EU: REACH ANNEX XVII RESTRICTION ON MICROPLASTICS WAS PUBLISHED ON SEPTEMBER 27, 2023.

WHAT ARE THE IMPACTS FOR IVDs and MDs ?

On 27 September 2023, the European Union's Official Journal (OJEU) published Regulation (EU) 2023/2055, introducing a new restriction on microplastics under Annex XVII to REACH regulation which will enter into force from 17 October 2023 with some exemptions and with transition period for some items.

The new restriction aims to reduce emission of intentional microplastics from the products. It covers all synthetic polymer particles below five millimeters that are organic, insoluble and resistant to degradation. The new restriction and some items have longer transition period.

The *In Vitro* Diagnostic devices under Regulation (EU) 2017/746 are excluded from this restriction but:

- **From 17 October 2026, the manufacturers shall provide instructions for use and disposal explaining to professional users and the general public how to prevent releases of synthetic polymer microparticles to the environment.**
- **From 2027, the manufacturers/suppliers shall submit a report to the Agency* by 31 May of each year containing information on the synthetic polymer microparticles (such as description of the end uses, identity of the polymers, quantity released to the environment.**

The Medical devices under Regulation (EU) 2017/745 are not excluded but take the benefit of a transition period of 6 years considered as necessary for reformulation and transition to suitable alternatives. So, the application date is 17 October 2029.

Below are the details of the Regulation (EU) 2023/2055 which impact IVDs and MDs

Restriction on microplastics

Target substance	Synthetic polymer microparticles Synthetic polymer microparticles means polymers that are solid and which fulfil both of the following conditions: (a) are contained in particles and constitute at least 1 % by weight of those particles; or build a continuous surface coating on particles; (b) at least 1 % by weight of the particles referred to in point (a) fulfil either of the following conditions:

	(i) all dimensions of the particles are equal to or less than 5 mm; (ii) the length of the particles is equal to or less than 15 mm and their length to diameter ratio is greater than 3. Note: The microparticles which are degradable or solubility greater than 2g/L can be exempted. The rules to proof degradability and solubility are specified in Appendices 15 and 16.
Scope of restriction	Substances on their own or, where the synthetic polymer microparticles are present to confer a sought-after characteristic, in mixtures
Limit	Prohibited as a substance on its own; mixtures: < 0.01% by weight
Exemption	- Synthetic polymer microparticles: (i) which are contained by technical means so that releases to the environment are prevented when used in accordance with the instructions for use during the intended end use; (ii) the physical properties of which are permanently modified during intended end use in such a way that the polymer no longer falls within the scope of this entry; (iii) which are permanently incorporated into a solid matrix during intended end use.

REFERENCES:

[1] Regulation (EU) 2023/2055
[2] European Green Deal
[3] Circular Economy Action Plan

IMPACT FOR IVDs:

ANNEX:
4. Paragraph 1 shall not apply to the placing on the market of :
- (b) medicinal products within the scope of Directive 2001/83/EC and veterinary medicinal products within the scope of Regulation (EU) 2019/6 of the European Parliament and of the Council (*);

- (e) in vitro diagnostic devices, including devices within the scope of Regulation (EU) 2017/746 of the European Parliament and of the Council (****);

However:

8. From 17 October 2026 suppliers of products containing synthetic polymer microparticles referred to in paragraph 4, point (e), and from 17 October 2025 suppliers of products containing synthetic polymer microparticles referred to in paragraph 4, point (d), and paragraph 5, shall provide instructions for use and disposal explaining to professional users and the general public how to prevent releases of synthetic polymer microparticles to the environment.

10. The information referred to in paragraphs 7, 8 and 9 shall be provided in the form of clearly visible, legible and indelible text or, where appropriate regarding the information in paragraphs 7 and 8, in the form of pictograms. The text or pictograms shall be placed on the label, the packaging, or the package leaflet of the products containing synthetic polymer microparticles or, regarding the information in paragraph 7, on the safety data sheet. In addition to the text or pictograms, suppliers may provide a digital tool that gives access to an electronic version of that information.
Where instructions for use and disposal are provided in accordance with paragraphs 7, 8 and 9 in the form of a text, they shall be in the official languages of the Member States where the substance or mixture is placed on the market, unless the Member States concerned provide otherwise.

12. From 2027, suppliers of products containing synthetic polymer microparticles referred to in paragraphs 4, points (b), (d) and (e), and paragraph 5, placed on the market for the first time to professional users and the general public, shall submit the following information to the Agency* by 31 May of each year:
(a) a description of the end uses for which the synthetic polymer microparticles were placed on the market in the previous calendar year;
(b) for each end use for which the synthetic polymer microparticles were placed on the market, generic information on the identity of the polymers placed on the market in the previous calendar year;
(c) for each end use for which the synthetic polymer microparticles were placed on the market, an estimate of the quantity of synthetic polymer microparticles released to the environment in the previous calendar year, which shall include also the quantity of synthetic polymer microparticles released to the environment during transportation.
(d) for each use of synthetic polymer microparticles, a reference to the applicable derogation or derogations laid down in paragraph 4, point (b), (d) or (e), or 5 point (a), (b) or (c).

***Note MediMark : Agency: European Chemicals Agency (ECHA)**

IMPACTS FOR MDs:

6. Paragraph 1 shall apply as follows regarding the following uses
- (f) from 17 October 2029 for "devices", within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council (*****), unless those devices contain microbeads;

Exemtions:

5. Paragraph 1 shall not apply to the placing on the market of the following synthetic polymer microparticles, as substances on their own or in mixtures:
- (a) synthetic polymer microparticles which are contained by technical means so that releases to the environment are prevented when used in accordance with the instructions for use during the intended end use;
- (b) synthetic polymer microparticles the physical properties of which are permanently modified during intended end use in such a way that the polymer no longer falls within the scope of this entry;
- (c) synthetic polymer microparticles which are permanently incorporated into a solid matrix during intended end use.

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