume exemptions for microplastics similar to other REACH requirements (e.g. registration, authorisation)?	Derogations from the restriction that are currently foreseen are listed in Table 17 of the Annex XV restriction report. The SR&D exemption applies.
9.3	For microplastics incorporated in a final use (film/coating of an article) is there any disposition regarding microplastics related with the end of life of the article (Waste treatment/management)?	Where microplastics are permanently incorporated into a film or coating during the manufacture of an article i.e. under derogation 5c the proposed restriction does not foresee any specific conditions for the end of life of the article.
9.4	Some wet wipes contain plastic fibres that will be regulated by the Single Use Plastics Directive (subject to marking requirements & paying extending producer responsibility schemes). Would the proposed restriction on intentionally	No. The Dossier Submitter understands that the individual polymer fibres in non-woven textiles would exceed the proposed upper size limit for a microplastic fibre of 15mm or would be chemical bonded to each other such that they would exceed the upper size limit for a non-fibrous particle of 5mm.

#	Question	Answer
	added microplastics mean that they would be doubly regulated?	
9.5	How would carbon black be considered under the proposed microplastic definition?	Carbon black would not fulfil the polymer definition within the meaning of Article 3(5) of the REACH Regulation. Therefore it is out of the scope of the restriction proposal.