# Implementation of the reporting requirements of the REACH restriction on microplastics

#### 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;

<sup>&</sup>lt;sup>1</sup> <a href="https://eur-lex.europa.eu/eli/reg/2023/2055/oj">https://eur-lex.europa.eu/eli/reg/2023/2055/oj</a>



- (b) polymers that are degradable as proved in accordance with Appendix 15;
- (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:

- <u>Starting from 2026</u>: 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);
- <u>Starting from 2027</u>: 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, 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 the information is made available to
  the Member States Competent Authorities.
- Finally, we provide an estimated timeline for the 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 shall be reported per use and indicating the applicable derogation(s). The specific information to be reported shall depend on which derogation applies to the use in question.

- Manufacturers of SPM and industrial downstream users (DUs) using SPM at an industrial site shall benefit from the derogation in paragraph 4a and 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, shall 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.

<sup>\*</sup> 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.



#### 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 placing the product on the market for the time 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. In this case, the legal entity shall submit only one dossier and within that dossier they shall report the SPM emissions 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 shall report the estimated SPM emissions per use. The use will be selected from a pick-list with the following options:

- Manufacture or use of pellets, flakes and powders for plastic manufacturing at industrial sites
- 2. Other manufacture or use at industrial sites
- 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 products for consumer/professional uses in e.g. medicines and in vitro diagnostic devices and will need to report under each of these three uses (use 1, 3 and 5). The reporting of all uses will be submitted in a single dossier per legal entity.

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 Appendix I provides a description of the elements in tabular form.

#### 2.3.1 Description of Use

The description of the use will consist of the following:

- Use name in free text form
- Sector(s) of use (SU)<sup>2</sup> (pick-list)
- Product Categor(ies) (PC) (pick-list)
- Technical function(s) (TC) (pick-list)

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. Multiple descriptors may be selected from the pick-lists, if applicable.

The use name shall be relevant enough to ensure an understanding of the use and 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 report 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).

A pre-selected list of entries (codes and descriptions) from the Harmonised System<sup>3</sup> developed by the World Customs Organisation shall be used for reporting the generic identity of the polymers (further described in Appendix II). The pre-selected list comprises 4-digit codes of section VII of the Harmonised System, including headings 3901 to 3914 from chapter 39 and headings 4001 and 4002 from chapter 40. The reporting tool will show the pre-selected list of 4-digit codes as a pick-list from which the generic identity of the polymer(s) in use shall be identified. The user will be able to select several codes in case more than one type of polymer is in use. The pick-list will offer an additional option of 'other' to be selected when the polymer(s) in use is not included in the list. Whenever the option 'other' is selected, the generic identity of the polymer(s) shall be identified in English in a free text field.

#### 2.3.3 Emissions

As described in entry 78, the reporting entity reports information on <u>annual estimated SPM emissions</u> to the environment arising from the derogated use reported. The estimated environmental emissions shall comprise a total sum considering all compartments (such as air, water and soil). This estimate shall also include any emissions that occur during transportation. The estimation shall include losses from intentional uses and operational losses after all mitigation measures, as well as from any incidents such as accidents or spills. The following

<sup>&</sup>lt;sup>2</sup> 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

<sup>&</sup>lt;sup>3</sup> Harmonized System | WCO Trade Tools



information should be provided:

#### **Option A: Quantity of particles containing SPM**

The reported total volume of the particles including that of the SPM plus that of any non-polymeric component of the particles.

In addition, it is optional to provide the concentration range of SPM in the particles. If not provided, a default assumption of 100% will apply.

Concentration range of SPM pick-list options:

0.1-10 %

10-30 %

30-50 %

50-70 %

70-90 %

90-100 %

#### **Option B: Quantity of SPM**

An estimation of the total annual volume (dry weight of SPM reported in kg or tonnes) of the polymers fulfilling the SPM definition in Entry 78, left-hand column released to the environment for the reported use. The reported total volume only includes that of the SPM (i.e. the polymer(s) contained in or coating the particles) excluding any other components such as additives and fillers.

All quantities for both options A and B are to be reported in kilograms (if below 1 tonne) or tonnes when exceeding 1 tonne. 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 total downstream emissions occurring within the EEA from the moment the product is placed on the market to the moment it is disposed of after end use. Note: emissions shall 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. The estimated transport emissions will be reported together with the other estimated emissions for the use as one aggregated estimate.



#### 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 (**<u>manufacturers and/or industrial downstream users</u>), 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 <u>professional and /or consumer uses</u>, there are two categories of derogations that may apply:

- Paragraph 4 Derogations for specific product categories<sup>4</sup>
  - 4b. Medicinal and veterinary medicinal products
  - 4d. Food additives
  - 4e. In vitro diagnostic devices
- Paragraph 5 Derogations due to minimised risks<sup>5</sup> 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.

## 3. Reporting Process

## 3.1. Reporting tool

The reporting will be done in **IUCLID**.

A new working context in IUCLID will contain the relevant templates to collect the information sought in entry 78 (only the relevant fields will be displayed to the reporters to facilitate data entry).

- Dossier header with the standard submission meta data, legal entity, update, year of reporting
- Substance entity: a generic reference substance for SPM will be available in the system

<sup>&</sup>lt;sup>4</sup> As defined in entry 78 paragraph 4, points (b), (d), and (e) respectively.

<sup>&</sup>lt;sup>5</sup> As defined in entry 78 paragraph 5, points (a), (b), and (c) respectively.



named "synthetic polymer microparticles".

- 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 reported in the previous calendar year, and it will be possible to update it for the reporting of the following calendar year. Attachments for providing specific information according to paragraph 14 of Entry 78 to Member State Competent Authorities upon their requests can be added to the report at all times following the timelines agreed for their submission.

ECHA foresees that one IUCLID dossier will be submitted per legal entity which will include the 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. REACH-IT will allow a legal entity to give permission to a user of another legal entity to work and submit a dossier on their behalf. However, the original legal entity will be responsible for the data submitted on their behalf. The estimated emissions shall 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

Aggregated information from the reporting of SPM emissions will be disseminated on ECHA's website. The format for the dissemination of information is still under development and will be fully implemented once the first reporting exercise is finalised in May 2026.

#### Confidentiality

The following information is considered confidential and will be accessible only by ECHA and Member State Competent Authorities (MSCAs) and <u>not subject to dissemination</u>:

- legal entity and site information
- information provided at the request of MSCAs per paragraph 14 of Entry 78.

All data reported by individual legal entities will be disseminated in aggregated form to avoid any potential disclosure of confidential business information.

#### **Information sharing with Member States**

Entry 78 specifies that the information submitted under paragraphs 11 and 12 shall be made 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 information available 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 all IUCLID dossiers will be accessible by the Member States for retrieving the information.

#### **Further information requested by Competent Authorities**

In addition, 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) and the function of those polymers in their products to the Member States Competent Authorities upon their request.

As discussed above in section 3.1., each legal entity may attach the requested information to their IUCLID dossier according to the timelines agreed with the national authority. The attachments will be accessible to the Member States Competent together with the IUCLID dossiers.

#### 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 reporting system according to the criteria defined in section 3 above will be ready and in use by December 2025.



## **Appendix I - 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	Туре	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	<ol> <li>Manufacture or use of pellets, flakes and powders for plastic manufacturing at industrial site</li> <li>Other manufacture or use at industrial site</li> <li>Consumer and/or professional use in medicinal or veterinary products</li> <li>Consumer and/or professional use in food additives</li> <li>Consumer and/or professional use in in-</li> </ol>
		vitro diagnostic devices  6. Other consumer or professional use
Use name	Free text	The name of the use in English
Product category	Pick-list	For derogations 4a, b, d, e, and 5a, b and c
Sector of end use Technical function		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 may not be applicable for certain uses e.g. TF and PC for manufacturing and SU for consumer uses.  Multiple descriptors may be selected, where applicable.
Derogation	Pick-list	The reporter can select one option below:
Derogation for use at industrial sites (para 4a)		<ul> <li>Use at industrial sites; or</li> <li>None of the above.</li> </ul> (Selectable only for uses 1 and 2) OR
Derogation	Pick-list	The reporter can select one option below:



Information	Туре	Description
Derogated sectors (para. 4 b, d or e)		<ul> <li>Medicinal and veterinary medicinal products;</li> <li>Food additives;</li> <li>In vitro diagnostic devices; or</li> <li>None of the above.</li> </ul> (The first 3 options selectable only for uses 3, 4 and 5. Otherwise 'none of the above') AND/OR
Derogation  Derogations due to minimised risks (para. 5 a, b or c)	Pick-list	<ul> <li>SPM which are contained by technical means;</li> <li>SPM with physical properties permanently modified during intended end use;</li> <li>SPM which are permanently incorporated into a solid matrix.</li> </ul>
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 of 'other' is selected, the free text for the description of the generic identity of the polymer is activated and must be filled.
Estimated emission quantity	Numeric Kilograms/year OR Tons when >1 ton/year Expressed as dry weight Optional field for option A: Concentration range of SPM in the particles Pick-list options:	With respect to the specific use:  Option A: estimated annual volume of particles containing SPM released to the environment. Optional pick-list for SPM concentration in the particles.  Option B: estimated annual volume of SPM6 released to the environment.

<sup>&</sup>lt;sup>6</sup> as described in section 2.3.3



Final

Information	Туре	Description
	0.1-10 %	
	10-30 %	
	30-50 %	
	50-70 %	
	70-90 %	
	90-100 %	
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 0.



## Appendix II – List of codes to be used for the generic identity of the polymers

Generic information on the identity of the polymers used for the purpose of reporting required by paragraphs 11 and 12 of the restriction entry 78 as described in section 2.3.2 will be based on the list of CN/TARIC codes and descriptions, also called the <a href="EU product classification">EU product classification</a> system. The CN/TARIC codes consist of three integrated components:

- The <u>Harmonized System (HS)</u> which is a nomenclature developed by the World Customs Organization (WCO) organised in a hierarchical structure by:
  - sections
  - chapters (2 digits)
  - headings (4 digits)
  - sub-headings (6 digits)

The HS is updated every 5 years.

- The <u>Combined Nomenclature (CN)</u> Annex I to Council Regulation (EEC) No 2658/87 which is the EU's eight-digit (8 digits) coding system, comprising the HS codes with further EU subdivisions. The CN is updated every year.
- The EU Customs Tariff TARIC which comprises the eight-digit code (8 digits) and descriptions of the Combined Nomenclature plus two additional digits (TARIC subheadings with 10 digits); The <a href="TARIC database">TARIC database</a> is updated every month.

The <u>Harmonized System (HS)</u> to the headings level (4 digits) will be utilised for the purpose of reporting the generic identity of the polymers, according to paragraphs 11 and 12 of the restriction, as described below.

In order to set up and maintain the IT system for reporting and for managing the future submitted data to ECHA, in the absence of a numerical identifier for the specific polymers such as a CAS number, it is key to use a standardised numerical identifier such as the HS code.

HS headings for REACH restriction entry 78 reporting on generic information on the identity of the polymers		
HS code	<b>Description</b> (*For the purpose of restriction entry 78 reporting on the generic identity of the polymers, ignore the expression 'in primary forms' or 'in primary forms or in plates, sheets or strip')	
3806	Rosin and resin acids, and derivatives thereof; rosin spirit and rosin oils; run gums.	
3901	Polymers of ethylene, in primary forms.	
3902	Polymers of propylene or of other olefins, in primary forms.	
3903	Polymers of styrene, in primary forms.	
3904	Polymers of vinyl chloride or of other halogenated olefins, in primary forms.	
3905	Polymers of vinyl acetate or of other vinyl esters, in primary forms; other vinyl polymers in primary forms.	
3906	Acrylic polymers in primary forms.	
3907	Polyacetals, other polyethers and epoxide resins, in primary forms; polycarbonates, alkyd resins, polyallyl esters and other polyesters, in primary forms.	
3908	Polyamides in primary forms.	
3909	Amino-resins, phenolic resins and polyurethanes, in primary forms.	



3910	Silicones in primary forms.		
3911	Petroleum resins, coumarone-indene resins, polyterpenes, polysulphides, polysulphones and other products specified in Note 3 to this Chapter, not elsewhere specified or included, in primary forms.		
3912	Cellulose and its chemical derivatives, not elsewhere specified or included, in primary forms.		
3913	Natural polymers (for example, alginic acid) and modified natural polymers (for example, hardened proteins, chemical derivatives of natural rubber), not elsewhere specified or included, in primary forms.		
4001	Natural rubber, balata, gutta-percha, guayule, chicle and similar natural gums, in primary forms or in plates, sheets or strip.		
4002	Synthetic rubber and factice derived from oils, in primary forms or in plates, sheets or strip; mixtures of any product of heading 4001 with any product of this heading, in primary forms or in plates, sheets or strip.		
9999	Other (Any polymer not covered by the other headings) + Generic information on the identity of the polymers*		
	*Text field to be filled by the submitter concerning the generic information on the identity of the polymers not covered by other headings.		