

MedTech Europe Clarification Questions on the REACH Restriction on Synthetic Polymer Microparticles¹ 30 August 2024

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MedTech Europe seeks to issue several clarification questions to the European Commission and the European Chemicals Agency (ECHA) to understand better the requirements for medical technology manufacturers in their efforts to comply with the REACH Restriction on Synthetic Polymer Microparticles.

Scope of the Restriction

1. Are polymer microparticle manufacturers **supplying** the IVD industry covered by the IVD derogation? If not, how will the Restriction impact the IVD industry suppliers?
2. Can it be concluded that both “devices” and “products containing SMP” are limited in scope to what is considered under the REACH definitions of substances, mixtures and articles (further outlined in the REACH substances in articles Guideline) as “Object consists of a substance or mixture and an article”? Can we conclude that if an object is not a substance or mixture as per REACH and “ECHA guidance SIA 2.3”, it is not in scope of this Regulation and none of the follow-up obligations named in REACH entry 78 apply?
2. We understand that reporting and IFUD obligations for derogated uses of SMP lie with the entity placing the product on the market. Does this mean that industrial downstream users, using derogated SMP in the EU, to manufacture mixtures intended **only for export outside** the EU, are not subject to the reporting and IFUD obligations, since these mixtures are only exported? Or are all industrial downstream users of SMP subject to the reporting and IFUD obligations, even if the final products are intended for export only?
3. A clarification is needed on how to handle **bulk microplastic pellets in industrial settings** for hygiene purposes in this Restriction (e.g. reporting requirements, emission control requirements).

¹ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ%3AJOL_2023_238_R_0003&qid=1695804976302

Definitions

1. The REACH Regulation and the microplastics amendment do not contain any definitions of “professional use” and “industrial site” – what are the definitions of these terms?

Identity of microplastics

1. Several restriction requirements obligate the actors to know the identity of the microplastics. How detailed should microplastics be able to be identified? For example, how precise structural information is needed to fulfill the obligations?

Information provided to end users

1. Can the industry create/put forward a proposal for a pictogram for the IVD uses specified under paragraph 10?².
2. Will IFUD text or pictograms required under paragraph 10 be provided, for suppliers of products containing SPM described under paragraph 8?
3. Are there specific criteria for the warning phrases to be given to customers?
4. Is it the manufacturer’s/supplier’s responsibility to define the appropriate disposal method for products containing microplastics?
5. Would the disposal considerations contained in the current products’ SDS be sufficient to cover instructions for use and disposal requirements?
 - If not, will there be a specific text regarding disposal instructions required to be incorporated in the IFU? Could this text be incorporated into the SDS?
6. If the product does not require an SDS, would the manufacturer be obligated to determine and communicate the disposal requirements?

Annual reporting to ECHA

1. How, when and where will the reporting be done? Via ECHA submission portals?
2. Scenario of possible overlaps in reported data: the same actor both manufactures microplastics and then also supplies IVD products containing those particular microplastics. Should this actor

² For the pictogram to be used and (internationally) recognized, it needs regulatory approval, which takes time – e.g. ISO15223-2 for medical devices and IVDs

report to ECHA annually both in the role of the manufacturer **and** in the role of the IVD product supplier? What if there are several steps in the manufacturing process, each producing a different form of microplastics, also as production waste; do these different production steps need to be reported?

3. Can you please confirm that the information submitted by the industry under paragraphs 11 and 12 will not be made available to the public by ECHA or Member States Competent Authorities?
4. Do the information requirements for microparticles placed on the market apply only to IVD manufacturers placing a product on the market **for the first time**?
5. Is there any standard guideline on how to measure release to fulfill the reporting requirement of providing an estimate of the quantity of SMP released to the environment and also during transportation?
6. Shall the calculation be made considering the quantity of microparticles contained in **each** (IVD) kit per **total number** of kits placed on the European market in the previous year?
 - a. Should microparticles released due to scraps/rejects during production be considered?
7. Bearing in mind that the reagents are sold and transported in sealed containers, should the possible release of microparticles due to leakage be considered or would not be necessary?

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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