Document 141 - Definition of Microplastic within EU REACH Restriction

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Definition of microplastic within EU REACH Restriction

Summary

ATC has reviewed the definition of microplastic used within the context of the EU REACH restriction of microplastics as it relates to the fuel and lubricant additives industry with a view to understanding the impact of the restriction on additive products.

ATC notes that the process of polymerisation is not a determining factor in the proposed definition of a microplastic. The definition in fact refers to a presence of solid particles with the relevant physical parameters (dimension, polymer concentrations etc.).

In particular, ATC observes that the microplastic restriction focuses on the presence of polymer containing particles in products that are placed on the EU market. Where the polymer is not in the form of a solid particle it does not fall within the proposed definition of a microplastic. The type of solvent in which the polymer is dissolved is not an element of the definition. As such, additive polymer chemistry potentially meeting the microplastic size criterion (0.1 µm ≤ x ≤ 5 mm) which includes, but is not limited to, overbased detergents, viscosity modifiers, dispersants, defoamers, demulsifiers, and anti-foam agents is not considered as meeting the definition of a microplastic when solvated/dissolved in an organic solvent such as mineral oil or other hydrocarbon-based solvent or when emulsified/dissolved in an aqueous solvent.

In addition, if the formulation process is such that it can be concluded that *in-situ* chemical reactions do not take place (e.g. microplastics are not formed as a part of the formulation process) information from the starting material(s) is sufficient to conclude that microplastics are not present in the formulated product.

Background

A request from the European Commission to develop an EU-wide restriction under REACH on the placing on the market or use of intentionally added microplastics to avoid or reduce their release to the environment, was received by the European Chemicals Agency (ECHA) in November 2017. In January 2018 ECHA started to examine the request. Subsequently in January 2019, ECHA submitted a REACH restriction proposal on intentional uses of microplastics in products placed on the EU/EEA market.

Notably the request from the Commission included an initial definition of microplastic particles as 'synthetic water-insoluble polymers of 5mm or less in any dimension' (COM, 2017). ECHA then adopted a working definition for microplastic particles in March 2018 at the beginning of its analysis as 'any polymer, or polymer-containing, solid or semi-solid particle having a size of 5mm or less in at least one external dimension'. An ECHA call for evidence followed and requested stakeholder input on the definition and, where this was received, it was into account in the definition that was submitted within the REACH restriction proposal in January 2019. This definition was subsequently updated based on the consultation on the Annex XV proposal during RAC/SEAC opinion development and the full definition, together with information on physico-chemical properties, now reads as follows within paragraph 2 of the restriction:

• '**microplastic**' means a particle containing solid polymer[1], to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 1 nm ≤ x ≤ 5 mm, or (ii) a length of 3 nm ≤ x ≤ 15 mm and length to diameter ratio of > 3.

• '**microbead**' means a microplastic used in a mixture as an abrasive i.e. to exfoliate, polish or clean.

• '**particle**' is a minute piece of matter with defined physical boundaries; a defined physical boundary is an interface. Single molecules are not particles.

[1] Note that a 'polymer' substance is defined within Article 3(5) of Regulation (EC) No 1907/2006 (REACH).

• '**particles containing solid polymer**' means either (i) a particle of any composition with a continuous solid polymer surface coating of any thickness or (ii) a particle of any composition with a solid polymer content of ≥ 1% w/w.

• '**solid**' means a substance or a mixture which does not meet the definitions of liquid or gas.

• '**gas**' means a substance which (i) at 50°C has a vapour pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at 20°C at a standard pressure of 101.3 kPa.

• '**liquid**' means a substance or mixture which (i) at 50°C has a vapour pressure of not more than 300 kPa (3 bar); (ii) is not completely gaseous at 20°C and at a standard pressure of 101.3 kPa; and (iii) has a melting point or initial melting point of 20°C or less at a standard pressure of 101.3kPa; or fulfilling (b) the criteria in ASTM D 4359-90; or (c) the fluidity test (penetrometer test) in section 2.3.4 of Annex A of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).

Some important notes:

1) Per paragraph 1 of the restriction, polymers that meet the definition of a microplastic cannot be placed on the market as such or within a mixture as a microplastic in a concentration equal to or greater than 0.01% w/w. This holds from entry into force of the restriction unless such polymers that meet the definition of microplastic are specifically derogated by paragraphs 4 or 5, or the end use has a longer date for entry into force per paragraph 6.

   So unless the in-scope microplastic is used within an industrial setting only (whereby certain reporting and use instructions are required), or for the end uses with longer dates to entry into force, it is effectively banned from placing on the EU market from the date of entry into force.

2) Per paragraph 3 of the restriction, natural polymers[2] that have not been chemically modified, polymers that are (bio)degradable and polymers that have a water solubility > 2 g/L are not considered to be microplastics even if they meet the definition in paragraph 2. These exemptions are based on such polymers not being seen as contributing to the microplastic concern.

Discussion

''**Particles containing solid polymer**'' are particles in which a polymer is present in any composition as a solid, or a particle with a solid polymeric surface or outer shell per bullet point 4 of the microplastic definition. In the former case, when assessing the minimum content of solid polymer in a particle for it to be considered as a microplastic, the threshold is set at 1% (w/w) and so this means that if the solid polymer content in the particles is greater than 1% w/w and if the other criteria in paragraph 2 are met, the particles are considered to be within the scope of the proposed restriction. In the latter case of polymer encapsulation, there is no minimum threshold for the % w/w of solid polymer coating relative to the mass of the coated material. This means that where the polymer-coated particle is within the size range specified in the definition, the particle itself is considered as a microplastic. The reason being that the amount of polymer used for coating could differ considerably based on the application and the amount of polymer used for the coating application is of less importance compared to the final particles that are created by the coating application.

[2] As per definition in EU REACH guidance on monomers and polymers that have not been chemically modified (as defined in REACH Article 3(40))

As such, in the case of a polymer that is solvated/dissolved in an organic solvent such as mineral oil, other hydrocarbon-based solvent or emulsified/dissolved in an aqueous solvent the criterion of '**particles containing solid polymer**' within the definition of microplastic is not met.

As per paragraph 2 of the restriction, a ''**Particle**" is a minute piece of matter with defined physical boundaries; a defined physical boundary is an interface'. In other words there must be, all around the particle, a continuous boundary that indicates where the particle 'ends'. The term 'interface' is used within the restriction definition to describe this boundary. It follows that on the other side of the boundary, there may be a continuous phase (i.e. gas, liquid, solid), or another particle. In this context single polymeric molecules are not considered to be particles even if they have defined physical boundaries.

As such in the case of a polymer that is solvated/dissolved in an organic solvent such as mineral oil, other hydrocarbon-based solvent or emulsified/dissolved in an aqueous solvent the criterion of '**particle**' within the definition of microplastic is not met, as the polymer cannot be distinguished from the surrounding matter once solvated/dissolved or emulsified.

Note that during drafting of the REACH restriction for microplastics, ECHA decided that solubility in water would not be an appropriate criterion to describe a microplastic but that, instead, the concept of the presence of a solid particle would be emphasised. They considered that as a polymer that was not present as a solid particle would not be a microplastic then this was, to all intents and purposes, equivalent to derogating 'soluble' polymers. However, stakeholders noted in the consultation process that the consequences of release of microplastics would inevitably be that some could immediately lose their particle form once in the environment (e.g. water-soluble polymers) which are different from microplastics. Hence we see within the REACH restriction that solid particles are referred to within the definition of microplastic, and later on within the restriction that polymers with water solubility >2 g/L are exempted.

Lastly with reference to ECHA Q&A on intentionally added microplastics as initially published on their website and subsequently incorporated into the Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC), Annex to Background Document:

> Page 443. "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 particles contain solid polymer 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*."
>
> Page 445. "2.15: *If a polymer is dissolved in oil, is it a microplastic?*
>
> *The restriction proposal focuses on presence of particles containing solid polymers in the product(s) placed on market. If the polymer is not in the 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*."

Supply Chain Communication and Reporting Requirements

Within a time period after implementation of the restriction paragraph 7 requires that:

i) Suppliers of a substance or mixture containing a microplastic derogated from paragraph 1 on the basis of paragraphs 4(a), 4(b), 4(d), 4(e) or 5 shall ensure that, where applicable, either the label and/or SDS and/or 'instructions for use' (IFU) and/or 'package leaflet' provides, in addition to that required by other relevant legislation, any relevant instructions for use to avoid releases of microplastics to the environment, including at the waste lifecycle stage.

ii) In addition, any supplier of a substance or mixture containing a microplastic derogated from paragraph 1 on the basis of paragraph 4(a) shall identify, where applicable, either on the label

and/or SDS and/or 'instructions for use' (IFU) and/or 'package leaflet' that (i) the substance or mixture is subject to the conditions of this restriction and (ii) the quantity (or concentration) of microplastic in the substance or mixture and (iii) sufficient information on the polymer(s) contained in the substance or mixture for downstream users or suppliers to comply with paragraph 8.

Within a time period after implementation of the restriction paragraph 8 requires that:

i) Any [industrial] downstream user using microplastic(s) derogated from paragraph 1 on the basis of paragraph 4(a) shall send to ECHA in the format required by Article 111 of REACH, by 31 January of each calendar year:

a) a description of the use(s) of microplastic in the previous calendar year,

b) For each use, generic information on the identity of the polymer(s) used,

c) For each use, an estimate of the quantity of microplastics released to the environment in the previous calendar year.

ii) Any supplier placing a microplastic derogated from paragraph 1 on the market for the first time for a professional or consumer end use allowed on the basis of paragraphs 4(b), 4(d), 4(e), or 5 shall send to ECHA in the format required by Article 111 of REACH, by 31 January of each calendar year:

d) a description of the intended end use(s) of microplastic placed on the market in the previous calendar year,

e) For each intended end use, generic information on the identity of the polymer(s) placed on the market,

f) For each intended end use, an estimate of the quantity of microplastics released to the environment in the previous calendar year.

Based on these requirements some typical supply chain scenarios for fuel and lubricant additives can be elaborated on for clarity as follows:

Where Company A in the EU supplies a product in a form that meets the definition of microplastic to EU company B, and company B formulates with it (eg further dilutes or modifies the product) such that the resulting product no longer meets the definition of microplastic and B then supplies onward to its customers C:

- Company A is derogated from the restriction where they are placing the product on the market for use at industrial sites but instructions for use (per paragraph 7 of the restriction requirements) have to be provided.
- Company B must do the annual reporting to ECHA (per paragraph 8 of the restriction requirements).
- Company C would not be using a microplastic-containing product. Therefore, they would not have obligations under the proposed restriction.

- Company A would also be derogated from the restriction where they are placing the product on the market for professional or consumer end use (per paragraph 5 (b) that exempts substances or mixtures containing microplastic where the physical properties of the microplastic are permanently modified during end use such that the polymers no longer fulfil the meaning of a microplastic).

Where Company A outside the EU supplies a product in a form that meets the definition of microplastic to EU company B who is EU importer, and company B formulates with it (eg further dilutes or modifies the product) such that the resulting product no longer meets the definition of microplastic and B then supplies onward to its customers C:

- Company A is outside of scope as they are not within the EEA, but can voluntarily provide instructions for use (per paragraph 7 of the restriction requirements) at industrial sites.
- Company B would not require instructions for use but they would need to have the equivalent information available to comply with their obligations under Occupational Safety and Health legislation.
- Company B must do the annual reporting to ECHA (per paragraph 8 of the restriction requirements).
- Company C would not be using a microplastic-containing product. Therefore, they would not have obligations under the proposed restriction.

References

ECHA Annex XV Restriction Report: Proposal for a Restriction on Intentionally Added Microplastics

ECHA Registry of Intentions until Outcome: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73

Committee for Risk Assessment (RAC), Committee for Socio-economic Analysis (SEAC) Background Document to the Opinion on the Annex XV dossier proposing restrictions on intentionally added microplastics, ECHA/RAC/RES-O-0000006790-71-01/F

Committee for Risk Assessment (RAC), Committee for Socio-economic Analysis (SEAC) Annex to Background Document to the Opinion on the Annex XV dossier proposing restrictions on intentionally added microplastics, ECHA/RAC/RES-O-0000006790-71-01/F

ECHA Questions and Answers on the Restriction Proposal on Intentionally Added Microplastics (Dossier Submitter Proposal) Version 2.0

Appendix

Microplastic Decision Trees related to REACH definition

Within the Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) Annex to Background Document on the Opinion on the Annex XV dossier proposing restrictions on intentionally added microplastics that was published on 11 June 2020 are a number of decision trees to inform judgement on whether or not a product meets the definitions within the restriction. These decision trees may be useful to further assist in decision making.

It is noted by the Committees that 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.

Figure 12: Microplastics definition decision tree overview

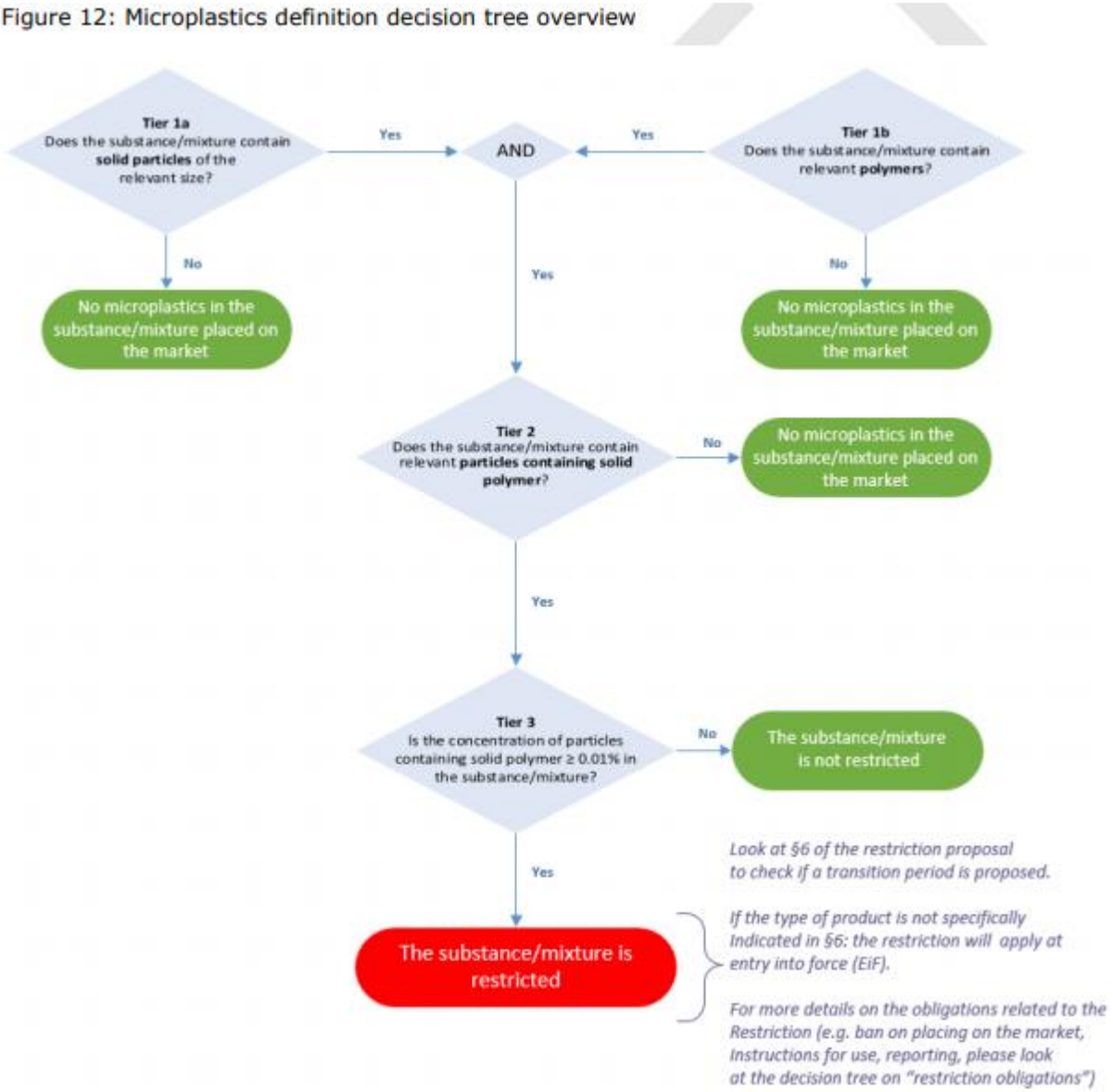

Figure 13: Microplastic decision tree - Tier 1a – relevant solid particles

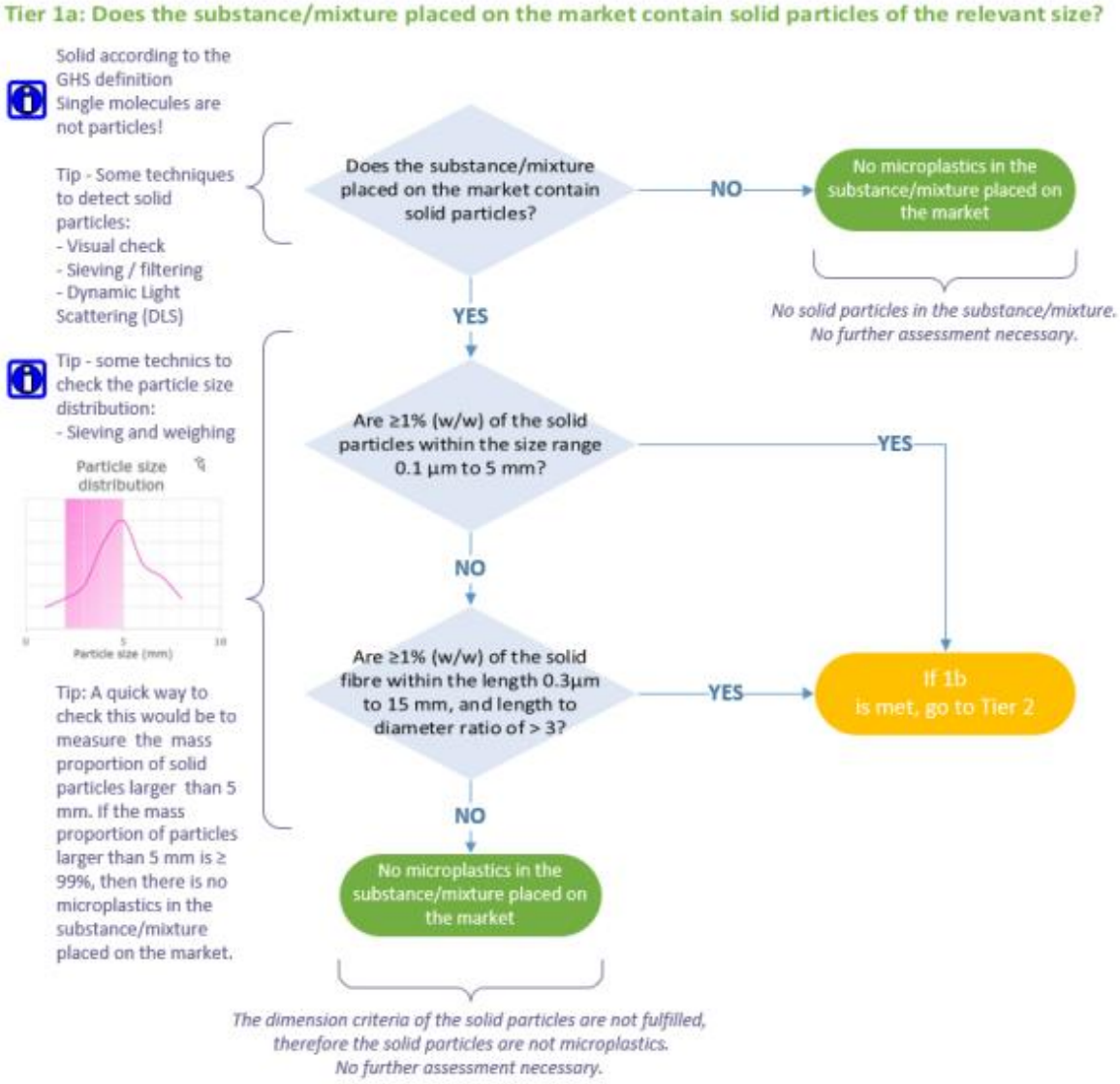

Figure 14: Microplastic decision tree - Tier 1b – relevant polymers

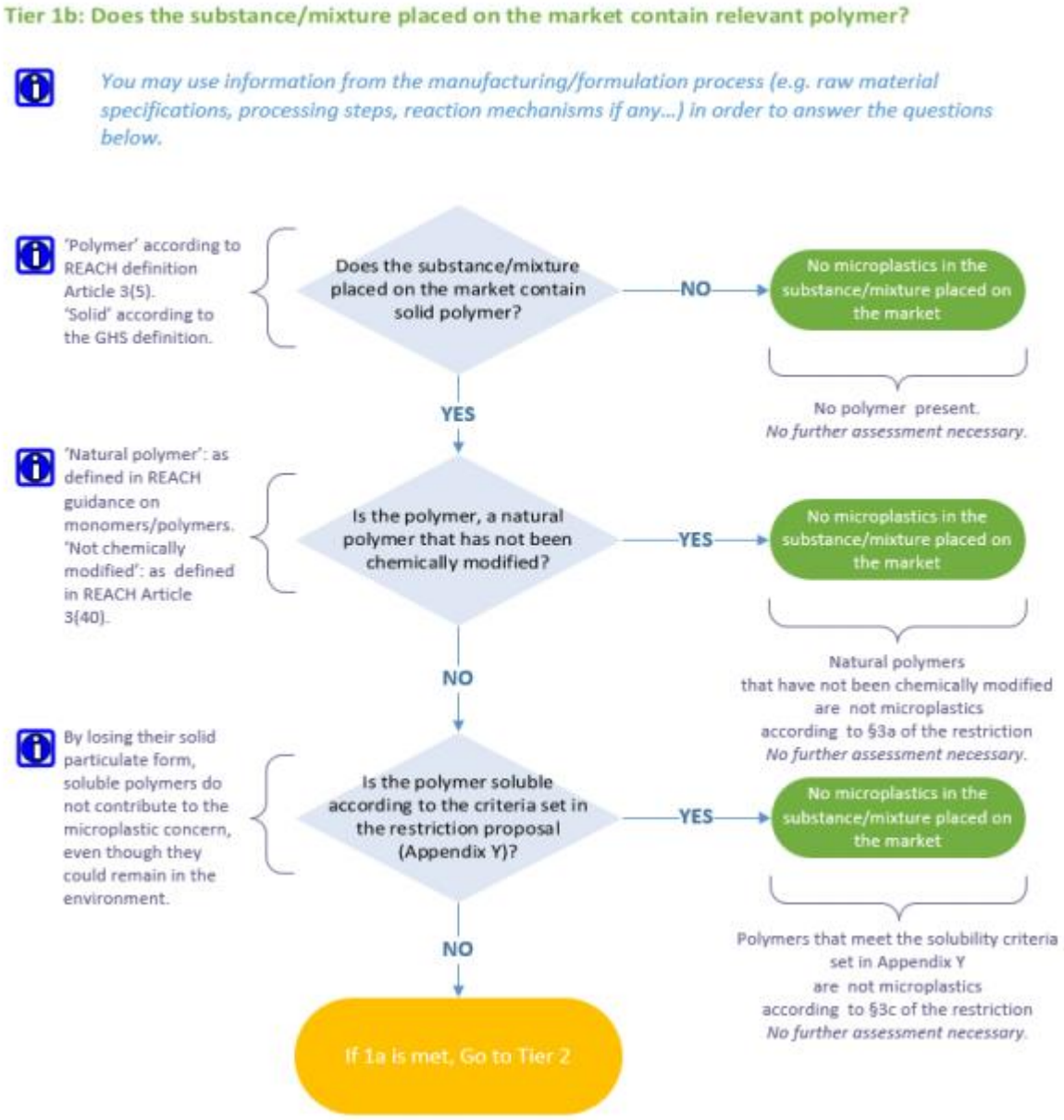

Figure 15: Microplastic decision tree - Tier 2 –Particle containing solid polymer

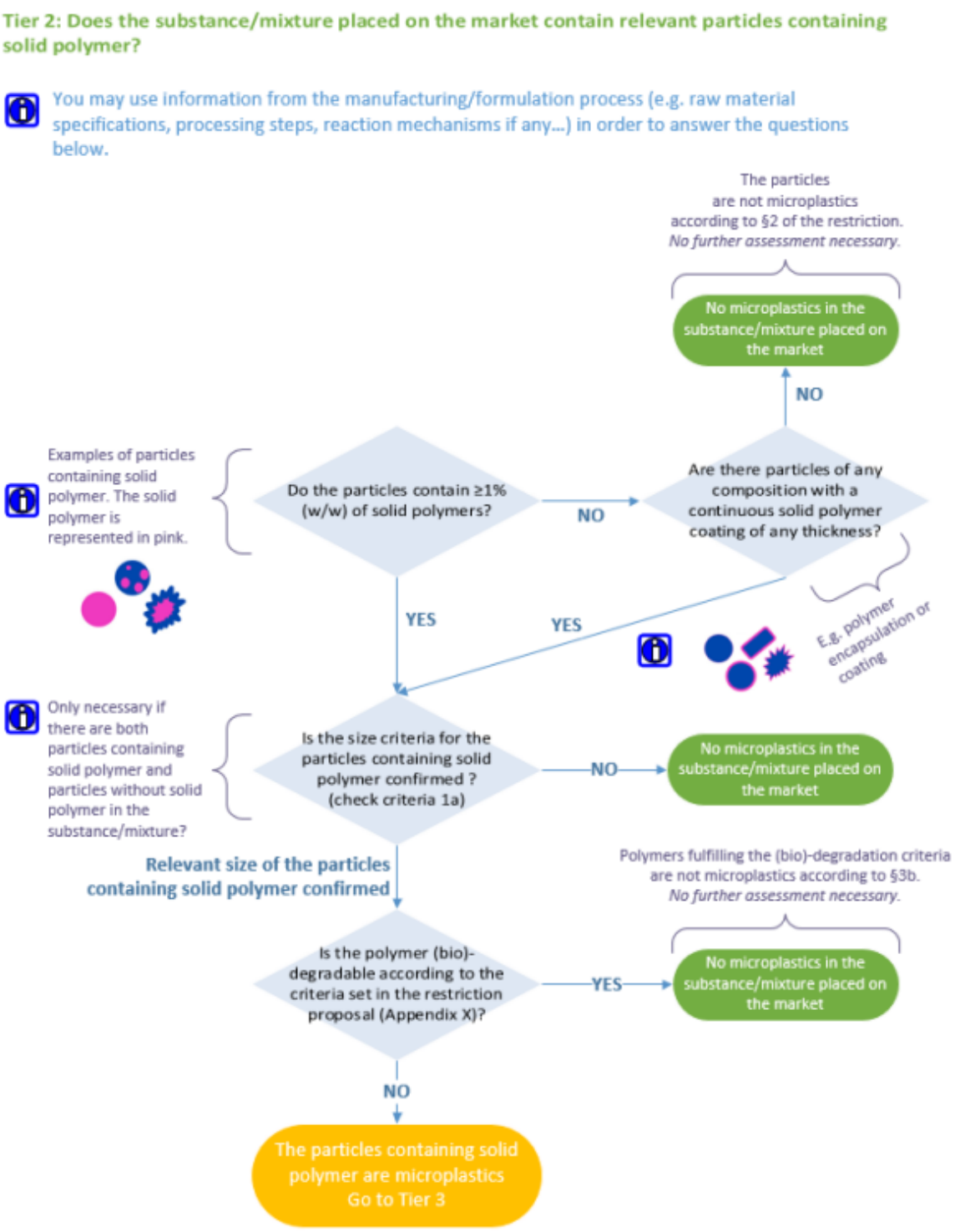

Figure 16: Microplastic decision tree - Tier 3 – concentration considerations