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Guidance Document for Synthetic Organic Ion Exchangers and Adsorbents Industry regarding the Regulation (EU) 2023/2055 on restriction of synthetic polymer microparticle (SPM)

Disclaimer : The aim of this Guidance Document is to assist individual companies in the supply chain with establishing company-specific manufacturing processes and procedures in accordance with the SMP restriction. This Guidance Document has been designed using the best knowledge currently available, but it may not be sufficient or appropriate in all situations and is to be relied upon at the user's own risk. The information is provided in good faith and no representations or warranties are made with regards to the accuracy or completeness, and no liability will be accepted for damages of any nature whatsoever resulting from the use or reliance on this Guidance Document.

This Guidance Document does not replace the requirements set by REACH and does not constitute formal legal advice.

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Introduction

SOIA (Synthetic Organic Ion Exchangers and Adsorbents), a sector group of Cefic (the European Chemical Industry Council), represents the five leading European manufacturers of ion exchange resins and adsorbents: DuPont, Finex Oy (a Jacobi Group Company), Lanxess, Purolite™ (an Ecolab company) and Resindion S.r.l. (a Mitsubishi Chemical Group Company), who supply resins worldwide under leading brand names. We are the industry contact point for regulatory matters impacting ion exchange resins, in particular in food processing and potable water applications.

This document aims to provide comprehensive guidance for the ion exchange resins and adsorbents industry regarding the REACH [1] restriction on synthetic microplastics particles (Entry 78 of Annex XVII REACH, as introduced by Commission Regulation (EU) 2023/2055). It is based on the questions and clarifications compiled by our member companies regarding the practical application of this restriction.

1. Definitions

Synthetic polymer microparticles are defined as solid polymers that meet the following criteria:

1) **Composition**:
    a. They are contained in particles and make up at least 1% by weight of those particles, or they form a continuous surface coating on particles.
    b. At least 1% by weight of these particles must either:
        i. Have all dimensions equal to or less than 5 mm, or
        ii. Have a length of 15 mm or less with a length-to-diameter ratio greater than 3.

2) **Exclusions**:
    a. Polymers formed naturally without chemical modification.
    b. Degradable polymers as per Appendix 15.
    c. Polymers with solubility greater than 2 g/L as per Appendix 16.
    d. Polymers without carbon atoms in their structure.

3) **Market Restrictions**:
    a. These microparticles cannot be marketed as standalone substances or in mixtures at concentrations of 0.01% by weight or higher if they are present to provide a specific characteristic.

[1] REACH: Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

Decision trees for synthetic polymer microparticle (SPM) identification

Figure 1. SPM identification; General decision tree.

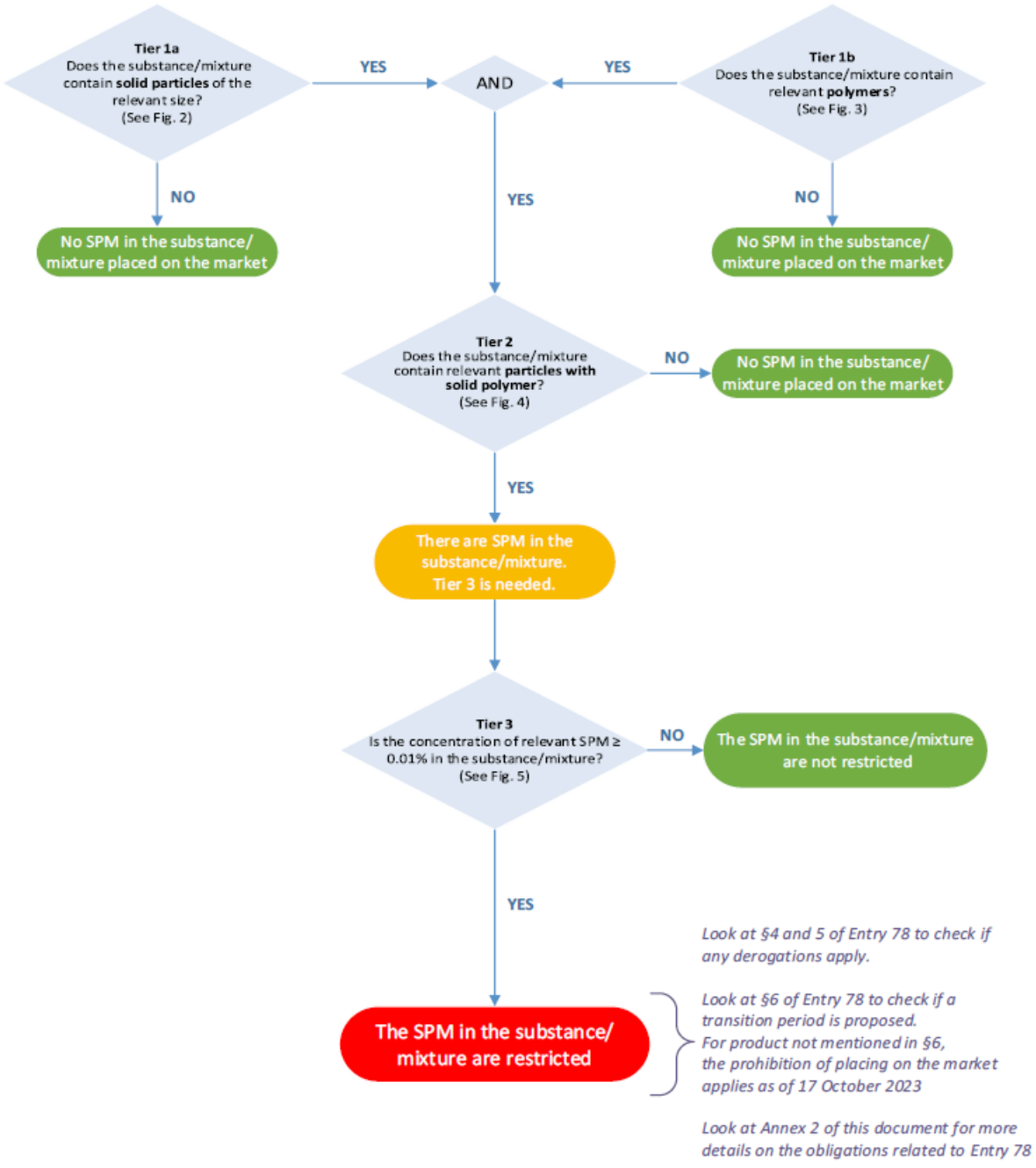

Chart sourced from Commission Regulation (EU) 2023/2055 Explanatory Guide Annex (Part III), it is included here for reference only.

2. Derogations

Paragraphs 4 and 5 of Entry 78 in Annex XVII of REACH outline exemptions from the market placement ban for certain uses of synthetic polymer microparticles (SPM) and products containing them. In some cases, multiple exemptions may apply to the same SPM. These exemptions come with additional requirements, such as providing Instructions for Use and Disposal (IFUD) and reporting emissions to ECHA.

Under Paragraph 4	**Within Scope**
a) SPM, as substances on their own or in mixtures, used at industrial sites	Directive (EU) 2010/75
b) Medicinal products and veterinary medicinal products	Directive (EC) 2001/83 and Regulation (EU) 2019/6
c) EU fertilising products	Regulation (EU) 2019/1009
d) Food additives	Regulation (EC) No 1333/2008
e) In vitro diagnostic devices	Regulation (EU) 2017/746
f) Food and Feed	Regulation (EC) No 178/2002

Under Paragraph 5	**Examples**
a) **SPM 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	chromatography columns, water filtering cartridges, toners
b) SPM 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	swellable polymers in diapers, paint.
c) SPM which are permanently incorporated into a solid matrix during intended end use	concrete fibers, pellets melted into moulded articles

The selection of appropriate derogation criteria should be guided by the use of the ion exchange resins (IER). It was recognised that different companies may have varying preferences in this regard. However, in a common practice scenario, it was agreed that options 4a (SPM for use at industrial sites) and/or 5a (SPM contained by technical means) are deemed applicable for all SOIA members.

It is also important to note that an SPM manufacturer may be covered by the derogation in Paragraph 4(a) to supply SPM to an industrial downstream user (DU) for use at industrial sites, and the industrial DU later may be covered by an applicable derogation in Paragraph 5 to place a finished product containing those SPM on the market for professional use and the general public. Different derogations may come with different IFUD and reporting requirements (see Sections 8 and 9 below). Each actor in the supply chain is responsible to comply with the obligations stemming from the derogation(s) applicable to them.

3. Transition Periods

Different transition periods for 'placing on the market' apply for different sectors. Paragraph 6 of the Entry 78 specifies the number of years after which the use of SPM at concentrations greater than 0.01% will be banned, depending on the intended application. However, this provision does not apply to ion exchange resins due to the applicable derogation.

4. Information duties

Suppliers of synthetic polymer microparticles referred to in paragraph 4, point (a), (e) and 5 , shall provide the following information:

Starting from 17 October 2025 The Suppliers of SPM referred to in paragraph 4a shall provide the following information: 1) instructions for use and disposal intended for industrial downstream users; 2) inclusion of the following statement: "The synthetic polymer microparticles supplied is subject to conditions laid down by entry 78 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council"; 3) the quantity or the concentration of SPM in the product;	**Starting from 17 October 2026** The suppliers of products containing SPM referred to in paragraph 4e -- Food additives **Starting from 17 October 2025** The suppliers of products containing SPM referred to in paragraph • 4d -- In vitro diagnostic devices • & 5-- Contained by technical means or permanently modified during use shall provide the following: 1) Instructions for use and disposal explaining to professional users

4) generic identity of the polymers contained in the substance or mixture (Paragraph 7) Obligation applied for use at industrial sites	and the general public how to prevent releases of synthetic polymer microparticles (Paragraph 8) Targeted to the use for professional and the general public

The information for **industrial** downstream users (DUs) may be provided in the safety data sheet (SDS), on the product package, in the package leaflet, or on the product label. . If the information is included as part of the SDS, sections 7, 8, 13, 14, 15, 16 and/or the appended exposure scenarios may be relevant, depending on the specific circumstances. Usually, the SPM statement needs to be included under SDS section 15 "The synthetic polymer microparticles supplied is subject to conditions laid down by entry 78 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council".

However, **for professional users and/or general public**, the information may be provided on the product label, the package, or in the leaflet.

5. Instructions for use and disposal (IFUD)

5.1 Instructions for use (IFU)

All applications for synthetic ion exchange resins and adsorbents will require some form of pre-treatment after removal from their original packaging and once loaded into the plant. In some industrial settings, this process is relatively simple, while in others, it can be more complex and may require a longer commissioning period.

End users are advised to familiarise themselves with, and consult with the resin manufacturer before taking delivery of resins for use in food stuff production:

- The importance of packaging
- Minimising on site storage prior to use/shelf life
- Correct storage conditions
- Inspection/cleanliness of IER vessels before loading
- Correct loading / commissioning procedure
- Pretreatment before placing in service
- Operating with defined manufacturers guidelines (E.g.: pressure drop, flow rates, operating temperatures and maximum temperature changes etc.)
- Regenerant quality (where applicable)

- Thorough testing of initial quality of product produced (approved)

For all food grade products there is a specific manufacturers pre-treatment procedure. In addition to the specialist production techniques employed in the production of food contact resins and adsorbents, each resin manufacturer also applies their own post treatment techniques. These are proprietary treatments developed by the manufacturer to ensure the resins meet the required food grade standards applicable to the product when produced.

The manufacturer also ensures that, if the products are transported and stored correctly on site before installation, and then treated in line with the manufacturer's instructions when placed in service, the products will meet the end user requirements.

For synthetic adsorbents some products are supplied with a specialist additive to maintain purity in storage prior to use.

No synthetic ion exchange resin or adsorbent should be used in a food contact application without first verifying that the material complies with food contact regulations and in a suitably clean condition at the time of commissioning.

- the IFU provided by suppliers of SPM for use at industrial sites should be targeted to industrial downstream users and should explain how the SPM (and the product containing them) should be used, handled, stored and disposed of in an industrial setting.
- the IFU provided by suppliers of SPM-containing products intended for professional use or the general public should explain how professionals and consumers should use, handle and store the product, including clean-up of tools; how they should dispose of the product and the product container/packaging (that may still contain residual product with SPM) after its intended use; etc.

Products containing SPM derogated under Paragraph 5(a) that are already provided with instructions explaining how to use the product appropriately/safely in a way that (also) prevents SPM emission, it is acceptable that the SPM-specific IFUD only consist of disposal instructions and that no SPM-specific use instructions are included.

5.2 Instruction for disposal (IFD)

Instruction for disposal should always be in accordance with applicable waste legislation. Where possible, suppliers are encouraged (but not obliged) to provide an electronic version of the IFD/IFUD through digital tools, e.g. a QR code, a hyperlink, etc, as provided in Paragraph 10 of entry 78. The electronic version of the IFUD cannot

replace the text or pictograms on the product label/packaging/leaflet/SDS (which need to be appropriate and self-explanatory) but can integrate the mandatory IFUD with additional information for the industrial users, professionals or consumers.

SPM are contained by technical means and they are not emitted to the environment when used according to the normal instructions accompanying the product and explaining how to use the product appropriately/safely, the normal product instructions are considered sufficient. The SPM-specific instructions should focus on the appropriate disposal of the product.

Disposal instructions for ion exchange resins and adsorbents typically involve the following steps:

a) Regeneration: If possible, regenerate the resin to extend its life. This involves using specific chemicals to restore the resin's ion exchange capacity.
b) Containment: Ensure that used resins and adsorbents are contained properly to prevent any environmental contamination. This includes using appropriate containers and labelling them correctly.
c) Incineration: For resins that cannot be regenerated or reused, high-temperature incineration is recommended. This method ensures the complete destruction of any hazardous substances contained in the resins.
d) Landfill: In some cases, resins can be disposed of in landfills designed to handle hazardous waste. However, this is less preferred due to potential leachability issues.
e) Compliance: Always follow local regulations and guidelines for the disposal of hazardous materials. This may include specific procedures for handling, transporting, and disposing of ion exchange resins and adsorbents.

The IFUD are mandatory for SPM, and products containing them, derogated under Paragraph 4(a), 4(d), 4(e), 5(a), 5(b) and 5(c), namely SPM. The IFUD need to be self-explanatory, i.e. they need to be clear and easy to understand without needing to search for any extra information or explanation.

IFUD provided by suppliers of SPM **for use at industrial sites**	IFUD provided by suppliers of SPM-containing products **for professional use or the general public**
should be targeted to **industrial downstream users** and should explain how the SPM (and the product containing them) should be used, handled, stored and disposed of in an industrial setting.	should explain how **professionals and consumers** should use, handle and store the product, including clean-up of tools; how they should dispose of the product and the product container/packaging (that may still contain residual product with SPM) after its intended use; etc.

6. Labelling Requirements

The information should be provided in text or pictograms 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.

7. Reporting

Reporting Requirements by 31 May each year.

The elements to be reported	
1) Description of the use(s) 2) Generic information on the identity of the polymers 3) Estimate of the quantity of SPMs released to the environment 4) Applicable derogation(s)	
Industrial uses	Professional and consumer uses
• Manufacturers and downstream users: pellets, flakes and powders used as feedstock in plastic manufacturing at industrial sites ➢ Annual reporting requirements from 2026 • Manufacturers and downstream users: other uses at industrial sites ➢ Annual reporting requirements **from 2027**	• Suppliers: products placed on the market for the first time to professional users and the general public ➢ Annual reporting requirements **from 2027**

According to the regulation, SOIA members have reporting obligations starting from 31 May 2027. Below you can find the overview of the reporting data:

Information	Type	Description and the Options
Reporting year	Numerical input	**Starting from May 2027** The reporter should enter the year for which they are submitting the information i.e. the previous calendar year.
Use/end use	Pick-list	1. Manufacture or use of pellets, flakes and powders for plastic manufacturing at industrial site. 2. **Other manufacture or use at industrial site.** 3. Consumer and/or professional use in medicinal or veterinary products. 4. Consumer and/or professional use in food additives. 5. Consumer and/or professional use in in-vitro diagnostic devices. 6. **Other consumer or professional use.**
Use name	Free text	The name of the use in English.
Product category (PC)	Pick-list	**For derogations 4a**, b, d, e, and **5a**, b and c. **The reporter can select their use descriptors from pick-lists** that will be based on the standard descriptors in ECHA Guidance Chapter R.12. Multiple descriptors may be selected, where applicable, e.g.: **- PC2 Adsorbers;;** **- PC32 Polymer preparations and compounds ;** **- PC36 Water softeners;** **- PC37 Water treatment chemicals;** **- PC40 Extraction agents**
Sector of end use	Pick-list	Same as above. (see ECHA Guidance Chapter R.12.) **e.g.: SU0 Other**
Technical function	Pick-list	Same as above. Available options include: **- Adsorbent** **- Anti scaling agent** **- Chelating agent** **- Ion exchange agent**
Derogation for use at industrial sites (para 4a)	Pick-list	The reporter can select one option below: • **Use at industrial sites**; or • None of the above. (Selectable only for uses 1 and 2) OR

Derogated sectors (para. 4 b, d or e)	Pick-list	• Medicinal and veterinary medicinal products; • Food additives; • In vitro diagnostic devices; or • None of the above. (The first 3 options selectable only for uses 3, 4 and 5. Otherwise 'none of the above'). AND/OR
Derogations due to minimised risks (para. 5 a, b or c)	Pick-list	The reporter can select one or more options below: • **SPM which are contained by technical means**; • SPM with physical properties permanently modified during intended end use; • SPM which are permanently incorporated into a solid matrix.
Site(s)	Select or create site record	The site(s) will only be applicable for manufacturers and industrial downstream users. The site(s) will be linked to the use.
Generic information on the identity of polymers	Pick-list	The reporter can select one or several entries from the list of applicable codes from the Harmonised System. In case 'other' is selected, the free text for the description of the generic identity of the polymer is activated and must be filled. **e.g.: 9999 other** **(3914 Ion-exchangers based on polymers of headings)**
Estimated emission quantity	Numeric Kilograms/year OR Tons when >1 ton/year Expressed as dry weight Pick-list options:	With respect to the specific use: Option A: Concentration range of SPM in the particles (estimated annual volume). - 0.1-10 %, - 10-30 %, - 30-50 %, - 50-70 %, - 70-90 %, - 90-100 %. Option B: Estimated annual volume of SPM released to the environment, which should include the following: - End use emissions - Emissions during transportation
Attachments		Optional attachments can be submitted.

8. Summary of SPM Emissions Reporting Requirements

Who Must Report?

✓ Manufacturers & industrial downstream users (under Paragraph 4(a)):
- Report their own SPM emissions (including transport, even by third parties).
- Example: Report by 31 May 2027 for Jan–Dec 2026 emissions.

✓ Suppliers (manufacturers/importers/downstream users) placing derogated SPM products on the market for the first time (to professionals/public):
- Report their own emissions (including transport).
- Report downstream emissions (from product use to disposal).

✓ Importers supplying SPM/products to professionals/public:
- Report own emissions (from EU customs entry) + downstream emissions.

Who Does NOT Report?

✗ Importers of SPM/products for industrial use (exempt under Paragraph 11).

✗ Distributors, retailers, professional end users, consumers (even if they modify products).
- Reporting duty lies with the first supplier placing the product on the market.

Key Rules

➢ No double reporting – Only the first supplier to professionals/public reports.

➢ Transport emissions (even by third parties) must be included.

➢ Industrial importers exempt, but importers serving professionals/public must report.

The reporting will be IUCLID-based, the submission tool will likely be REACH-IT or the new ECHA Industry Portal.

Reference:

Commission Regulation (EU) 2023/2055
https://eur-lex.europa.eu/eli/reg/2023/2055/oj\

Commission Explanatory Guide on SPM restriction – Intro + Part I
https://single-market-economy.ec.europa.eu/document/download/ec80269d-7ef6-43de-8667-2041a8607209_en?filename=20250326_EGMP_Intro%2BPartI_forPub.pdf

Commission Explanatory Guide on SPM restriction – Part II
https://single-market-economy.ec.europa.eu/document/download/da9156fc-103f-4ce4-9aac-2ab251e0f793_en?filename=20250326_EGMP_Part%20II_forPub.pdf

Commission Explanatory Guide on SPM restriction – Part III Annex
https://single-market-economy.ec.europa.eu/document/download/52c6a19e-800e-43ea-a8a6-35496ddd71af_en?filename=20250326_EGMP_Part%20III_forPub.pdf

ECHA Guidance on SPM Reporting
https://echa.europa.eu/documents/10162/17233/microplastics_reporting_system_requirements_en.pdf/ab93bd4f-b691-ac2a-d780-b1483e29cd9e?t=1744711355908

ECHA Guidance Chapter R.12.
https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf/ea8fa5a6-6ba1-47f4-9e47-c7216e180197