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Reporting System Proposal

1. Introduction

Regulatory context

Entry 78 of Annex XVII of the REACH Regulation, introduced by Commission Regulation (EU) 2023/2055 of 25 September 2023 (commonly known as “the microplastics restriction”)¹, sets out reporting requirements for certain uses of synthetic polymer microparticles (**SPM**) subject to a derogation. The reporting requirements concern estimated annual emissions of SPM to the environment, and apply to manufacturers, industrial downstream users and suppliers placing SPM on the market for consumer and professional uses for the first time. The information will be submitted annually to ECHA.

According to the Regulation, the purpose of the reporting requirements is to contribute to the monitorability of the effectiveness of the instructions for use and disposal and improve the evidence base for the risk management of the uses exempted from the prohibition of placing on the market. To ensure the optimal use of the reported information and facilitate enforcement, the information will be made available to the Member States by ECHA.

Legal requirements

Definition of Synthetic Polymer Microparticle (SPM)

The definition of what constitutes SPM can be found in the left-hand column of entry 78. SPM are defined as **polymers** that are solid and 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.

The following polymers are excluded from this designation:

- (a) polymers that are the result of a polymerisation process that has taken place in nature, independently of the process through which they have been extracted, which are not chemically modified substances;
- (b) polymers that are degradable as proved in accordance with Appendix 15;

¹ <https://eur-lex.europa.eu/eli/req/2023/2055/oj>

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(c) polymers that have a solubility greater than 2 g/L as proved in accordance with Appendix 16;

(d) polymers that do not contain carbon atoms in their chemical structure.

Derogated uses subject to reporting requirements

Paragraph 4

(a) synthetic polymer microparticles, as substances on their own or in mixtures, for use at industrial sites;

(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;

(d) food additives within the scope of Regulation (EC) No 1333/2008 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

Paragraph 5

(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.

Reporting Timelines

Paragraphs 11 and 12 of entry 78 describe the reporting requirements for the different actors in the supply chain. The information shall be submitted to ECHA by 31 May each year, starting from 2026 or 2027, depending on the uses. The manufacturers, industrial downstream users and suppliers of SPM that are subject to the reporting requirements shall submit information on estimated emissions of SPM for the previous calendar year.

The obligation to report emission information begins in different years depending on the type of use. The starting years are set out in paragraph 11 and 12 of entry 78, as follows:

- Starting from 2026: manufacturers and industrial downstream users of SPM in the form of pellets, flakes, and powders used as feedstock in plastic manufacturing at industrial sites (meaning that by the end of May 2026 they should report estimated emissions for the calendar year of 2025);
- Starting from 2027: other manufacturers of SPM and other industrial downstream users using SPM at industrial sites (meaning that by the end of May 2027 they should report estimated emissions for the calendar year of 2026);
- Starting from 2027: suppliers of products containing SPM referred to in paragraphs 4,

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points (b), (d) and (e), and paragraph 5 of the entry, that place those products on the market for the first time to professional users and the general public (meaning that by the end of May 2027 they should report estimated emissions and related information for the calendar year of 2026).

Structure of this document

The present document is structured as follows:

- First, we provide an overview of the reporting requirements.
- Secondly, we describe in detail each part of the reporting requirements.
- Thirdly, we describe the information that is to be reported.
- Fourthly, we describe how the reporting requirements are implemented technically, how the data is stored, processed and treated, and how Member States requests to access the data are considered.
- Finally, we provide a provisional timeline on the design and implementation of the reporting system.

2. The reporting requirements

2.1. Overview

As defined in entry 78, the reporting requirements set out an obligation to report estimated SPM releases to the environment from certain uses derogated from the prohibition of placing on the market. The information shall be submitted by (or on behalf of) each legal entity that is subject to the reporting requirements. The estimated emissions will be reported per use, and indicating the applicable derogation(s). The specific information to be reported will depend on which derogation applies to the use in question.

- **Manufacturers of SPM and industrial downstream users (DUs) using SPM at an industrial site** will benefit from the derogation in paragraph 4a and will report estimated emissions of SPM from their own use, including during transportation, according to paragraph 11. They will report estimated emissions per legal entity, indicating the site(s) where the emissions take place.
- **Suppliers* of products containing SPM** benefitting from a derogation in paragraphs 4b, 4d or 4e, or 5a, 5b or 5c, that place those products on the market for the first time **to professional users and the general public**, will report – in addition to their own estimated emissions according to paragraph 11 if applicable – the estimated downstream SPM emissions occurring until the product is disposed of as waste (e.g. the estimated downstream emissions from distributors, including retailers, and end users), including from transportation, according to paragraph 12.

* NOTE: For the purpose of reporting under entry 78, a **supplier can be a manufacturer, importer or industrial downstream user** that places the products on the market for the first time for professional use or use by the general public. Distributors do not have reporting obligations under entry 78.

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2.2. Reporting entity

The reporting entity is the actor specified in paragraphs 11 and 12, i.e. the manufacturer or industrial downstream user of SPM or the supplier of a product containing SPM for the time on the market to be used by professionals or consumers.

Emissions of SPM shall be reported by (or on behalf of) each legal entity that is subject to the reporting requirements. Legal entities are therefore the reporting entity, which means that the information must be provided separately for each legal entity.

It should be noted that an industrial downstream user of SPM may also be the supplier that places a product containing SPM on the market for the first time to professional users and consumers. In this case, both paragraphs 11 and 12 apply. The legal entity will submit one dossier and within that dossier they will need to report separately for their own use (paragraph 11) and, if they place the product (per paragraph 4b, 4d or 4e or paragraph 5) on the market for the first time to professional users and consumers, the end uses for which the SPM were placed on the market (paragraph 12).

2.3. Obligation to report by use

The manufacturer, industrial downstream users or supplier will report the estimated SPM emissions per use. The use will be selected from a pick-list with the following options:

1. Manufacture or use of pellets, flakes and powders for plastic manufacturing at industrial sites
2. Other manufacture or use at industrial sites (including formulation)
3. Consumer and/or professional use in medicinal and veterinary medicinal products
4. Consumer and/or professional use in food additives
5. Consumer and/or professional use in in vitro diagnostic devices
6. Other consumer and/or professional use

Therefore, **the level of granularity for the estimation of emissions will be per use as defined in the pick-list above.** One reporting entity may have reporting obligations arising from several uses, i.e. an industrial manufacturer or downstream user may also be a supplier of the SPM-containing product for consumer/professional uses in e.g. medicines and in vitro diagnostic devices and will need to report under these three uses (use 1,3 and 5).

For each use applicable to the reporting entity, the following elements will be provided:

- a) Description of use
- b) Generic identity of the polymer(s)
- c) Estimation of emissions
- d) Applicable derogation(s)

These elements are described in detail below. Table 1 in the Appendix provides a description of the elements in tabular form.

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2.3.1 Description of Use

The description of the use will consist of the following:

- Brief description of the use in free text form
- Sector(s) of use (SU)² (pick-list) (where applicable)
- Product Categor(ies) (PC) (pick-list) (where applicable)
- Technical function(s) (TC) (pick-list) (where applicable)

For the manufacture and/or use at industrial sites, the following additional information will be provided:

- Identification of the industrial site(s) where the use takes place

(The sector of use (SU), product category (PC) and technical function (TF) are defined following the standard use descriptors from ECHA guidance R.12 on use description)

The description of the use should be relevant enough to ensure an understanding on the conditions under which the use takes place. The purpose of the brief description is to provide an intuitive name for the record allowing it to be easily recognisable later. It should be representative for the use, and preferably not too long (useful for subsequent updates). The description should be provided in English.

2.3.2 Generic identity of the polymers used

Entry 78 states in point (b) of paragraphs 11 and 12, that the reports for each use shall include generic information on the identity of the polymers used or placed on the market. This must be in line with the information on the identity of the polymers that is communicated by suppliers per paragraph 7(d).

Two options are currently being considered for reporting the generic identity of the polymer(s) as follows:

Option 1: The CAS number and CAS name of the polymer(s) can be selected from a pre-existing list (from the inventories of reference substances available in IUCLID) and when they do not appear in the existing list of substances, the reporter can create a new substance. When a polymer does not have a CAS number, an option to provide other identifiers will be possible.

Several substances can be reported within the same use by linking records within the report.

Option 2: A pre-selected list of entries (codes and descriptions) from the Harmonised System³ developed by the World Customs Organisation. The list will comprise 4-digit and 6-digit codes originating from headings 3901 to 3914 from chapter 39, as well as headings from chapter 40, in particular 4001 and 4002 of section VII of the Harmonised System.

The list will appear as a pick-list, and selection of multiple codes will be possible, in case more than one type of polymer is applicable for the use. There will be an additional option of "other"

² Please note that not all descriptors are applicable for all uses e.g. sector of use is not relevant for consumer uses and product category and technical function are not applicable for manufacturing. This will be defined further in instructions for reporting

³ [Harmonized System | WCO Trade Tools](#)

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when the applicable polymer is not covered by the pick-list options.

2.3.3 Emissions

As described in entry 78, the reporting entity reports information on annual estimated emissions to the environment arising from the derogated use reported. This estimate should also include any emissions that occur during transportation. Therefore, the following information should be provided for each use (two options for the emission estimation are currently being considered):

Option A: Quantity of particles and concentration of SPM in the particles

Estimated emission of the particles containing or coated by the polymer(s) fulfilling the definition of an SPM

An estimation of the total annual volume of the particles released to the environment for the use reported (i.e. the particles containing or coated by the SPM are contained);

AND

The concentration range of the SPM (i.e. the applicable polymer(s)) in the in particles. The reporter should make a selection from a list of pre-defined ranges. If the concentration of SPM is not known, a conservative assumption of the highest concentration range (90-100%) should be made.

a. Proposed SPM concentration ranges (pick-list):

- i. 1-10 %
- ii. 10-50 %
- iii. 50-70 %
- iv. 70-90 %
- v. 90-100 %

Option B: Quantity of SPM

Estimated emissions of SPM (i.e. the polymers contained in or coating the particles): An estimation of the total annual volume of the polymers fulfilling the SPM definition in Entry 78, left-hand column released to the environment for the reported use;

In option A, the reported total volume of the particles includes that of the SPM plus that of any non-polymeric component of the particles. In Option B, the reported total volume only includes that of the SPM (i.e. the polymer(s) contained in or coating the particles).

All quantities are to be reported in kilograms. The regulation does not foresee a lower limit for reporting, and estimated emissions shall be reported for uses subject to the reporting requirement, including for those uses where very low or zero emissions are estimated.

End use emissions

In addition to their own emissions, suppliers of products containing SPM that place the product on the market for the first time to professional users and the general public are required to estimate the downstream emissions from the moment the product is placed on the market to the moment it is disposed of after end use. All emissions (occurring within the EEA) from the

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end use are reported for the use as a single figure.

Note: emissions should be estimated up to and including the disposal stage after end use, but excluding the waste stage.

Emissions during transportation

As set out in entry 78, the reported emissions shall include an estimation of the quantity of SPM released to the environment during transportation. These emissions will be reported together with the emissions from use/end use.

The actor who will assume responsibility for the obligation for reporting transport emissions should be based on the legal liabilities set out in the contractual agreements between companies.

2.3.4 Derogations

As described in Entry 78, the reporting requirements concern uses that are derogated from the ban on the placing on the market of SPM. The derogated uses are defined in paragraphs 4 and 5 of entry 78.

The reporting entity will be required to select the applicable derogation(s) from a picklist containing all the derogated uses subject to reporting requirements (paragraphs 4a, 4b, 4d, 4e, 5a, 5b and 5c)

For industrial uses (manufacturers and/or industrial downstream users), there is only one applicable derogation: "*synthetic polymer microparticles, as substances on their own or in mixtures, for use at industrial sites*", according to paragraph 4(a) of entry 78.

For end uses reported by suppliers placing the product on the market for the first time for professional and /or consumer uses, there are two categories of derogations that may apply:

- Paragraph 4 – Derogations for specific product categories⁴
 - 4b. Medicinal and veterinary medicinal products
 - 4d. Food additives
 - 4e. In vitro diagnostic devices
- Paragraph 5 - Derogations due to minimised risks⁵ during the intended end use of a product.
 - 5a. SPM which are contained by technical means
 - 5b. SPM with physical properties that are permanently modified
 - 5c. SPM which are permanently incorporated into a solid matrix

In cases where several derogations could be applicable (e.g. 4e and 5a), all relevant derogations should be selected.

⁴ As defined in entry 78 paragraph 4, points (b), (d), and (e) respectively.

⁵ As defined in entry 78 paragraph 5, points (a), (b), and (c) respectively.

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3. Reporting Process

3.1. Reporting tool

It is proposed that the reporting will be done using **IUCLID**.

A new working context will be added to IUCLID that will contain the relevant IUCLID templates to collect the information sought in entry 78 (only the relevant fields of will be displayed to the reporters to facilitate data entry; this is supported by IUCLID via the use of 'custom definitions').

- Dossier header with the standard submission meta data, legal entity, update, year of reporting
- Substance entity: a generic reference substance for SPM falling under entry 78 (yet to be defined)
- The template will contain fields for the information to be reported by use described in section 2.3.

Dossier updates will be possible as well as re-use of information from previous years for subsequent yearly reporting for ease of reporting. The template will contain the information from the previous calendar year, and these can be amended in the report to be submitted by 31 May each year. After 31 May the data for the previous calendar year can no longer be modified after a specific timepoint (to be defined).

ECHA foresees that one dossier will be submitted per legal entity, in which it will include reporting for each use that is applicable to that legal entity. Therefore, it is not expected that multiple dossiers would be submitted by the same legal entity.

3.2. Submission

The submission of the dossiers will be coordinated via **REACH-IT**.

Every legal entity will submit their own IUCLID dossier. The submission portal will allow a legal entity to give permission to a user of another legal entity to work and submit on their behalf. Still in the system the original legal entity will be responsible for the data submitted on their behalf. The estimated emissions must still be reported separately for each legal entity; one Reporting entity/legal entity may not report aggregated total emissions for a group of legal entities.

3.3. Dissemination

We have a target to disseminate aggregated information. Options for this could include e.g. an annual static report or dynamic data. This is under development and will be revisited in May 2026 when data has been submitted for the previous calendar year.

Confidentiality

Which information may be considered confidential is still under development and subject to consultation.

3.4. Information sharing with Member States

Entry 78 specifies that the information submitted under paragraphs 11 and 12 shall be made

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available to the Member States.

In addition to information sharing on reporting, paragraph 14 of entry 78 foresees that further specific information on polymer identity and the function of the polymer may be requested by Member State Competent Authorities. This is done separately from the reporting under paragraphs 11 and 12.

Making available of information to Member States

Paragraph 13 of entry 78 specifies that the information submitted as a part of the Reporting Requirement shall be made available to Member States.

It is foreseen that the reporting format within IUCLID developed for companies to report data according to paragraphs 11 and 12 of entry 78 will also be accessible by the Member States for retrieving the information.

Further information requested by Competent Authorities

Paragraph 14 of entry 78 specifies that manufacturers, importers and industrial downstream users of products containing SPM shall provide specific information on the identity of polymers (including at least the information laid down in points 2.1 to 2.2.3 and 2.3.5 to 2.3.7 of Annex VI of REACH) covered by the entry and contained in those products and the function of those polymers in the products to Competent Authorities upon their request.

Companies will be able to submit attachments in the system, which can be accessed by the Competent Authorities.

4. Timeline

In entry 78 the first submission of data is required by **31 May 2026** from manufacturers and industrial downstream users of SPM in the form of pellets, flakes, and powders used as feedstock in plastic manufacturing at industrial sites. The system should be ready well in advance of that, no later than December 2025.

Appendix - Description of reporting data

The table below describes each piece of information and the foreseen type of input that will be submitted to ECHA as part of the annual reporting requirements. Information is submitted per legal entity, per use and per reporting year. Several uses may be reported per submission.

Information	Type	Description
Reporting year	Numerical input	The reporter should enter the year for which they are submitting the information i.e. the previous calendar year
Use/end use	Pick-list	<ul style="list-style-type: none"> • Manufacture or use of pellets, flakes and powders for plastic manufacturing at industrial site • Other manufacture or use at industrial site

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Information	Type	Description
		<ul style="list-style-type: none"> Consumer and/or professional use in medicinal or veterinary products Consumer and/or professional use in food additives Consumer and/or professional use in in-vitro diagnostic devices Other consumer or professional use
Brief description of use	Free text	The purpose is to provide an intuitive name for the record allowing it to be easily recognisable later.
Product category	Pick-lists	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. Please note that some of the descriptors are not applicable for certain uses e.g. TF and PC for manufacturing and SU for consumer uses. Multiple descriptors may be selected, where applicable.
Sector of end use		
Technical function		
Derogation <i>Derogation for use at industrial sites (para 4a)</i>	Pick-list	The reporter can select: <ul style="list-style-type: none"> use at industrial sites; or None of the above. OR
Derogation <i>Derogated sectors (para. 4 b, d or e)</i>	Pick-list	The reporter can select one: <ul style="list-style-type: none"> Medicinal and veterinary medicinal products; Food additives; In vitro diagnostic devices; or None of the above. AND/OR
Derogation <i>Derogations due to minimised risks (para. 5 a, b or c)</i>	Pick-list	The reporter can select one: <ul style="list-style-type: none"> 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; or None of the above.

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Information	Type	Description
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 (option 1)	Match or create	CAS name and CAS number can be selected from a pre-existing list. When the substances do not appear in the existing list of substances, the reporter can create a new substance. Several substances can be linked within the same entry. There will also be an option to report other identifiers in the absence of a CAS number and name.
Generic information on the identity of polymers (option 2)	Pick-list	The reporter can select one or several: List of applicable codes from the Harmonised System to be confirmed.
Estimated emission quantity	Numeric kilograms/year	With respect to the specific use, the estimated annual volume of particles⁶/SPM⁷ released to the environment.
SPM concentration⁶	Selection from a pick-list of pre-defined ranges	(For option A only) With respect to the whole particles, an estimate of the <u>concentration range of the SPM (i.e. the polymer(s) contained in or coating the particles) in the particles.</u>
Attachments		Optional attachments can be submitted. This is foreseen to facilitate information flow e.g. arising from Member State Competent Authority requests for further information detailed in section 3.4.

⁶ In line with Option A described in section 2.3.3 (green highlight)

⁷ In line with Option B described in section 2.3.3 (yellow highlight)