



Press Release

Brussels (Belgium), 18 December 2025

IPEC Federation announces the release of its **Best Practices Guide for European REACH Restriction on Synthetic Polymer Microparticles (SPM) for Pharmaceutical Excipients (Version 1, 2025)**. Originally issued in 2022 as a joint How-to developed by IPEC-Americas and IPEC Europe, the document is now issued by IPEC Federation.

The IPEC Federation Microparticles Best Practices Guide provides practical recommendations for preparing and sharing microparticle data needed to support potential excipient derogations under the European Union REACH SPM restriction.

This updated publication follows the release of the European Commission's final Guidance on the REACH restriction of synthetic polymer microparticles (SPM), and the European Chemicals Agency's (ECHA) Reporting Requirements for intentionally added microplastics.

The document offers a streamlined process to help polymer manufacturers, suppliers, and downstream industrial users - including drug product manufacturers – meeting regulatory expectations associated with the restriction.

Readers are encouraged to consult this Guide together with the relevant regulatory and supporting documents:

- The Regulation: Annex XVII of EC 1907/2006, Entry 78 (EU 2023/2055)
- The Guidance: REACH Restriction of Synthetic Polymer Microparticles (Entry 78 of Annex XVII REACH, introduced by Commission Regulation (EU) 2023/2055)
 - Explanatory Guide Part I – Narrative
 - Explanatory Guide Part II – Q&A
 - Explanatory Guide Part III – Annexes
- The Reporting Requirements: Implementation of the Reporting Requirements of the REACH Restriction on Microplastics — ECHA, April 2025 (v1.1)

The guide is made available, initially exclusively to IPEC members for a three-month period, on the IPEC Federation and national/regional members' websites. Thereafter, the guide will be made available to the general public.

For further information, please contact the IPEC Federation Secretariat at:
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