December 2022

CTPA Microplastics Webinar
14 December 2022
Questions and Answers

Disclaimer: This Q&A was created in December 2022 and is applicable to the draft microplastics restriction under EU REACH published in September 2022. The draft legislation can be accessed here. Members of CTPA can access further guidance on the relevant Reference Zone page for this topic.

Question (Q). What is the definition of 'solid'?
Answer (A). The Annex to the microplastics restriction states that a 'solid' means "*a substance or a mixture other than liquid or gas*"; a liquid and a gas are then defined as below:

- *"'gas' means a substance or mixture which at 50 °C has a vapour pressure greater than 300 kPa (absolute), or is completely gaseous at 20 °C at a standard pressure of 101,3 kPa;*
- *'liquid' means a substance or mixture that meets any of the following conditions:*
  - *the substance or mixture at 50 °C has a vapour pressure of not more than 300 kPa, is not completely gaseous at 20 °C and at a standard pressure of 101,3 kPa, and has a melting point or initial melting point of 20 °C or less at a standard pressure of 101,3 kPa;*
  - *the substance or mixture fulfils the criteria in the American Society for Testing and Materials (ASTM) D 4359-90 Standard Test Method for Determining Whether a Material Is a Liquid or a Solid;*
  - *the substance or mixture passes the fluidity test (penetrometer test) described in chapter 2.3.4 of Part 2 of Annex A to the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) concluded at Geneva on 30 September 1957."*

Therefore, in order to determine whether a substance is a solid, a company needs to exclude it from meeting the definitions of liquid or gas.

Q. Is there a definition of make-up products?
A. The most recent version of the draft Restriction Annex contains the following definition for make-up:

"'*Make-up product' means any substance or mixture intended to be placed in contact with specific external parts of the human body, namely the epidermis, eyebrows and eye lashes, with a view to, exclusively or mainly, changing their appearance*."

Q. How can I determine if a coating is a solid or not?
A. No official guidance on this point is available yet. In the absence of guidance, manufacturers are advised to work with their raw material suppliers on suitable evidence showing that a coating is a liquid and therefore out of scope.

Q. Are the criteria to determine whether a polymer is a microplastic exclusive?
A. For a polymer to be classed as a microplastic and be in scope of the restriction, it must meet all relevant criteria: polymer, either on its own or forming a coating, of a specific size, containing carbon atoms, solid, synthetic, non-biodegradable. If one of these criteria is not met, then the polymer is out of scope.

Q. Is there a list of cosmetic ingredients that is impacted by the microplastics restriction?
A. There is no list of ingredients within the scope of the EU REACH microplastics restriction, because the restriction is based on whether a substance meets a set of specific criteria, rather than the chemical or INCI name of the substance. Therefore, it is not possible to determine exactly which ingredients are in scope just

based on an INCI name, because the same INCI name can take different physical forms in different product types. For example, a polymer as a raw material may meet the definition of a microplastic; it maintains these properties when used in a shower gel, but it may lose them when used in a creamy eye shadow, leading to different requirements under the microplastics restriction.

Q. Are there specific criteria for the length of the biodegradability test?
A. The Appendix to the Annex of the draft microplastics restriction provides the list and details of biodegradability test methods, which include the length criteria for the test.

Q. If a raw material is a natural starch coated by a polymer, where the latter constitutes >1% of the solid particle, shall the biodegradability test be carried out on the whole particle or the polymer on its own?
A. The Appendix to the Restriction Annex which concerns biodegradation states:
"*Where the test material is composed of a single polymer but contains other non-polymeric organic substances in concentration higher than 10% by weight of the test material, and test methods from groups 1, 2 and 3 are used to prove degradation, the following applies:*

- *the degradation of the test material and of the polymer in the test material shall be tested separately;*
- *it shall be demonstrated, by any appropriate means, that the polymer contributes to the degradation of the test material observed during testing and meets the pass criteria in the relevant permitted test method set out in this Appendix*."

Q. If a raw material on its own is biodegradable, but when added to the finished product it loses this property, does it become a microplastic?
A. The biodegradation testing required to prove that a raw material is biodegradable, and therefore out of scope of the restriction, is outlined in the Appendix to the restriction Annex. It states that the test material shall be comparable in terms of composition, form, size and surface area to the polymer particles present in the product or, if not technically feasible, to the particles that are disposed or released to the environment. Therefore, the restriction indicates that it is preferential to test the raw materials as placed on the market, but companies should consider this on a case by case basis if a material's properties are expected to dramatically change when it is released into the environment.

Q. Are there specific test methods to demonstrate the solubility of a polymer when included in a product?
A. The microplastics restriction provides solubility test methods for the raw material solubility in water. The permitted test methods are OECD Guideline 120 and OECD Guideline 105.

The restriction does not give specific solubility test methods to investigate the solubility of polymers in other media, such as emulsions. CTPA is unfortunately unable to advise on suitable methods to investigate the solubility of polymers in other media. Testing houses may be able to advise on these methods, to investigate if the polymer may solubilise within a product formulation and therefore no longer meet the definition of a microplastic.

Q. Is the labelling requirement only applicable to nail and make-up products?
A. As per the third sub-paragraph of paragraph 7 of the draft restriction, lip, nail and make-up products containing microplastics which are not derogated out of scope of the restriction shall have the following statement 'This product contains microplastics' on the label 8 years after the restriction enters into force. There is no other "contains microplastics" labelling requirement for other cosmetic products categories.

The first sub-paragraph of paragraph 7 of the draft restriction states that products under derogation 5b) shall provide instructions for use and disposal to avoid releases of synthetic polymer microparticles to the environment. Derogation 5b) covers microplastics whose physical properties are permanently modified during intended end use in such a way that the polymer no longer falls within the scope of the restriction.

Q. If the product is out of the scope of the microplastics restriction, why are there labelling obligations?
A. It is important to highlight that if a product contains a microplastic that loses its properties when included into a finished product, it is still in scope of the restriction, but it is derogated from the scope of the ban. This means that it can be used subject to the labelling (and reporting) conditions given in the legal text of the draft restriction proposal.

Q. Would paragraph 6c) of the restriction exclude products derogated under 5b)?
A. It is our interpretation that if a product contains a mixture of polymers in scope of paragraph 6c) [with mandatory labelling of the statement 'This product contains microplastics'] and polymers in scope of derogation 5b) [microplastics whose physical properties are permanently modified during intended end use in such a way that the polymer no longer falls within the scope of the restriction, but instructions for use and disposal apply], then the product must comply with the requirements applicable to all polymers included. This means that both labelling requirements of 6c) and 5b) shall be met.

Q. What is the difference between the instructions for use and disposal given by the ingredients' supplier to the downstream user, and those given by the finished product manufacturer to the consumer?
A. The instructions for use and disposal given by the raw material supplier to the downstream user (e.g. manufacturer of cosmetic products) shall cover specific uses and disposals relevant for industrial sites and processes. These are generally provided on the Safety Data Sheets of the raw material. The full obligations are listed in paragraph 7b) of the restriction.

The instructions for use and disposal given by the brand owner to the consumer are relevant to the consumer use of the product and the specific routes for release into the environment during consumer use. These are to be provided on the product packaging or leaflet. The full obligations are listed in paragraph 7a) of the restriction.

Q. As a contract manufacturer of finished cosmetic products, do I have reporting obligations to ECHA?
A. The reporting obligations will be clarified in further guidance by the EU Commission. According to the draft restriction proposal, "*manufacturers and industrial downstream users of synthetic polymer microparticles*" and "*other industrial downstream users using synthetic polymer microparticles at industrial sites*" have reporting obligations to the European Chemicals Agency (ECHA). However, paragraph 56 of the draft regulation text states that "*to avoid double reporting, when there is more than one actor in the supply chain placing on the market the same product containing synthetic polymer microparticles, only the first actor within that supply chain should provide the required information to the Agency*."

Therefore, as a contract manufacturer of finished cosmetic products you may have reporting obligations only if your raw material suppliers further up the supply chain do not report to ECHA, in relation to the use of the material at an industrial site for cosmetic product manufacturing. You will have to liaise with them to ensure that the reporting obligations are fulfilled.

Q. Do companies have to report to ECHA the estimated release to the environment of microplastics, or the amount used?
A. Companies shall report to ECHA the estimated amount of microplastics released into the environment, not the estimated amount of microplastics used.

Q. If the brand owner of a cosmetic product outsources the obligations of the Responsible Person with a third-party consultancy company, who is responsible for reporting to ECHA?
A. This is a commercial decision between the two parties. First of all, it is important to check that no other actors further up in the supply chain are already reporting the same information to ECHA. If the reporting obligations fall to the Responsible Person selling the cosmetic products, then the brand owner and the third-party consultancy acting as the RP shall agree between themselves who shall carry out the reporting to ECHA. It shall be part of the legal contract between the two parties, stipulating the services requested and provided.

Q. If a manufacturer of raw materials is based outside of the EU and sells ingredients to an EU company, does it have any obligations under the microplastics restriction?
A. A manufacturer of raw materials or finished cosmetic products based outside of the EU has no obligations under the draft microplastics restriction, as they are outside of the EU jurisdiction. However, the EU importer or brand owner of such raw material or finished product containing microplastics would be the first actor in the supply chain with responsibilities under the restriction. In order to meet these obligations, the EU importer or brand owner should ask the non-EU supplier for the relevant information needed for compliance.

Q. Are the deadlines for the transition periods referring to 'placing on the market' or 'making available on the market – off shelf'?
A. The deadlines for the transition periods refer to 'making available on the market', therefore the off-shelf date.

The REACH Regulation does not distinguish between 'placing on the market' and 'making available on the market'; the two terms are interchangeable as per the definition under Article 2 of REACH: "*placing on the market: means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market*.".

Q. Is the reporting to ECHA only submitted once within the supply chain, or multiple actors (e.g. raw material supplier, manufacturer of finished cosmetic product, brand owner) have to carry out their own reporting?
A. Paragraph 56 of the draft regulation text states that "*to avoid double reporting, when there is more than one actor in the supply chain placing on the market the same product containing synthetic polymer microparticles, only the first actor within that supply chain should provide the required information to the Agency*."

Therefore, communication within the supply chain is key to ensure companies are aware of who has met the reporting obligations. Communications up the supply chain, from the downstream user to the supplier, is also important to ensure the supplier reports all relevant information relating to that use of the microplastic.

Q. Can the Only Representative (OR) of non-EU based suppliers of raw materials meet the obligations under the microplastics restriction?

A. Under EU REACH, an EU-based OR is appointed by non-EU companies to fulfil their obligations under EU REACH, if they supply or place chemicals on the EU market. In the context of the draft microplastics restriction, the OR of a non-EU based supplier may fulfil the reporting obligations to cover for their downstream users. However, it is vital for downstream users to communicate with their supplier and ensure obligations are fulfilled.

Q. Is Great Britain going to implement the same microplastics restriction under UK REACH?

A. The EU draft microplastics restriction will only be applicable in the EU and Northern Ireland. Great Britain has a separate chemical framework, UK REACH, under which the UK agency (the Health and Safety Executive – HSE) will carry out an evidence project to understand which regulatory measures are more suited for microplastics placed or used on the GB market. Therefore, this restriction will not automatically be implemented in GB.