



WHITEPAPER

MICROPLASTICS RESTRICTION UNDER REACH

Entry 78, Annex XVII of Regulation (EC) No 1907/2006

Regulatory framework, information and reporting obligations, transition periods
and practical recommendations

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1. Executive Summary

With Regulation (EU) 2023/2055, the European Union has introduced one of the most far-reaching restrictions in European chemicals law.¹ The new Entry 78 in Annex XVII of the REACH Regulation prohibits placing intentionally added synthetic polymer microparticles on the market since 17 October 2023. The objective is to progressively halt the irreversible accumulation of microplastics in the environment.

This whitepaper provides a comprehensive analysis of the regulatory framework. It explains the definition of synthetic polymer microparticles, the core prohibition, the staggered transition periods for different product groups, and the differentiated exemptions. A particular focus lies on the information obligations within the supply chain and the reporting obligations to ECHA, which take effect progressively from 2026. Finally, practical recommendations for affected companies are formulated.

¹ Commission Regulation (EU) 2023/2055 of 25 September 2023 amending Annex XVII to Regulation (EC) No 1907/2006 (REACH), published in OJ EU on 27.09.2023.

2. Background and Objectives

2.1 The Microplastics Problem

Microplastics have become a global environmental burden. Tiny plastic particles are now found in virtually all environmental compartments – in soils, freshwater, oceans, the atmosphere, and even in human tissue. The core problem: once released into the environment, microplastics are virtually impossible to remove. They accumulate over decades and centuries, fragment into ever smaller particles, and enter food chains.

A distinction is made between **unintentionally released** microplastics (e.g. tyre abrasion, fibres from textile washing) and **intentionally added** microplastics, which are deliberately incorporated into products to impart specific properties such as colour, texture, abrasiveness or flowability. The REACH restriction addresses exclusively the latter category.

2.2 Regulatory Genesis

On 9 November 2017, the European Commission requested ECHA to prepare a restriction dossier under Annex XV of the REACH Regulation.² Following extensive consultations and opinions from the Committee for Risk Assessment (RAC) and the Committee for Socio-Economic Analysis (SEAC), Regulation (EU) 2023/2055 was adopted on 25 September 2023 and became binding on 17 October 2023. The legal act supplements Annex XVII of REACH with Entry No. 78 and two new appendices (15 and 16) on proof of biodegradability and solubility respectively.

2.3 Positioning within the EU Plastics Framework

The restriction fits into a series of European measures against plastic pollution. These include the Single-Use Plastics Directive (EU) 2019/904, the new Packaging Regulation (EU) 2025/40, and the Pellet Loss Regulation (EU) 2025/2365, which entered into force in December 2025. Together, these instruments form an increasingly comprehensive regulatory framework addressing both intentional and unintentional sources of microplastics.

²ECHA – Microplastics Restriction: <https://echa.europa.eu/hot-topics/microplastics>

3. Scope and Definitions

3.1 Definition of Synthetic Polymer Microparticles

Entry 78 defines synthetic polymer microparticles on the basis of several cumulative criteria. A particle falls within the scope if all of the following conditions are met:

- It is a solid polymer resulting from a synthetic polymerisation process (not a natural polymer)
- The particle has a size of less than 5 mm in any dimension
- Fibre-like particles with a length below 15 mm are also covered, provided their diameter is below 5 mm
- The polymer is organic (contains carbon atoms in its chemical structure)
- The polymer is water-insoluble (solubility < 2 g/l)
- The polymer is not readily biodegradable

3.2 Exclusions from Scope

The following are explicitly not considered synthetic polymer microparticles:

- Polymers resulting from a polymerisation process that took place in nature and that have not been chemically modified (natural polymers)
- Polymers for which biodegradability has been demonstrated in accordance with Appendix 15 of Annex XVII
- Polymers with a demonstrated solubility exceeding 2 g/l in accordance with Appendix 16
- Inorganic polymers (without carbon atoms in their chemical structure)

3.3 The Core Prohibition

The prohibition under paragraph 1 states in essence: synthetic polymer microparticles shall not be placed on the market as such or in mixtures at a concentration of $\geq 0.01\%$ by weight, where they are present to impart a desired property on the mixture. The prohibition targets the placing on the market – i.e. if the first availability is on the EU market. The use as a component of articles is not directly covered.

Important: The concentration threshold of 0.01% by weight is very low. Companies should verify whether even trace amounts of synthetic polymers in their products exceed this limit.

4. Transition Periods and Grandfathering

4.1 Grandfathering of Existing Stocks

Paragraph 16 of the entry clarifies that the prohibition does not apply to synthetic polymer micro-particles as such or in mixtures that were first placed on the market before 17 October 2023.³ These products may continue to be distributed at all levels of the supply chain. However, companies should be able to provide seamless documentation that the initial placing on the market occurred before the cut-off date – for example through batch numbers, delivery notes or inventory records.

4.2 Product-Group-Specific Transition Periods

Paragraph 6 of the entry provides for staggered transition periods for various product groups.⁴ The following table provides an overview:

Product Group	Transition	Prohibition Starts
Rinse-off cosmetics	None	17 October 2023
Loose glitter	None	17 October 2023
Granular infill for sports surfaces	8 years	17 October 2031
Detergents, waxes, polishes	5 years	17 October 2028
Medical devices & In vitro diagnostic medical devices (IVD)	5 years	17 October 2028
Fertilisers & plant protection products	5–10 years	Staggered 2028–2033
Leave-on cosmetics (excl. make-up/lip/nail)	6 years	17 October 2029
Make-up, lip products, nail products	12 years	17 October 2035

Table 1: Overview of transition periods under paragraph 6 of Entry 78 (simplified, non-exhaustive).

4.3 Labelling Obligation for Exempted Cosmetics

For cosmetic products benefiting from a 12-year transition period (make-up, lip products, nail products), a labelling obligation takes effect 8 years after entry into force – i.e. from October 2031. These products must bear the statement “This product contains microplastics.” The SEAC considered this a proportionate alternative to an earlier ban, given the low emission contributions of these product groups.

³ Cf. Recital (60) of Regulation (EU) 2023/2055 and paragraph 16 of Entry 78.

⁴ Pursuant to paragraph 6 of Entry 78 in Annex XVII of the REACH Regulation.

5. Exemptions in Detail

5.1 General Exemptions (Paragraph 4)

The placing-on-the-market prohibition does not apply to synthetic polymer microparticles for use in:

- Industrial installations – subject to additional information obligations from 17 October 2025 and reporting obligations
- Medicinal products within the meaning of Directive 2001/83/EC and veterinary medicinal products within the meaning of Regulation (EU) 2019/6
- EU fertilising products within the meaning of Regulation (EU) 2019/1009
- Food additives within the meaning of Regulation (EC) No 1333/2008
- In vitro diagnostic medical devices, as well as food and feed

5.2 Technical Exemptions

Additionally, the restriction does not apply where the particles:

- Are contained by technical means such that release to the environment is prevented during intended use (e.g. encapsulated fragrances in intact containers)
- Are permanently incorporated into a solid matrix so that they cannot be released as individual particles
- Permanently modify their physical properties during end use so that the polymer no longer falls within the scope of the restriction

Note: : Even for exempted uses, information and reporting obligations may apply. Exemption from the prohibition does not mean exemption from all obligations.

6. Information Obligations in the Supply Chain

6.1 Supplier Obligations for Microplastics

Suppliers placing synthetic polymer microparticles as such or in mixtures on the market must provide recipients with the following information. The presentation must be clearly visible, legible and indelible – on the label of the packaging or in the package insert:

- A formal declaration that the supplied synthetic polymer microparticles are subject to the conditions of Entry 78 in Annex XVII of Regulation (EC) No 1907/2006
- Information on the quantity or, where applicable, the concentration of synthetic polymer microparticles in the substance or mixture
- Instructions for proper use and disposal that minimise release to the environment
- Recommendations for risk management measures regarding release

In addition, suppliers may provide digital tools (e.g. QR codes, web links) enabling access to electronic versions of this information.

6.2 Enhanced Information Obligations for Industrial Installations

For synthetic polymer microparticles used at industrial installations, enhanced information obligations apply. From 17 October 2025, suppliers must provide their industrial customers with additional detailed information on the identity, quantity and release potential of the particles. This provision reflects the fact that, while industrial installations are exempt from the prohibition as points of use, they may constitute a significant source of environmental emissions.

6.3 Safety Data Sheet (SDS)

Where a safety data sheet is required for the substance or mixture pursuant to Article 31 of the REACH Regulation, the above information must be incorporated therein. This ensures that microplastics-related information is anchored in the existing system of chemicals legislation communication.

7. Reporting Obligations to ECHA

In addition to the information obligations in the supply chain, Entry 78 establishes comprehensive reporting obligations to the European Chemicals Agency (ECHA). Reports must be submitted by **31 May** of each year.⁵

7.1 Stage 1: From May 2026 – Manufacturers and Industrial Users

24 months after entry into force – i.e. for the first time by 31 May 2026 – **manufacturers and industrial downstream users** of synthetic polymer microparticles must report the following information to ECHA:

- A description of uses in the preceding calendar year
- For each use: information on the identity of the polymers used (CAS number, chemical name, polymer type)
- For each use: an estimate of the quantity of synthetic polymer microparticles released to the environment, including releases during transport

7.2 Stage 2: From May 2027 – Suppliers of Certain Products

36 months after entry into force, extended reporting obligations apply for suppliers of products containing synthetic polymer particles that are first placed on the market for professional users or the general public. This concerns two groups:

- Products under sectoral exemptions: medicinal products, veterinary medicinal products, food additives, in vitro diagnostics
- Products under general (technical) exemptions: technical containment, matrix incorporation, permanent physical modification

In addition to the information listed under 7.1, these reports must also identify the specific exemption invoked.

7.3 Reporting Period and Data Collection

Reports relate to the preceding calendar year. This means that data for calendar year 2025 must be available for the first report due in May 2026. Companies should therefore establish systematic data collection processes now, capturing usage quantities, polymer identities and release estimates.

Deadline	Reporting Entities	First Report	Content
24 months	Manufacturers, industrial downstream users	31 May 2026	Uses, polymer identity, release quantities
36 months	Suppliers (sectoral + technical exemptions)	31 May 2027	As above + identification of exemption

Table 2: Overview of reporting obligations under Entry 78.

⁵ Cf. paragraph 10 of Entry 78: Reporting obligations for manufacturers and industrial downstream users.

8. Proof of Biodegradability and Solubility

Regulation (EU) 2023/2055 supplements Annex XVII with two new appendices governing the evidence that a polymer falls outside the scope of the restriction:⁶

8.1 Appendix 15: Provisions for Demonstrating Biodegradability

The appendix specifies the conditions and test methods under which a polymer is deemed “demonstrated to be biodegradable.” Specific test protocols are defined for various environmental compartments (soil, water, sediment). A polymer is considered biodegradable if it mineralises to a defined proportion within specified timeframes. The requirements are intentionally stringent to prevent so-called “greenwashing” through supposedly biodegradable plastics.

8.2 Appendix 16: Provisions for Demonstrating Solubility

The appendix governs proof that a polymer has a solubility exceeding 2 g/l in water and thus falls outside the scope. Testing must be conducted under standardised conditions (temperature, pH, ionic strength) and be reproducible.

⁶ Appendices 15 and 16 of Annex XVII contain provisions for demonstrating biodegradability and solubility respectively.

9. Recommendations for Companies

9.1 Immediate Actions

1. Impact assessment: Systematically review your entire product portfolio for intentionally added synthetic polymer microparticles. Include raw materials and semi-finished products.
2. Stock documentation: Comprehensively document which products were first placed on the market before 17 October 2023 (batch numbers, delivery notes, inventory data as at the cut-off date).
3. Exemption review: Determine whether your products fall under any of the general or sectoral exemptions and what additional obligations are associated.
4. Data collection for reporting: Establish systematic capture processes for usage quantities, polymer identities and release estimates immediately.

9.2 Medium-Term Actions

5. Alternatives search: Identify microplastics-free alternatives for affected formulations and products. Transition periods are finite.
6. Supply chain communication: Update safety data sheets, labels and package inserts. Ensure all required information is included.
7. ECHA reporting capability: Prepare the technical infrastructure to submit reports on time.
8. Training: Raise awareness among employees in production, procurement and sales regarding the new requirements.

9.3 Strategic Perspective

The restriction is part of a broader regulatory trend towards reducing plastic emissions. Companies that proactively switch to alternatives and build transparent supply chains position themselves not only in regulatory compliance but also competitively. The market for microplastics-free solutions is growing – innovation leaders benefit early.

10. Conclusion and Outlook

The REACH restriction on intentionally added microplastics represents a paradigm shift in European chemicals policy. For the first time, synthetic polymer microparticles are comprehensively regulated – with the clear aim of halting their irreversible accumulation in the environment. The combination of a placing-on-the-market prohibition, staggered transition periods, information obligations and ECHA reporting requirements creates a sophisticated regulatory framework.

For science and for organisations such as Wasser 3.0, this development represents a welcome strengthening of the prevention principle. Every gram of microplastics that is prevented from entering the environment, doesn't need to be removed later at an enormous cost. At the same time, the effectiveness of the restriction will depend on how consistently the reporting obligations are implemented and how the reported data are evaluated. Based on the incoming reports, ECHA will for the first time gain a comprehensive picture of the use and emission landscape of intentionally added polymer microparticles – a decisive prerequisite for evidence-based regulatory follow-up.

The restriction does not stand in isolation but is part of an increasingly dense European regulatory framework against plastic pollution. Together with the Pellet Loss Regulation, the Single-Use Plastics Directive and the new Packaging Regulation, an instrumentarium is emerging that addresses both intentional and unintentional sources of microplastics equally. Companies are well advised to view this development not as a burden but as a driver of innovation.

Do you need support with microplastic analysis and quantification?

Then get in touch with us.



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