REACH restriction of synthetic polymer microparticles

(Entry 78 of Annex XVII REACH, as introduced by Commission Regulation (EU) 2023/2055)

– Explanatory Guide –

Version 1

Contents

About this document 2

Glossary 3

Definitions 4

Useful links 9

Part I - Narrative Part 11

1. **How to verify whether a product is concerned by entry 78** 12
2. **What are the substances in the scope of the restriction? Which polymers can be considered synthetic polymer microparticles (SPM)?** 13
3. **Testing the degradation of polymers** 21
4. **Testing the solubility of polymers** 27
5. **Prohibition of placing on the market** 28
6. **Derogations from the prohibition of placing on the market** 33
7. **Sector-specific transitional periods for the application of the prohibition of placing on the market** 41
8. **Information requirements, including instructions for use and disposal (IFUD)** 45
9. **Reporting of estimated emissions** 50
10. **Information to competent authorities** 55
11. **Products already on the market at entry into force** 56

About this document

The purpose of this Explanatory Guide is to explain the provisions and facilitate the implementation of entry 78 of Annex XVII of REACH[1] (as introduced by Commission Regulation (EU) 2023/2055) restricting synthetic polymer microparticles (commonly known as "the microplastics restriction").

The document includes a narrative part (Part I), a set of 'questions and answers' (Q&As) (Part II) and several Annexes (Part III) with workflows and illustrative examples. Part II compiles replies (in the form of Q&As) provided to Member States and stakeholders during the 5 ½ year-long process leading to the adoption of the restriction on 25 September 2023, and the 3 months following adoption.

The document was prepared by Commission technical services[2] in consultation with the European Chemicals Agency (ECHA) and the Member States. As such, it does not necessarily represent the views of the European Commission. It has been endorsed by Member States by consensus, except for the view that articles with glitter affixed on their surface do not fall within the scope of the restriction (see Part I, Section 5; Part II, Q&A 2.25, 17.2, 17.6, 17.7, 17.8, 19.1, 19.3; Part III, Annex 3, A3.3), where AT, BE, DE and NL expressed the position that the restriction applies to glitter not permanently affixed on the surface of articles.

This Explanatory Guide is intended to be regularly updated to include additional information as new needs for clarifications emerge from the practical experience of implementing the restriction. While the first version of this document was prepared by the European Commission technical services, updates and future versions of the document will be published by the European Chemicals Agency and shall supersede this version. Questions concerning this Explanatory Guide and/or the microplastics restriction should be addressed to ECHA (http://www.echa.europa.eu/support) or to the national helpdesks which have been specifically set up to answer questions on the implementation of REACH (https://echa.europa.eu/support/helpdesks).

This document is not legally binding, and stakeholders remain wholly responsible for their compliance with the REACH Regulation and other legal obligations. Only the Court of Justice of the European Union can give authoritative interpretations of EU law.

Change history

Version n.	Change	Date	Prepared by
1	N/A (first version)	07/03/2025	Commission

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

[2] The Commission technical services were supported by the external contractor WSP under contract No 090202/2024/912008/ENV.B.2, implementing the Framework Contract ENV.B.2/FRA/2020/0010.

Glossary

ADR	Agreement concerning the International Carriage of Dangerous Goods by Road
AISE	International Association for Soaps, Detergents and Maintenance Products
B2B	Business to Business
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CPR	Regulation (EC) No 1223/2009 on cosmetic products
DLS	Dynamic Light Scattering
DNA	Deoxyribonucleic acid
DU	Downstream User
ECHA	European Chemicals Agency
EEA	European Economic Area
EMA	European Medicines Agency
EPS	Expanded polystyrene
EU	European Union
FFF	Field Flow Fractionation
FPR	Fertilising Product Regulation
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
GLP	Good Laboratory Practice
IFUD	Instructions For Use and Disposal
ISO	International Organization for Standardization
OECD	Organisation for Economic Co-operation and Development
OJEU	Official Journal of the European Union
PET	Polyethylene terephthalate
PPORD	Product and Process Orientated Research and Development
PPWR	Packaging and Packaging Waste Regulation
PVA	Polyvinyl alcohol
QR code	Quick Response Code
RAC	Committee for Risk Assessment
REACH	Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RNA	Ribonucleic acid
SDS	Safety Data Sheet
SEAC	Committee for Socio-Economic Analysis
SPM	Synthetic Polymer Microparticle(s)
TFEU	Treaty on the Functioning of the European Union

Definitions

The table below lists the main definitions relevant to the application of entry 78, together with their sources.

Term	Definition	Source	Link
Article	An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.	REACH, Article 3(3)	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId27
Cosmetic product	Any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.	CPR, Article 2(a)	https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02009R1223-20240424#tocId10
Downstream user	Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user.	REACH, Article 3(13)	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId37
Gas	A substance or mixture which at 50°C has a vapour pressure greater than 300 kPa (absolute), or is completely gaseous at 20°C at a standard pressure of 101,3 kPa.	Entry 78 of Annex XVII of REACH, Paragraph 2(c)	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId1199
Importer	Any natural or legal person established within the Community who is responsible for import.	REACH, Article 3(11)	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId35
Lip product	A cosmetic product which is intended to be applied on the lips.	CPR, preamble to Annexes II to VI	https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02009R1223-20240424#tocId9

Term	Definition	Source	Link
Liquid	A 'liquid' means a substance or mixture that meets any of the following conditions: (i) the substance or mixture at 50 °C has a vapour pressure of not more than 300 kPa, is not completely gaseous at 20 °C and at a standard pressure of 101,3 kPa, and has a melting point or initial melting point of 20 °C or less at a standard pressure of 101,3 kPa; (ii) the substance or mixture fulfils the criteria in the American Society for Testing and Materials (ASTM) D 4359-90 Standard Test Method for Determining Whether a Material Is a Liquid or a Solid; (iii) the substance or mixture passes the fluidity test (penetrometer test) described in chapter 2.3.4 of Part 2 of Annex A to the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) concluded at Geneva on 30 September 1957.	Entry 78 of Annex XVII of REACH, Paragraph 2(d)	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId1199
Make up product	Any substance or mixture intended to be placed in contact with specific external parts of the human body, namely the epidermis, eye brows and eye lashes, with a view to, exclusively or mainly, changing their appearance.	Entry 78 of Annex XVII of REACH, Paragraph 2(e)	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId1199
Microbeads	Synthetic polymer microparticles contained in cosmetics, make-up products, waxes and polishes for use as an abrasive, i.e. namely to exfoliate, polish or clean.	Entry 78 of Annex XVII of REACH, Paragraph 6(b)	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId1199
Mixture	A mixture or solution composed of two or more substances.	REACH, Article 3(2)	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId26
Monomer	A substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process	REACH, Article 3(6)	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId8
Nail Product	A cosmetic product which is intended to be applied on nails.	CPR, preamble to	https://eur-lex.europa.eu/legal-

Term	Definition	Source	Link
		Annexes II to VI	content/EN/TXT/HTML/?uri=CELEX:02009R1223-20240424#tocId9
Natural polymers	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. The concept of "natural polymers" is further detailed in the ECHA guidance on monomers and polymers.	Entry 78 of Annex XVII of REACH; ECHA guidance on monomers and polymers, Chapter 3.2.1.3	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId1199; https://echa.europa.eu/documents/10162/23036412/polymers_en.pdf/9a74545f-05be-4e10-8555-4d7cf051bbed
Not chemically modified	A substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities. The term "chemically modified" is further explained in the ECHA guidance on monomers and polymers.	REACH, Article 3(40); ECHA guidance on monomers and polymers, Chapter 3.2.1.3	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId64; https://echa.europa.eu/documents/10162/23036412/polymers_en.pdf/9a74545f-05be-4e10-8555-4d7cf051bbed
Particle	A minute piece of matter, other than single molecules, with defined physical boundaries.	Entry 78 of Annex XVII of REACH, Paragraph 2(a)	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId1199
Placing on the market	Supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market.	REACH, Article 3(12)	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId36
Polymer	A substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following: (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one	REACH, Article 3(5)	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId29

Term	Definition	Source	Link
	other monomer unit or other reactant; (b) less than a simple weight majority of molecules of the same molecular weight. In the context of this definition a 'monomer unit' means the reacted form of a monomer substance in a polymer;		
Solid	A substance or mixture other than a liquid or gas.	Entry 78 of Annex XVII of REACH, Paragraph 2(b)	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId1199
Substance	A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.	REACH, Article 3(1)	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId25
Supplier of a substance or a mixture	Any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture.	REACH, Article 3(32)	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId56
Synthetic Polymer Microparticles	Polymers that are solid and which 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	Entry 78 of Annex XVII of REACH	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId1199

Term	Definition	Source	Link
	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; (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.		
Use	Use means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation.	REACH, Article 3(24)	https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20231201#tocId48

Useful links

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

Commission website on Commission Regulation (EU) 2023/2055: https://single-market-economy.ec.europa.eu/commission-regulation-eu-20232055-restriction-microplastics-intentionally-added-products_en

Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), consolidated version of 01.12.2023: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20231201

European Chemicals Agency (ECHA) preparatory work underlying Commission Regulation (EU) 2023/2055:

- Annex XV restriction dossier, public consultation comments, RAC and SEAC final opinion: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73
- Supplementary RAC opinion on the restriction dossier on intentionally-added microplastics: https://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment/opinions-of-the-rac-adopted-under-specific-echa-s-executive-director-requests

ECHA Guidance on requirements for substances in articles (useful to distinguish articles from mixtures, and to assess whether a mixture is an integral part of an article): https://echa.europa.eu/documents/10162/2324906/articles_en.pdf

ECHA Catalogue of borderline cases between articles and substances/mixtures: https://echa.europa.eu/documents/10162/17240/borderline_cases_substances_articles_catalogue_en.pdf

ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12 “Use description” (useful to distinguish industrial uses from professional uses): https://echa.europa.eu/documents/10162/2324909/r12_guidance_draft_for_committees_201507_en.pdf

ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.16 “Environmental exposure assessment” (useful for estimating SPM emissions): https://echa.europa.eu/documents/10162/17224/information_requirements_r16_en.pdf

ECHA Guidance for monomers and polymers: https://echa.europa.eu/documents/10162/2324906/polymers_en.pdf

ECHA Guidance for Annex V- Exemptions from the obligation to register: https://echa.europa.eu/documents/10162/2324906/annex_v_en.pdf/

ECHA Guidance on Scientific Research and Development (SR&D), Product and Process Orientated Research and Development (PPORD):

http://echa.europa.eu/documents/10162/2324906/ppord_en.pdf/

ECHA's factsheet on “Information for parties involved in contractual arrangements for toll manufacturing”:
https://echa.europa.eu/documents/10162/17226/factsheet_toll_manufacturer_en.pdf

Part I - Narrative Part

The narrative part of the Explanatory Guide describes in simple terms the provisions and the intended implementation of the restriction of **"synthetic polymer microparticles" (SPM),** laid down in entry 78 of Annex XVII of the REACH Regulation, as introduced by Commission Regulation (EU) 2023/2055. The narrative part (Part I) should be read together with the Questions and Answers (Q&A) in Part II, and the Annexes (Part III) of this Explanatory Guide.

The general approach of entry 78 closely follows that one recommended in the relevant European Chemicals Agency (ECHA) Annex XV restriction dossier and the corresponding final opinion of ECHA's scientific committees, where it was concluded that the intentional use of SPM, resulting in releases to the environment, poses a risk to the environment that is not adequately controlled. The restriction aims to address this risk. It entails a ban on the placing on the market of all polymers that meet the SPM definition unless their specific use is derogated from the ban. The restriction does not entail a ban on the use of the SPM. The ban on placing SPM on the market starts applying at different times for different uses depending on the transitional period assessed as necessary taking into account the socio-economic impacts. The restriction measures laid down in entry 78 differ depending on whether using the SPM or the product containing them inevitably leads to SPM releases into the environment, or whether the releases can be prevented or minimised. Note that the term "product" is used in the Explanatory Guide to refer to a substance, a mixture, or a combination of a substance/mixture and an article. The term is not used to refer to articles on their own, as SPM that are articles under REACH, or an integral part of an article according to ECHA Guidance on requirements for substances in articles, are excluded from the scope of entry 78.

The main provisions of the restriction are outlined below:

- **Paragraph 1** of entry 78 lays down a general ban on the placing on the market of SPM, on their own or intentionally present in mixtures; the scope of the ban is broad enough to capture all cases where using the SPM or the product containing them inevitably results in the release of those SPM into the environment; or where there is not sufficient information to exclude that SPM are released.
- **Paragraphs 4 and 5** include derogations from the ban on the placing on the market for certain cases where using the SPM or the product containing them does not release SPM, or those releases can be prevented/minimised; or to avoid overregulation of certain uses and sectors.
- **Paragraph 6** lays down transitional periods for certain SPM uses, i.e. the time before the ban on the placing on the market in Paragraph 1 starts applying to those uses. (For uses not listed in Paragraph 6, the ban in Paragraph 1 applies as of 17 October 2023, date of entry into force of the restriction, unless derogations under Paragraphs 4, 5 or 16 apply).
- The risk of most (products containing) SPM derogated from the ban on the placing on the market under Paragraphs 4 and 5 are managed through the measures outlined in Paragraphs 7-12:

- **Paragraphs 7, 8 and 10** lay down requirements for suppliers of derogated SPM to provide instructions on how to handle and dispose of the (SPM in the) product to prevent or minimise the SPM loss to the environment;
- **Paragraphs 11 and 12** lay down requirements for reporting to ECHA of estimated SPM emissions, to monitor the effectiveness of the Instructions for Use and Disposal (IFUD) and the restriction in general.

- **Paragraphs 14 and 15** lay down the information that manufacturers, importers and industrial downstream users of products containing SPM have to provide to competent authorities at those authorities' request.
- **Paragraph 16** lays down a derogation for SPM placed on the market before the entry into force of the restriction on 17 October 2023 and not granted a transitional period under Paragraph 6.

1. How to verify whether a product is concerned by entry 78

This Section lists the recommended verification steps to be followed to determine whether a product (a substance, a mixture, or a combination of substance/mixture and an article) is in the scope of entry 78 (SPM in articles[3] are excluded from the scope of the entry). It is recommended to carry out the verification steps in the order given. A negative outcome in any of the steps 1 to 4 is sufficient to conclude that the product is not in the scope of entry 78. Step 5 is to verify whether the product containing the SPM is subject to a ban on placing on the market or to IFUD and reporting obligations. Sections 2 to 7 of this Narrative Part, together with Part III, Annexes 1-2, can help to carry out the recommended verification steps:

1. Verify whether the product **contains SPM**. If no polymer fulfilling the SPM definition is present in the product, entry 78 does not apply.

   → for help identifying SPM, see Sections 2 to 4 of this Narrative Part, and the workflows (Tiers 1a, 1b and 2) in Part III, Annex 1.

2. Verify whether the product consists of **SPM on their own**, or is **a mixture containing SPM**, or is **a combination of an article and a mixture containing SPM** (i.e. the mixture is not an integral part of the article). If the object is regarded as an article, including when the SPM (or the mixture containing them) is an integral part of the article, entry 78 does not apply.

   → for help identifying SPM on their own or in mixtures, and discriminating substances/mixtures from articles under REACH, see Sections 2 and 5 of this Narrative Part, Part III, Annexes 1 and 3 and chapter 2.3 of ECHA guidance on requirements for substances in articles.

3. If the product consists of a mixture containing SPM, verify whether the **SPM are intentionally present** in the mixture, i.e. they are present or added to grant a

[3] SPM that are articles under REACH, or are an integral part of an article according to ECHA Guidance on requirements for substances in articles.

specific, sought-after property to the mixture. If the presence of SPM is unintentional (e.g. from the breakdown of plastic packaging, or larger plastic/polymeric objects), entry 78 does not apply.

→ for help, see Section 5 of this Narrative Part and Part III, Annex 1, Tier 3

4. If the product consists of a mixture containing SPM, verify whether the SPM are present in the mixture in **concentration equal or greater than 0.01 % by weight** (of the mixture). If the SPM concentration in the mixture is lower than 0.01% w/w, entry 78 does not apply.

   → for help, see Section 5 of this Narrative Part and Part III, Annex 1, Tier 3.

5. Following steps 1-4, if it is confirmed that entry 78 applies, verify whether any of the **derogations in Paragraphs 4, 5 or 16 of entry 78** apply. If **any of those derogation applies**, the SPM are permanently derogated from the ban on the placing on the market but are usually subject to mandatory IFUD (Paragraphs 7, 8 and 10 of entry 78) and reporting obligations (Paragraph 11 and 12 of entry 78). If **no derogation applies**, the SPM cannot be placed on the market, on their own or in mixtures, as of 17 October 2023 or, for uses granted a transitional period in Paragraph 6 of entry 78, after the date indicated in that Paragraph.

   → for help, see Sections 6 and 7 of this Narrative Part, and Part III, Annex 2, Box 3 and 4.

2. What are the substances in the scope of the restriction? Which polymers can be considered synthetic polymer microparticles (SPM)?

Entry 78 targets solid polymers that are "synthetic polymer microparticles" (SPM) and therefore have the potential to accumulate into the environment as microplastics.

The left-hand column of entry 78 sets the specific conditions polymers must fulfil to be regarded as SPM and be in the scope of the restriction. These conditions are explained below. The workflows in Part III, Annex 1, can also help assess whether a solid polymer is a SPM or whether a mixture contains SPM and would therefore be in the scope of entry 78.

As a **first condition,** to be regarded as SPM, the polymers have to be, at the same time:

- **solid**; and
- either **synthetic** polymers, **or** natural polymers that have been **chemically modified**; and
- **organic** (i.e. contain carbon atoms anywhere in their structure), and
- **not degradable**, when tested in accordance with Appendix 15 of Annex XVII of REACH; and

- "**insoluble**", i.e. they do not have a solubility higher than 2g/L when tested in accordance with Appendix 16 of Annex XVII of REACH.

The first condition is a consequence of the definition of SPM in the left-hand column of entry 78, which indicates that polymers have to be solid and that the following polymers are excluded from the scope of entry 78:

- Liquid polymers ("liquid" is defined in Paragraph 2(d) of entry 78; see also the Definitions section, page 5);
- Natural polymers, i.e. 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; as these polymers are naturally present in nature, they are considered inherently degradable; the term "not chemically modified" is defined in Article 3(40) of REACH and further explained in the ECHA guidance on monomers and polymers; the concept of natural polymers is further detailed in the same guidance;
- Degradable polymers, where degradation is proven in accordance with Appendix 15 of Annex XVII of REACH; these polymers degrade and do not accumulate in the environment;
- Soluble polymers, where solubility above 2 g/L is proven in accordance with Appendix 16 of Annex XVII of REACH; these polymers dissolve in water, and do not accumulate in the environment;
- Polymers without carbon in their structure (neither in their backbone nor in their side chains), as there is not enough data proving they accumulate in the environment.

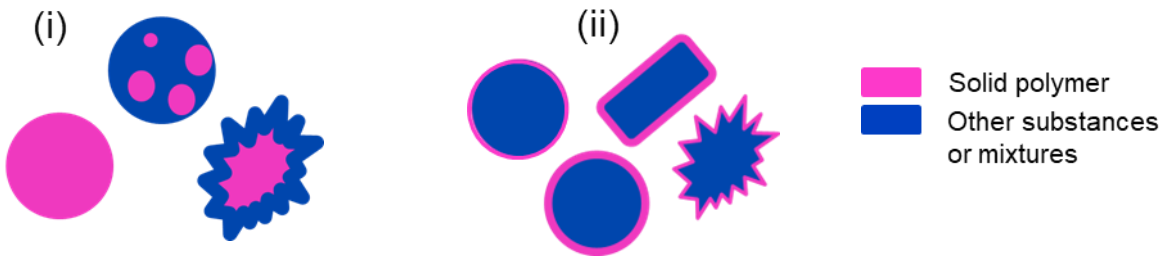
NB: For the purpose of the subsequent explanations in this Section, the term "solid polymers" refers to polymers fulfilling the first condition above.

As a **second condition,** to be regarded as SPM, the solid polymers must be either:

i. **contained in particles** in concentration equal or greater than 1% w/w, i.e. the weight of the polymer(s) is between 1% and 100% of the total weight of the particle containing the polymer(s); or
ii. **build a continuous coating around particles** (including particles with a liquid core, such as vesicles); no concentration limit applies in this case; the coating needs to be "continuous", i.e. the coating cannot be made of isolated polymer patches that do not touch each other; however, a continuous coating does not necessarily cover the entire surface of the particle completely and the presence of small gaps in the coating is possible.

Figure 1 shows examples of SPM (the solid polymer in pink) either (i) contained in particles or (ii) coating particles. The SPM is the polymeric constituent of the particle. The other, non-polymeric substances or mixtures (in blue) are not a SPM.

Figure 1. Examples of SPM contained in particles (i) or coating particles (ii)

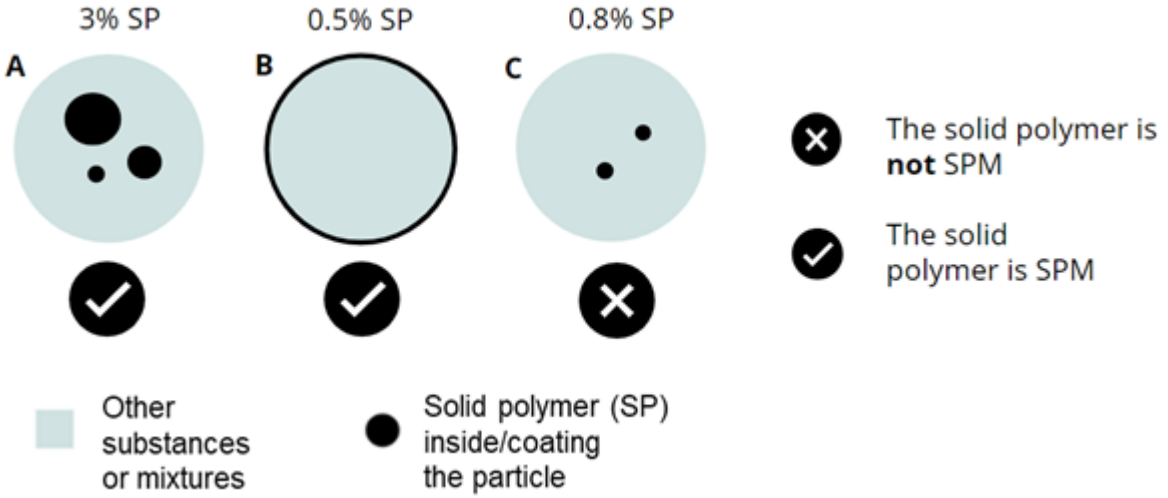


Modified from ECHA Annex XV restriction report

Note that, when two or more solid polymers (fulfilling the first condition) are contained in the same particle, their concentrations must be combined when calculating whether the 1% concentration limit in point (i) above is met (i.e., the combined concentration of the solid polymers in the particle should be used for the calculations). If the combined concentration of solid polymers in the particle is at least 1% w/w, then the combination of those solid polymers (i.e. the polymeric constituent of the particle) is an SPM (provided the other SPM conditions are also met).

As indicated in point (ii) above, there is no concentration limit when the solid polymers coat particles. Polymers that coat particles (including vesicles) are to be regarded as SPM even if the polymer(s) represent less than 1% of the weight of the coated particle. Illustrative examples of the application of concentration limits to identify SPM are presented in Figure 2.

Figure 2. Examples of application of concentration limits to SPM contained in particles or coating particles



Source: Norwegian Environment Agency. Modified by the European Commission.

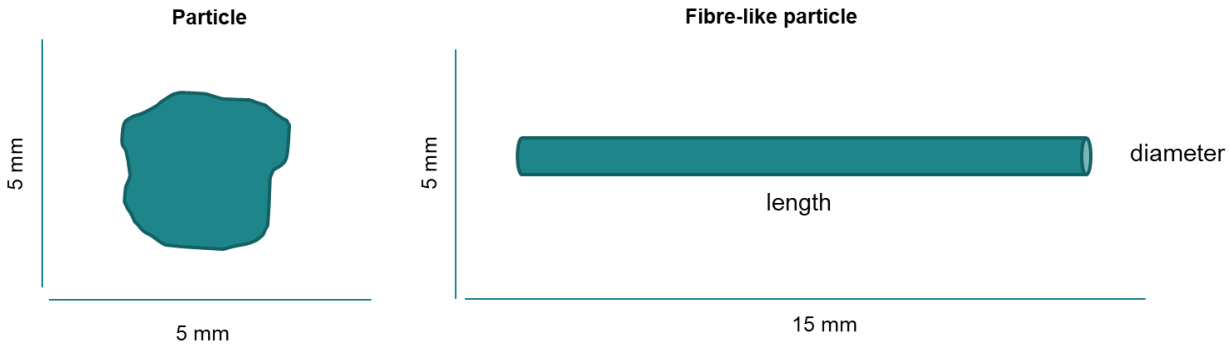
In Figure 2A, the solid polymer (black dot) is an SPM because it is contained in the particle (light grey circle) and it represents at least 1% of the weight of that particle. In Figure 2C, the solid polymer is not an SPM because it is contained in the particle and represents less than 1% of the weight of that particle. In Figure 2B, the solid polymer (black circumference) coats the

particle and therefore is an SPM even if it represents less than 1% of the weight of that particle.

The scope of the restriction is limited to solid polymers contained in or building a continuous surface coating on particles, as it is only for these kinds of polymers that an unacceptable risk has been demonstrated. This is why the restriction refers to these polymers as "synthetic polymer microparticles". It was decided not to employ the common term 'microplastics' – although widely known and used – because potentially misleading, as the scope of the restriction covers more solid polymers than just those constituting what most people would think of as "plastic".

As third condition, for polymers to be regarded as SPM**, at least 1% by weight of the particles** containing or coated by the solid polymers **need to measure 5 mm or less in all dimensions** or, for particles with a length-to-diameter ratio greater than 3 (fibre-like particles), at least 1% of the particles containing or coated by the solid polymers need to **have a length of 15 mm or less**. To identify fibre-like particles, the mean length-to-diameter ratio can be used.

Figure 3. Particles (left) vs fibre-like particles (right)

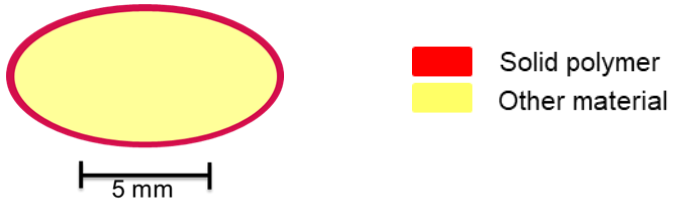


A polymer (or a combination of polymers) that fulfils the three conditions above is a SPM. A polymer (or a combination of polymers) that does not fulfil one or more of the three conditions above is not a SPM (and therefore is not in the scope of the restriction).

Some additional illustrative examples of how the three conditions above should be applied are provided in Figure 4. Here tablets (i.e., solid mixtures) of different size and composition are used to illustrate different cases, but the same conclusions would apply to other mixtures.

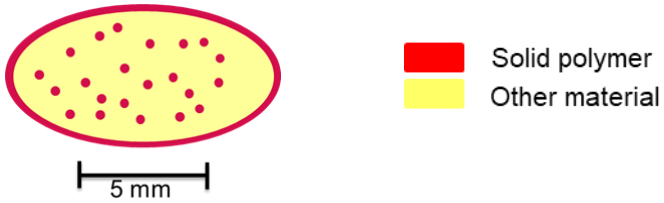
Figure 4. Application of the SPM conditions to (solid) mixtures

A. Tablet > 5 mm, with a continuous solid polymer coating.



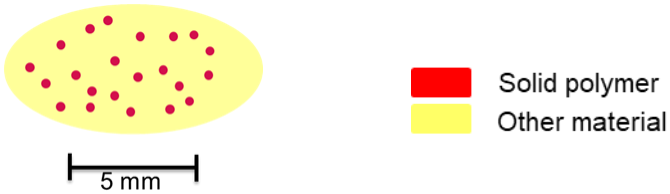
The solid polymers in the coating are not SPM, because they coat a particle (the tablet, in this case) that is >5 mm in size.

B. *Tablet > 5 mm, with a continuous solid polymer coating, and a core containing granules, powder, crystals or flakes that are smaller than 5 mm and are made of 100% w/w solid polymer(s).*



The solid polymers in the coating are not SPM because they coat a particle (the tablet, in this case) that is >5 mm in size**; the solid polymers in the granules, powder, crystals or flakes are SPM** because (i) the polymers are contained in particles (the granules, powder, crystals or flakes, in this case) that are smaller than 5 mm and (ii) the polymers constitute at least 1% of the weight of those particles (specifically, they constitute 100% of the weight of the granules, powder, crystals or flakes).

C. *Tablet > 5mm, with a core containing granules, powder, crystals or flakes that are smaller than 5 mm and are made of 100% w/w solid polymer(s).*



The solid polymers in the granules, powder, crystals or flakes are SPM because (i) the polymers are contained in particles (i.e. the granules, powder, crystals or flakes) that are smaller than 5 mm and (ii) the polymers constitute at least 1% of the weight of those particles (specifically, they constitute 100% w/w of the granules, powder, crystals or flakes).

D. *Tablet < 5mm, with a continuous solid polymer coating*

The solid polymers in the coating are SPM because they coat a particle (the tablet, in this case) that is < 5 mm in size. As the solid polymer is coating the tablet (rather than being contained in the tablet), the polymer concentration in the tablet is irrelevant (the 1% w/w threshold only applies when the polymer is contained in a particle, not when it is coating a particle).

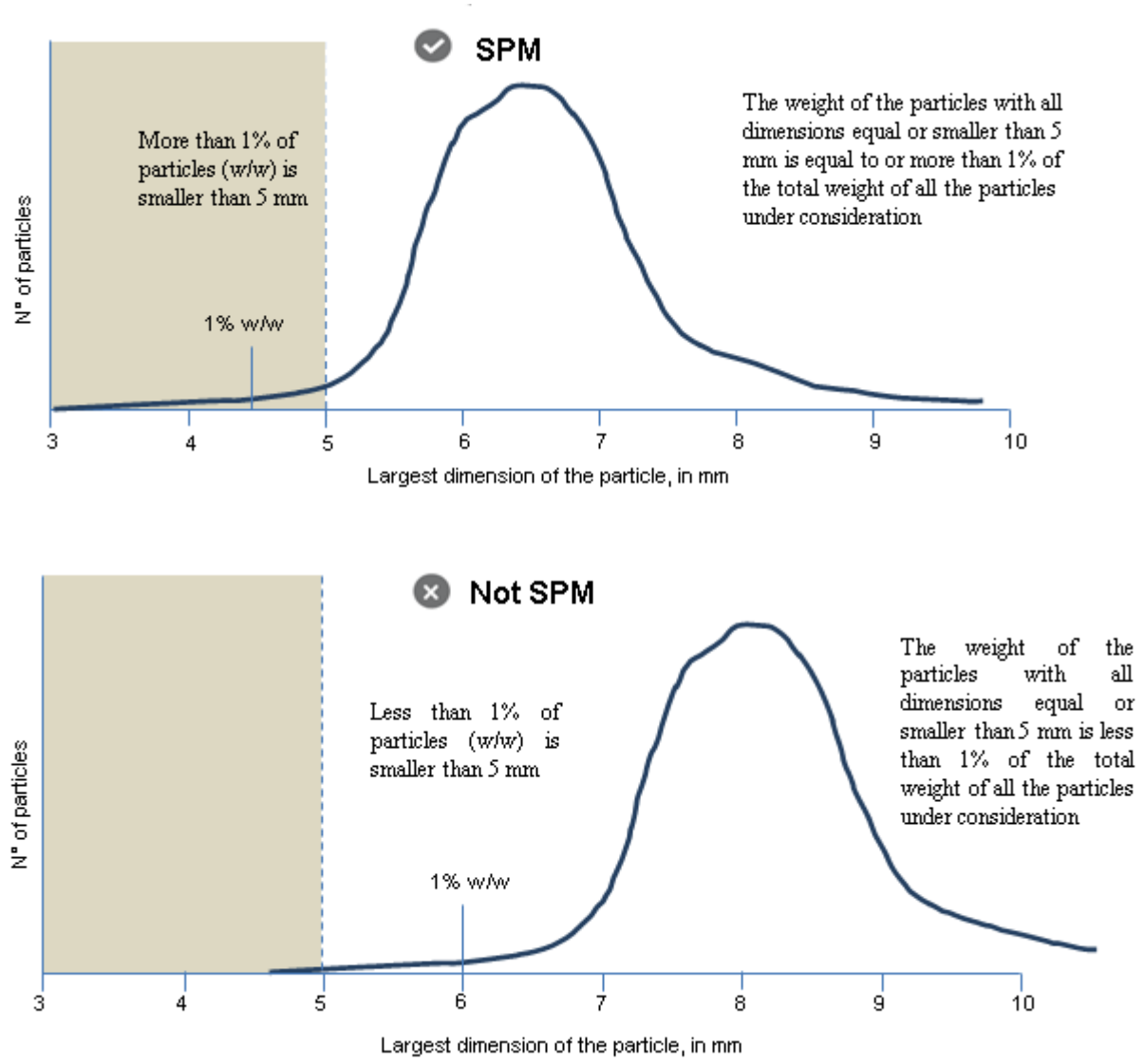
E. Tablet < 5 mm, with a continuous solid polymer coating, and a core containing 10% w/w of solid polymer(s)

In this case, both the solid polymers coating the tablet and those in the tablet core are SPM. **The solid polymers coating the tablet are SPM** because they coat a particle (i.e. the tablet) whose size is < 5 mm.
The solid polymers in the tablet core are SPM because (i) the polymers are contained in a particle (i.e. the tablet) that is smaller than 5 mm and (ii) the polymers constitute at least 1% of the weight of that particle (specifically, they constitute 10% of the weight of the tablet).

Note that the conclusions concerning solid polymers in the tablet core in examples B and C imply the presence of particles in the tablet core, such as granules, powder, crystals or flakes, or other solid particles. If the tablet core (or, more generally, the mixture) does not contain particles, then the polymers in the core are not SPM (see workflow in Part III, Annex 1, Figure 2).

When assessing compliance with the third condition (particle size), it should be kept in mind that, in a batch of particles containing or coated by solid polymers, **it is sufficient that at least 1% of the particles fulfils the size requirements** for all particles to be considered as fulfilling that criterion. What this means in practice is that if only 1% by weight of the particles under consideration (i.e. containing at least 1% by weight of solid polymers or coated by them) are smaller than 5 mm in all dimensions - or are shorter than 15 mm, if they have a length-to-diameter ratio > 3, and the remaining 99 % by weight are bigger than 5 mm - or longer than 15 mm, if they have a length-to-diameter ratio > 3, then the solid polymers in the totality of those particles would be considered SPM and fall in the scope of the restriction (including the polymers in the 99 % of particles that are bigger than 5 mm, or longer than 15 mm if they have a length-to-diameter ratio > 3). Illustrative examples of size distributions of particle batches fulfilling and not fulfilling the size criterion are presented in Figure 5. In the top example, more than 1% w/w of particles in the batch measure less than 5 mm, so the solid polymers contained in or coating all the particles in the batch are SPM. In the bottom example, less than 1% w/w of particles in the batch measures 5 mm or less, therefore the solid polymers in the particles are not SPM.

Figure 5. Additional particle size requirements



Entry 78 does not set a lower size limit for the particles containing or coated by SPM. Setting a lower size limit could have excluded relevant nanoparticles from the scope of the proposed restriction and led to regrettable substitution with particles of smaller size and possibly higher risk. This would have reduced the effectiveness of the restriction. In the absence of a lower size limit, it is possible to have SPM in or coating particles that measure only a few nanometres. However, it is acknowledged that the currently available analytical technology does not always allow measurement and quantification of particles smaller than 0.1 µm, particularly in complex matrices, making it difficult to quantify the amount of SPM in the product and therefore, verify the compliance with the concentration limit referred to in Paragraph 1. Consequently, the restriction includes a **temporary 0.1 µm lower size limit** for enforcement purposes (0.3 µm for fibre-like particles). This allows enforcing the restriction until reliable detection and quantification methods for particles with dimensions below 0.1 µm are developed. The temporary lower size limit does not apply to those cases where the available analytical methods or the documentation accompanying the product allow

quantifying the concentration of SPM in the product. While the temporary 0.1 µm lower size limit applies, **it is acceptable to consider only the weight of particles in the 0.1 µm - 5 mm size range** when verifying if at least 1% of the particles containing or coated by SPM fulfils the size requirements.

It should be noted that the reference in Paragraph 3 (i.e. the temporary lower limit of 0.1 µm) is dynamic, so the temporary lower limit will no longer apply as soon as methods are developed allowing the reliable detection and quantification of particles below 0.1 µm. To ensure that stakeholders and Member States authorities are informed, any improvement in detection technology leading to the temporary lower limit in Paragraph 3 not being applicable anymore will be included in future updates of this document. If Paragraph 3 no longer applies, there will be no lower size limit for the particles containing or coated by SPM. Should setting a new temporary lower limit be necessary (e.g. to align with the limits of quantification of the improved detection technology), entry 78 will need to be amended to include the new temporary limit value. This will ensure harmonisation and legal certainty across the EU.

Text Box 1 – Examples of SPM in products

Synthetic microbeads in a 'rinse-off' facial scrub

Synthetic microbeads are added to a cosmetic product, e.g., a 'rinse-off' facial scrub, to function as exfoliating agents. Assuming that all the microbeads measure less than 5 mm and are (partly) made of polyethylene (which is a solid, organic, insoluble, non-biodegradable, synthetic polymer), the polyethylene would be regarded as SPM if it represents at least 1% by weight of the microbeads.

Synthetic polymer glitter

Considering individual glitter pieces measuring less than 5 mm and made of solid, organic, insoluble, non-biodegradable, synthetic polymer coated with aluminium to reflect light, the polymer is a SPM if its weight constitutes at least 1% by weight of the glitter pieces. In the case where more than one solid, organic, insoluble, non-biodegradable, synthetic polymer is present, the polymers are SPM if their combined weight constitutes at least 1% of the weight of the glitter pieces.

Note that, if the polymers in the glitter are polymers that are inorganic, natural, biodegradable or soluble in water, then those polymers are not SPM and are outside of the scope of the restriction.

Similarly, glitter that contains less than 1% by weight of solid, organic, insoluble, non-biodegradable synthetic polymer(s) is also out of scope.

Equally, glitter where more than 99% by weight of the individual glitter pieces are larger than 5 mm in any dimension, or larger than 15 mm, if individual glitter pieces have a length to diameter ratio greater than 3, are also out of scope.

3. Testing the degradation of polymers

In order to prove that a solid polymer is degradable for the purpose of entry 78 (and therefore not in the scope of the restriction), it is necessary to test the degradation of the polymer in accordance with the standard test methods listed in Appendix 15 of Annex XVII of REACH.

Good Laboratory Practice

Appendix 15 requires the degradation tests to be carried out according to the principles of good laboratory practice (GLP) developed in accordance with the Organisation for Economic Cooperation and Development (OECD) and laid down in Directive 2004/10/EC, i.e. in GLP-compliant laboratories subject to national competent authority GLP monitoring programmes (including authorities from the European Economic Area (EEA), such as Norway, and from Israel, Japan, and Switzerland, with whom the EU has concluded Mutual Recognition Agreements for GLP).

Verifying the GLP compliance of laboratories is the responsibility of the national competent authorities that administer the national GLP monitoring programmes. The list and contact details of EU national GLP monitoring authorities is published on the Commission's website. The Commission also publishes and regularly updates the list of inspected test facilities.

In accordance with Directive 2004/10/EC and Directive 2004/9/EC, acceptable GLP data can also come from a laboratory:

- from non-EU countries that are OECD members[4] or full adherents to the OECD mutual acceptance of data (MAD) system[5];
- from countries that are provisional adherents to the OECD MAD system and in which laboratories have been inspected jointly by the GLP monitoring authority concerned and by an OECD GLP monitoring authority.

Tests that are conducted in a laboratory situated in a country which has not joined the OECD MAD system can be accepted as GLP-compliant tests under the following conditions:

- Before performing the test, the GLP compliance of the laboratory has been inspected by:
    - an EU or an EEA GLP monitoring authority; or
    - GLP monitoring authorities in Israel, Japan and Switzerland (with whom the EU holds mutual recognition agreements); or
    - other GLP monitoring authorities of OECD member states or full adherents to the OECD MAD system, on a case-by-case basis; or

[4] as of June 2024: Australia, Canada, Chile, Colombia, Costa Rica, Israel, Japan, Korea, Mexico, New Zealand, Switzerland, Turkey, United Kingdom and USA. Israel, Japan, and Switzerland, in addition to being OECD member states, have a Mutual Recognition Agreement for GLP with the EU.
[5] as of June 2024: Brazil, India, Malaysia, Singapore and South Africa, as well as Argentina for industrial chemicals, pesticides and biocides only.

    - other national GLP monitoring authority which has been assessed on-site by representatives of the EU GLP Working Group and whose Compliance Monitoring Programme could be regarded as being equivalent to the EU GLP Compliance Monitoring Programme; and
- The test facility has been found to be operating in compliance with GLP principles.

As alternative to GLP compliance, Appendix 15 allows tests to be carried out in laboratories with ISO 17025 accreditation, or laboratories accredited with other international (quality) standards recognised as being equivalent[6] by the Commission or ECHA.

Permitted Test Methods

Appendix 15 lists the permitted test methods for measuring degradation, organised into five groups on the basis of their design and underlying rationale. Groups 1 to 3 include relatively rapid but stringent screening tests. Groups 4 and 5 include screening and simulation tests which are increasingly more sophisticated, technically demanding and lengthy, but use testing conditions that more accurately mimic the environmental conditions where the degradation takes place. The test methods mainly measure biotic degradation (i.e., biodegradability) but the presence of some abiotic degradation during the test cannot be excluded – hence the use of the general term "degradation" in entry 78.

Groups 1-3 test methods measure degradation by measuring the mineralisation rate of the test material in accordance with the provisions of the chosen test method. The mineralisation rate is determined by measuring either the oxygen consumption or the evolution of carbon dioxide over the test duration. Polymers that pass any of those tests will degrade fully and rapidly in any environment. For this reason, it is sufficient for polymers to pass one of the tests in groups 1 to 3 to prove they are degradable in any environment and therefore out of the scope of the restriction. Group 4 and 5 test methods, on the other hand, measure degradation in conditions that depend on the environmental compartment where the test is carried out. Consequently, when using test methods in groups 4 or 5 to prove polymer degradation, it is required that polymers pass those tests in three different environmental compartments (water, sediment and soil) to ensure that only polymers capable of degrading in different environmental conditions - and therefore unlikely to accumulate in the environment in real life conditions - are excluded from the scope of the restriction.

The ISO test methods included in Group 4 (see Figure 6), are specifically designed to determine the biodegradability of natural and/or synthetic polymers or copolymers, including when mixed with formulation additives such as plasticisers, colourants or other compounds. The test methods assess the degradation of solid polymers relative to a reference material (typically, but not exclusively, cellulose). ISO tests are concluded when the biodegradation of the reference and test material reaches a plateau within a maximum of 6 months in aqueous tests and 24 months in soil/sediment tests. The test material may be used in powder form, but it may also be introduced as films, pieces, or fragments.

[6] Note: As of July 2024, there are no standards recognised as being equivalent.

Figure 6. ISO test methods included in Appendix 15.

Method	Reference	Analytical Method	Concentration of Test Material	Duration	Concentration of Inoculum	Inoculum	Pass level
Ultimate aerobic biodegradability of plastic materials in aqueous medium	EN ISO 14851	Respirometry: oxygen consumption	100 – 2000 mg OC /l	2 months (up to 6 months)	30 – 1000 mg/l SS	Activated sludge	≥ 90% relative to the degradation of the reference material in 6 months
Ultimate aerobic biodegradability of plastic materials in aqueous medium	EN ISO 14852	CO_2 evolution	100 – 2000 mg OC /l	≤ 6 months	30 – 1000 mg/l SS	Activated sludge; soil; compost	≥ 90% relative to the degradation of the reference material in 6 months
Ultimate aerobic biodegradability of plastic materials in soil	EN ISO 17556	Respirometry: oxygen consumption; CO_2 evolution	(Suitable concentrations) 1000 mg/kg 12500 mg/kg	6 months (up to 24 months)	-	No inoculum added	≥ 90% relative to the degradation of the reference material in 24 months
Aerobic biodegradation of non-floating plastic materials in a seawater/sediment interface	EN ISO 19679 / 18830	CO_2 evolution / oxygen consumption	150 – 300 mg/l (water +sediment)	≤ 24 months	-	No inoculum added	≥ 90% relative to the degradation of the reference material in 24 months
Determination of the aerobic biodegradation of non-floating materials exposed to marine sediment - Method by analysis of evolved carbon dioxide	EN ISO 22404	CO_2 evolution	solid, milled, 100 mg in 400 g sediment	≤ 24 months	-	No inoculum added	at least 90% mineralisation relative to the reference material; or 90% absolute mineralisation

The OECD simulation tests in Group 5 are used to simulate degradation half-lives under semi-realistic environmental conditions. They are technically complex to perform, as they require appropriately radiolabelled test materials. Obtaining these tests materials requires multiple steps in a certified radio-isotope laboratory: (i) synthesizing a monomer radiolabelled in the right position, (ii) the polymerisation of the monomer to form the polymeric material, and (iii) grinding or milling the radiolabelled material to the appropriate test size, where needed.

Agricultural and horticultural products

Appendix 15 sets specific conditions to prove (for the purpose of entry 78) the degradability of polymers used in **agricultural and horticultural products**, e.g., non-CE marked fertilising products (i.e. fertilising products not covered by the Fertilising Product Regulation

(FPR; Regulation (EU) 2019/1009) that are authorised according to national legislation in the respective Member State and thus are not CE-marked), plant protection products, coated seeds, etc. The intention is to have, for these polymers, degradability criteria that are consistent with the general biodegradability requirements set for polymers in CE-marked fertilisers (i.e. fertilising products within the scope of the FPR) by Article 42(6)[7] of the FPR. The objective is to ensure that the degradability[8] of polymers in non-CE-marked and CE-marked fertilisers can be verified using the same tests methods and comparable pass criteria (see Figure 7). To this end, Appendix 15 requires that the degradation of polymers used in agricultural and horticultural products (including non-CE marked fertilisers) needs to be proven in soil and water only, with pass criteria for group 4 and 5 test methods that have been adapted to reflect the conditions set in Article 42(6) of the FPR ('at least 90 % of the organic carbon converted into carbon dioxide in a maximum period of 48 months after the end of the claimed functionality period of the EU fertilising product indicated on the label'). Appendix 15 sets different conditions for proving the degradability of polymers which are used in non-CE marked fertilisers as coating agents or to increase the water retention capacity or the wettability ('coating/wetting polymers'), and polymers with other functions, e.g. technical additives, anti-caking or anti-dusting agents, used in non-CE marked fertilisers and other agricultural and horticultural products. The conditions to prove the degradation of coating/wetting polymers in non-CE marked fertilisers are set in Section 2.1 of Appendix 15. Section 2.2 sets the conditions to prove the degradation of (i) coating/wetting polymers used in agricultural and horticultural products other than fertilisers (e.g. plant protection products, coated seeds, etc), and (ii) polymers with other functions (e.g. technical additives, anti-caking or anti-dusting agents, etc.) used in non-CE marked fertilisers and in agricultural and horticultural products other than fertilisers.

For coating/wetting polymers in non-CE fertilisers, Section 2.1 provides that the applicable test methods and degradability criteria used to determine whether such polymers are degradable for the purpose of entry 78 are those laid down for coating/wetting polymers used in CE-marked fertilisers in Commission Delegated Regulation (EU) 2024/2770. As a result,

[7] Article 42(6) of the FPR says:
"By 16 July 2024, the Commission shall assess biodegradability criteria for polymers referred to in point 2 of component material category 9 in Part II of Annex II and test methods to verify compliance with those criteria and, where appropriate, shall adopt delegated acts pursuant to Paragraph 1 which lay down those criteria.
Such criteria shall ensure that:
(a) the polymer is capable of undergoing physical and biological decomposition in natural soil conditions and aquatic environments across the Union, so that it ultimately decomposes only into carbon dioxide, biomass and water;
(b) the polymer has at least 90 % of the organic carbon converted into carbon dioxide in a maximum period of 48 months after the end of the claimed functionality period of the EU fertilising product indicated on the label, and as compared to an appropriate standard in the biodegradation test; and
(c) the use of polymers does not lead to accumulation of plastics in the environment."

[8] The conditions to prove (for the purpose of entry 78) the degradability of polymers used in non-CE-marked fertilisers are set in Appendix 15 of the entry. The biodegradability conditions to be complied to by polymers used in CE-marked fertilisers are set in the FPR and in three delegated acts complementing the FPR: Commission Delegated Regulation (EU) 2024/2770 (coating agents and water retention polymers), Commission Delegated Regulation (EU) 2024/2790 (polymers in Component Material Category 1) and Commission Delegated Regulation (EU) 2024/2788 (polymers in Component Material Category 11).

the same degradability criteria apply to coating/wetting polymers, regardless of whether they are used in CE- or non-CE marked fertilisers.

For coating/wetting polymers used in agricultural and horticultural products other than fertilisers, and polymers with other functions used in non-CE marked fertilisers and in agricultural and horticultural products other than fertilisers, Section 2.2 requires that degradation is proven in soil and water and, if group 4 and 5 test methods are used, specific pass criteria must be met that take into account the functionality period of the product. The harmonisation between, on the one hand, the criteria to prove degradation for the purpose of entry 78 when these polymers are used in non-CE-marked fertilisers and, on the other hand, the biodegradability requirements for the same polymers in CE-marked fertilisers is ensured by two additional delegated acts: Commission Delegated Regulation (EU) 2024/2790 (polymers in Component Material Category 1) and Commission Delegated Regulation (EU) 2024/2788 (polymers in Component Material Category 11) . Those delegated acts require that, in order to be used in CE-market fertilisers, polymers that have other functions other than coating/wetting have to fulfil the degradability requirements set out in Section 2.2 of Appendix 15.

Figure 7. Overview of (bio)degradability requirements for polymers used in CE-marked and non-CE marked fertilisers.

	In non-CE-marked fertilisers	**In CE-marked fertilisers**
Coating/wetting polymers	Degradability criteria set in Section 2.1 of Appendix 15. Section 2.1 requires the degradation criteria for coating/wetting polymers in non-CE marked fertilisers to be the same as the biodegradation criteria set by Commission Delegated Regulation (EU) 2024/2770 for coating/wetting polymers in CE-marked fertilisers (see right).	Biodegradability criteria for coating/wetting polymers in CE marked fertilised are set by Commission Delegated Regulation (EU) 2024/2770.
Polymers that have other functions than coating/ wetting (e.g. technical additives, anti-caking or anti-dusting agents)	Degradability criteria set in Section 2.2 of Appendix 15.	Biodegradability criteria of polymers which have other functions are set by Commission Delegated Regulation (EU) 2024/2790 (for polymers in Component Material Category 1) and Commission Delegated Regulation (EU) 2024/2788 (for polymers in Component

		Material Category 11). The biodegradability criteria for these polymers in CE fertilisers are the same as those laid down in Section 2.2 of Appendix 15 for non-CE marked fertilisers (see left).

Test material

The particles containing or coated by solid polymer(s) ('polymer particles)', present in the product as placed on the market or disposed of/released to the environment, will frequently be mixtures comprising one or more polymers together with other substances (e.g. additives) that could have a profound effect on polymer degradability. Therefore, an important issue to consider when assessing the polymer degradability is the relevance of the test material on which the test is performed.

All test methods in groups 1-5 need to be carried out on a **test material** that is comparable in terms of composition, form, size and surface area to the polymer particles, present in the product as placed on the market. In certain cases it may not be possible to test the polymer particles that are placed on the market, because e.g. it is not possible to isolate them from the product they are present in, or there are other substances in those particles (that could not be separated because of the production process) that would confound the performance of the degradability test system, e.g. plant protection product active substances or biocidal product active substances that killed the degrading organisms. When testing the polymer particles as placed on the market is not possible, the test material should be comparable to the polymer particles as disposed of or released to the environment (see Section 3 of Appendix 15). (Note that Appendix 15 refers to polymers, rather than "synthetic polymer microparticles", as polymers that are tested using the methods in that Appendix may be degradable and therefore not be SPM.)

For an example of a test material that is comparable to the polymer particles as placed on the market, please see Text Box 2 below.

Text Box 2 - Example of appropriate test material:
If the product to be tested for degradation is loose glitter, placed on the market as individual glitter pieces that measure, on average, 1 mm x 1 mm, are 100 µm thick and contain 60% w/w of polyethylene terephthalate (PET), the test material should be the same glitter that is placed on the market or, at the very least, have the same characteristics, i.e. should measure, on average, 1 mm x 1 mm x 100 µm and contain 60% w/w of PET.

Where a test material containing polymer particles of a given particle size meets the degradation pass criteria, it can be assumed that a test material containing smaller polymer particles of the same chemical composition (i.e. particles with higher surface to volume ratios

and thus less surface limitation to degradation) would also meet the pass criteria, so such test material would not need to be tested separately.

Confirmatory testing

If the test material contains more than one polymer, or a single polymer combined with other non-polymeric, organic substances in a concentration > 10% w/w, and groups 1-3 test methods are used to prove degradation, the presence of multiple polymers or organic substances with different level of degradability could confound the testing results (the test material may overall meet the pass criteria even if one of the solid polymers in the material does not biodegrade sufficiently). In this case, it is necessary to prove the degradation of both the test material and the individual polymer(s) ('**confirmatory testing**') in order to verify that all polymers in the test material contribute to the observed degradation and achieve the required degradation levels. This ensures that the test results are as predictive as possible of the degradation behaviour of the polymer particles in real life conditions, and only polymers that actually degrade once released to the environment are derogated. An example of cases where confirmatory testing is required include test materials containing one or more polymers mixed with non-polymeric organic additives (e.g. colorants, plasticisers) representing more than 10% of the weight of the test material.

The confirmatory testing can be performed by either:

- running separate tests on the test material and on each of the polymers in the test material; or
- testing only the test material - so one test - but during that test, demonstrating (e.g., by monitoring the changes in the individual polymer concentration during testing using appropriate analytical techniques) that each polymer in the test material contributes to the observed degradation and its degradation meets the pass criteria.

Confirmatory testing is not required when group 4 and 5 test methods are used because, unlike group 1-3 test methods, they are designed in a way that prevents confounding of the results in case of polymers with very different degradability.

4. Testing the solubility of polymers

In order to prove that a solid polymer is soluble for the purpose of entry 78 (and therefore not in the scope of the restriction), it is necessary to test the solubility of the polymer in accordance with Appendix 16 of Annex XVII of REACH. Similarly to degradability testing, polymer solubility needs to be tested according to good laboratory practice (GLP) in (i) GLP-certified laboratories or (ii) laboratories subject to national competent authority GLP monitoring programmes, or (iii) in laboratories with ISO 17025 accreditation, or (iv) laboratories accredited with other international standards recognised as being equivalent by the Commission or ECHA.

For more information on GLP compliance, see the subsection on GLP in Section 3 of this narrative part.

Appendix 16 lists the 2 permitted test methods (OECD Guideline 120 and OECD Guideline 105) for testing solubility. OECD Guideline 120 was specifically developed for polymers. These tests assess the combined solubility of all molecular weight fractions of a polymer.

Appendix 16 also sets the conditions under which the solubility test should be carried out (temperature: 20 °C; pH 7; loading: 10 g/L; test time: 24 h) and the solubility to be reached to pass the test (> 2g/L).

Test material

As when testing degradability, when testing solubility it is necessary to use a test material that is comparable in terms of composition, form, size and surface area to the polymer particles, i.e. the particles containing or coated by solid polymer(s), present in the product as placed on the market or, if not possible, the polymer particles disposed of or released to the environment. For an example of a test material that is comparable to the polymer particles as placed on the market, please see Text Box 2 in Section 3 above.

However, there are two exceptions to the above rule. The first concerns polymer particles that, when placed on the market, disposed of or released, have all dimensions greater than 0.25 mm or are longer than 0.25 mm and have a length to diameter ratio greater than 3. The OECD Guideline 120 requires that, before performing the test, these particles are milled so that at least one dimension, or their length, measures between 0.125 mm and 0.25 mm. The milling is necessary to ensure standardised, reproducible results and does not affect the conclusions that can be drawn from the test. The condition of the test and the pass criterion are sufficiently strict that a polymer that passes the test is regarded as soluble for the purpose of entry 78, regardless of whether the test was performed on milled or intact particles.

The second exception concerns testing the solubility of polymer particles that, in addition to containing or being coated by solid polymers, also contain or are coated by inorganic substances. The presence of inorganic substances in the tested particle is likely to confound the result of the test. For this reason, when the particle also contains or is coated by inorganic substances, it is necessary to test the solubility of the individual polymer(s) rather than that of the polymer particle as placed on the market, disposed of or released.

5. Prohibition of placing on the market

Paragraph 1 of entry 78 prohibits the placing on the market of solid polymers fulfilling the definition of SPM, either **on their own or, when present to confer a sought-after characteristic**, **in mixtures** in **a concentration equal to or greater than 0.01** % by weight of the mixture. The concentration limit of 0.01 % w/w corresponds to the lowest concentration level reported to ECHA where SPM could still confer a sought-after characteristic to a product.

As mentioned in Section 2 of this narrative part, SPM can be either one polymer, or a combination of polymers. SPM are to be regarded as placed on the market **"on their own"** when the SPM (i.e., the solid polymer or polymers fulfilling the SPM conditions) are not

mixed with other substances. This would be the case, for example, of particles (e.g., pellets, powder, flakes) that are 100% made of one polymer, or a combination of polymers, fulfilling the SPM conditions.

Text Box 3 - Examples of SPM on their own (non-exhaustive):
pellets/powder/flakes of a synthetic solid polymer (or polymers) meeting the SPM conditions (e.g., uncompounded PET or uncompounded PVC; uncoloured Styrofoam (polystyrene) beads.

SPM are to be regarded as placed on the market "in mixtures" when the SPM (i.e., the solid polymer or polymers fulfilling the SPM conditions) are mixed with other substances. SPM are placed on the market **"in mixtures"** in the following cases:

- **Case 1.** The SPM, i.e. a solid polymer (or polymers) contained in or coating a particle (and fulfilling the other SPM conditions) is mixed with other substances within that particle (i.e. the particle which contains or is coated by the SPM is a mixture of the SPM and other substances).

Text Box 4 - Examples of Case 1 mixtures (non-exhaustive list):
- Rubber granulate used as infill material for sport surfaces (it is a mixture of styrene-butadiene co-polymer (the SPM) and other substances);
- a piece of glitter where PET (the SPM) is mixed with aluminium and other substances;
- an encapsulated fragrance or flavour (a mixture of the fragrance or the flavour and the SPM encapsulating it);

- **Case 2**. SPM on their own (e.g. particles made 100% of SPM) are mixed with other substances in the final product.

Text Box 5 - Examples of Case 2 mixtures (non-exhaustive list):
- dishwasher tablets containing polymer powder (the SPM) mixed with other ingredients;
- cosmetic formulations to which polymer powder or flakes (the SPM) have been added.

- **Case 3.** Case 1 or case 2 mixtures are further mixed with additional substances in the final product.

Text Box 6 - Examples of Case 3 mixtures (non-exhaustive list):
- glitter in nail polish;
- encapsulated fragrances in fabric softeners;
- encapsulated flavours in chewing gum;
- infill material for synthetic sport surfaces made of rubber granulate mixed with sand.

Application of the concentration requirements for the prohibition of placing on the market in Paragraph 1

Paragraph 1 applies if the total weight of the SPM (i.e., the solid polymer(s)) is ≥ 0.01% than the total weight of the mixture (including the weight of the SPM) as placed on the market. If SPM derogated under Paragraph 4 or 5 are present in the mixture, their weight also contributes to the total weight of the mixture.

Text Box 7 - Examples of calculations for different types of mixtures (cases 1, 2 and 3 above):

Case 1 mixtures. Paragraph 1 applies if, for example:

- 1 Kg of infill material made of rubber granulate (total weight of the mixture) contains ≥ 0.1 g (i.e. 0.01% w/w) of styrene-butadiene co-polymer (total weight of the SPM);
- 1 Kg of loose glitter (total weight of the mixture) contains ≥ 0.1g of PET (total weight of the SPM).

Case 2 mixtures. Paragraph 1 applies if, for example:

- 1 Kg of cosmetic formulation (e.g. blush, cream) contains ≥ 0.1g of polymer powder or flakes.
- 1 Kg of washing powder contains ≥ 0.1g of polymer pellets, powder or flakes.

Case 3 mixtures. Paragraph 1 applies as follows:

Example 1: Glitter in nail polish. Paragraph 1 applies if the weight of PET (the SPM) in the glitter is ≥ 0.01% of the total weight of the nail polish, i.e. if 1 Kg of nail polish (total weight of the mixture) contains ≥ 0.1g of PET from glitter (total weight of the SPM). The amount of glitter needed to reach 0.1 g of PET and trigger the application of Paragraph 1 depends on the concentration of PET in the glitter:

- Considering glitter A that is composed of particles of 100% of PET (each glitter particle is an SPM on its own), 1 kg of nail polish cannot be placed on the market if it contains 0.1 g or more of glitter A (as 0.1 g of glitter A contains 0.1 g of SPM (the PET), which equals to 0.01% of the total weight of the nail polish, so Paragraph 1 applies).

- Considering glitter B that is composed of glitter particles containing 1% w/w of PET (1% of the glitter is an SPM and 99% is other constituents), 1 kg of nail polish cannot be placed on the market if it contains 10 g or more of glitter B (as 10 g of glitter B contain 0.1 g of SPM (the PET), which equals to 0.01% of the total weight of the nail polish, so Paragraph 1 applies).

- Glitter C is composed of glitter particles that contain 1% PET (1% of the glitter is an SPM and 99% are other constituents) and vary in size from 3 to 6 mm. The size distribution of the glitter particles is such that 10 g of glitter C contains 0.1 g (1% w/w) of glitter particles that measure less than 5 mm, and 9.9 g (99% w/w) of glitter pieces measuring at least 5 mm or more. Given that the glitter particles contain at least 1% of SPM (the PET) **and** at

least 1% w/w of the glitter particles measure less than 5 mm, the totality of the SPM in glitter C (i.e. the PET in both the glitter particles measuring less than 5 mm and those measuring at least 5 mm and more) is in the scope of the restriction and needs to be considered for the concentration limit in Paragraph 1. This means that, if 10 g of glitter C are added to 1 Kg of nail polish, the amount of PET to be considered for calculating the concentration limit in Paragraph 1 is 0.1 g (i.e. the PET contained in the totality (10 g) of glitter C added to the nail polish) and not 0.001 g (i.e. the PET contained in the 0.1 g of glitter C pieces that measure less than 5 mm). Consequently, 1 Kg of nail polish cannot be placed on the market if it contains 10 g or more of glitter C (as 10 g of glitter C include 0.1 g of SPM (the PET), which equals to 0.01% of the total weight of the nail polish, so Paragraph 1 applies)].

Example 2: Fabric softeners containing fragrance encapsulates (fragrances encapsulated with a polymer shell). Paragraph 1 applies if 1 Kg of fabric softener (total weight of the mixture) contains ≥ 0.1 g of polymer shell/coating (total weight of the SPM).

Example 3: Chewing gum containing flavours encapsulated with a polymer shell (the SPM). Paragraph 1 applies if 1 Kg of chewing gum (total weight of the mixture) contains ≥ 0.1g of polymer shell/coating (total weight of the SPM).

Example 4: infill material made of styrene-butadiene rubber granulate mixed with sand. Paragraph 1 applies if 1 Kg of infill material (total weight of the mixture) contains ≥ 0.1g of styrene-butadiene co-polymer (total weight of the SPM) from the rubber granulate.

Sought-after characteristic

For SPM in mixtures, Paragraph 1 of entry 78 applies when the SPM is present in the mixture (product) **to confer a sought-after characteristic**. This means that, in practice, the prohibition on the placing on the market only applies to those mixtures where the **presence of the SPM is intentional** because the SPM provides a specific, sought-after characteristic to the product. To give some concrete examples, this would be the case of (non-exhaustive list):

- SPM providing a certain consistency, texture, fragrance or colour to a cream, a detergent or any other product; or
- SPM used as binder, filler, diluent, lubricant, disintegrant, coating, etc. in solid oral forms of medicinal products (e.g. tablets)
- SPM coating granular fertilisers, to control their release to the soil or water; or
- SPM added to a mixture (product) to provide bulk, fluidity, elasticity, shock resistance, heat resistance, etc.
- Etc.

When the presence of SPM in a mixture is not intentional, the prohibition of placing on the market in Paragraph 1 of entry 78 does not apply. This is the case, for example, of any product containing SPM from wear and tear/abrasion/degradation of plastic packaging, including food or feed, sewage sludge or compost containing SPM from (human) waste. These products are also not subject to IFUD and reporting requirements.

Text Box 8 - Examples of how to apply Paragraph 1 when considering that the SPM provides a sought-after characteristic.

Synthetic microbeads in a 'rinse-off' facial scrub

The first example is that of microbeads – measuring less than 5 mm and containing more than 1% w/w of PET – added to a cosmetic product, e.g., a 'rinse-off' facial scrub, to function as exfoliating agents. Paragraph 1 applies as follows: given that the 'rinse-off' facial scrub is considered a mixture, and the PET (i.e. the SPM) is added to confer a sought-after characteristic to the mixture, namely to grant exfoliating properties to it, the total PET concentration in the 'rinse-off' facial scrub, as placed on the market, must not reach 0.01% of the total weight of the scrub. The concentration limit is set below the level where SPM can effectively function as a scrub. Note that the PET weight should exclude the weight of the non-polymeric component of the microbeads, if any. The weight of the non-polymeric component of the microbeads should however count towards the total weight of the 'rinse-off' facial scrub, as placed on the market,

Synthetic glitter

The second example is that of glitter made of individual glitter pieces measuring less than 5 mm and made of PET (i.e. the SPM) coated with aluminium to reflect light, and possibly including other additives/substances. Paragraph 1 applies as follows: given that the glitter, i.e. the PET together with the aluminium, as well as any other additives or substances present, is regarded as a mixture, and the PET (i.e. the SPM) is present to confer a sought-after characteristic to the glitter, namely to provide the scaffold for the shiny aluminium coating, the glitter can be placed on the market only if the combined weight of the PET is less than 0.01% of the total weight of the glitter.

SPM in articles

Paragraph 1 does not apply to the placing on the market of SPM in articles, including articles which contain substances/mixtures that are an integral part of them (e.g. electronic candles, glittered articles).

Useful information to distinguish substances/mixtures from articles for the purpose of REACH can be found in the ECHA guidance on requirements for substances in articles, in the ECHA Catalogue of borderline cases between articles and substances/mixtures and in Part III of this Explanatory Guide, Annex 3. Information includes examples where products are considered as a combination of an article and a substance or mixture (and therefore the substance/mixture is in the scope of the restriction) and cases where mixtures or substances are regarded as integral parts of articles (and thus are outside of the scope of the restriction).

6. Derogations from the prohibition of placing on the market

Paragraphs 4 and 5 of entry 78 derogate certain SPM uses and products containing SPM from the prohibition of placing on the market. However, other obligations, such as IFUD (see Section 8 below) and reporting (see Section 9 below) usually apply.

In particular, to avoid over-regulation, Paragraph 4 derogates from the prohibition of placing on the market certain SPM uses and SPM-containing products where the products are regulated by other EU legislation, namely:

- **The use of SPM at industrial sites** (Paragraph 4(a)); the Industrial Emission Directive sets the general principles controlling industrial emissions; in addition, it was considered that, given the highly controlled industrial environment, industrial SPM emissions can be prevented or minimised if appropriate instructions for use are provided; for identifying a "use at industrial site", ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R12, includes a weight of evidence method that can help stakeholders and enforcement authorities distinguishing between uses at industrial site from widespread uses by professional workers
- **Medicinal products for human and veterinary use** (Paragraph 4(b)); the EU pharmaceutical legislation already provides for the minimisation of emissions of pharmaceutical ingredients into the environment; This derogation applies to medicinal products within the scope of Directive (EC) 2001/83 and Regulation (EU) 2019/6[9].
- **EU fertilising products** (Paragraph 4(c)); the Fertilising Products Regulation already regulates the use of synthetic polymers in CE-marked fertilisers; note that non-CE marked fertilisers are not derogated, as they are not covered by the Fertilising Products Regulation.
- **Food additives** (Paragraph 4(d)); covered by Regulation (EC) No 1333/2008;
- **In vitro diagnostic devices** (including accessory devices) covered by Regulation (EU) 2017/74**6** (Paragraph 4(e)). These are, for example, test kits used on biological samples to determine the status of a person's health, such as self-tests for pregnancy, COVID-19 tests, cancer genetic tests or high-throughput testing of blood donations for infections such as HIV. Note that medical or accessory devices within the scope of the more general Regulation (EU) 2017/74**5** (such as substance-based medical devices, e.g. devices referred to by the classification rule 21 or rule 4 in Annex VIII in Regulation (EU) 2017/745), are not derogated;
- **Food** (other than food additives) **and feed** covered by Regulation (EC) No 178/2002.

[9] The current wording of Paragraph 4(b) refers to "medicinal products within the scope of Directive 2001/83/EC and veterinary medicinal products within the scope of Regulation (EU)". This wording does not reflect the original intention of the regulators because it inadvertently excludes medicinal products used in clinical trials from the scope of the derogation. Commission services are currently preparing a Correcting Act to change the wording of Paragraph 4(b) so that the placing on the market of medicinal products used in clinical trials is included in the derogation.

Some considerations on the application of the derogation in Paragraph 4(a) (placing SPM on the market for use at industrial sites):

- Industrial sites are subject to regulatory oversight (typically permitting) and must comply with relevant local and EU occupational safety and environmental legislation.

- An industrial site typically features controlled access, specialised infrastructure and facilities designed to support large-scale industrial operations while minimising risks to workers, the general public and the environment.

- Small-scale craft production usually does not take place at industrial sites but it is rather considered a professional use.

    - For example, the placing on the market of SPM-containing glitter to make toys or decorations in a stall at a Christmas market or craft fair would not be derogated under Paragraph 4(a), but the placing on the market for the same use taking place in a workshop within an industrial site would. Although the SPM-containing glitter used in the toy/decoration production may be the same, and the resulting articles may be the same, the placing on the market of such glitter for use at an industrial site is derogated because industrial emissions are tightly regulated, so the resulting SPM emissions would be much better controlled in that location.

- As a general principle, uses taking place in the areas of the industrial site where manufacturing, production, assembly or processing activities are carried out should be considered as "use at industrial site", regardless of whether the actual work is carried out by employees of the site or by external service providers working at the industrial site, as the resulting releases will be collected in the area where the industrial operations take place.

    - For example, cleaning services removing production residues from industrial surfaces and equipment (e.g. tank-cleaning, boiler cleaning, cleaning of machinery, cleaning of industrial flooring where production/storage takes place, etc), maintenance and repair activities concerning industrial equipment, etc, are 'use at industrial site'.

- By contrast, professional uses (cleaning, repairs, maintenance, etc) that are performed in offices/administrative spaces at an industrial site, should not be considered a "use at industrial site", as the resulting releases will not be collected in the area where the industrial operations take place.

Paragraph 5 derogates SPM for which the release to the environment can be minimised during use, because the SPM are either:

- 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 (Paragraph 5(a));
    - E.g: SPM in chromatography columns, toners, water-filtering cartridges, diapers, incontinence pads or menstrual pads.

- Permanently modified during intended end use so that they stop being SPM (Paragraph 5(b));
    - Eg: swellable polymers in diapers and other applications; film-forming polymers in e.g. cosmetic products, detergents and maintenance products, paints and coatings.

- Permanently incorporated into a solid matrix during intended end use (Paragraph 5(c)):
    - Eg: SPM in concrete, SPM in most paints.

In general, an **intended end use** can be understood as a specific type of use intended as the final use of a product (i.e. a substance or mixture), after which there is no further intentional use.

End-users are users that use substances or mixtures but do not supply them further. Examples of end users include users (including consumers) of adhesives, coatings and inks, lubricants, cleaning agents, solvents and chemical reagents such as bleaching products, etc. Producers of articles may be end-users of certain substances/mixtures at industrial sites. Professional painters or consumers using paint are also end-users.

Some considerations on the application of Paragraph 5:

- These derogations intend to exclude from the ban in Paragraph 1 products for which SPM releases to the environment can be minimised or prevented during intended end use, because of the properties of the SPM or of the product, the way the product is intended to be used and the following of appropriate instructions for use and disposal (IFUD).
- For the derogation in Paragraphs 5(a) to apply, there should be no release of SPM to the environment when the product where the SPM are contained in by technical means is used as intended, in accordance with the IFUD. The IFUD should be feasible and within the capacity for the target users to achieve in practice – particularly when targeted to consumers and professional users. If SPM emissions can only be prevented by means of instructions so complex/stringent that a target user would be unable to implement them in practice, then the derogation may not apply. See also Section 8 on information requirements.
    - If during the intended use of the product, the SPM contained by technical means are transferred from the product onto a surface or material on which they are absorbed or remain otherwise affixed, this is not a reason for not applying Paragraph 5(a) because the SPM are not released into the

environment. For example, Paragraph 5(a) applies to toners and other ink cartridges because the ink is transferred onto the paper (or any other appropriate material) being printed.

- Paragraph 5(b) applies when the modification that results in the polymer not fulfilling the SPM conditions anymore is permanent, under intended end use.
    - For example, Paragraph 5(b) applies to film-forming SPM in nail polish, which are regarded as permanently losing their SPM nature because they coalesce to form a film (and the polymers stop being contained in particles) and, when the nail polish is removed using an appropriate solvent, the film-forming SPM do not reform. In short, the film-forming SPM stop being SPM when the nail polish is applied and do not reform when the nail polish is removed – the change to the conditions of the polymer is permanent. The same can be said for film-forming SPM in paints.
    - Paragraph 5(b) applies to swellable SPM that, during end use, become larger than 5 mm in any dimension, and remain larger under the intended conditions of use of the product until the product is disposed of.

Text Box 9 – Swellable polymers in diapers

An illustrative example is that of swellable SPM in diapers that are intended to be used for up to 8 h in a temperature range of 0-45°C. The swellable SPM are derogated under Paragraph 5(b) if they swell and remain bigger than 5 mm in any dimension (hence stopping being SPM) for up to 8 hr at any temperature between 0°C and 45°C and are therefore still swollen when the diaper is removed and disposed of.

- For Paragraph 5(c), the intention is to cover uses where SPM emissions are minimised because the SPM are permanently incorporated in a solid matrix that is intended to stay in place indefinitely, without a predetermined end date (most paints, for example). The derogation does not intend to cover uses where the solid matrix is intended to be frequently removed and replaced, and therefore the incorporation of the SPM in the solid matrix is temporary, such as cosmetic products.
- All efforts should be made to prevent emissions completely. However, it is understood that this may not always be possible, even in the presence of effective IFUD. For example, SPM emissions may occur during the application/formation and removal of the solid matrix but are minimised through appropriate IFUD and monitored through reporting (see Section 9 below) to ensure they remain limited. Such emissions should not preclude the application of Paragraph 5(c). SPM emissions while the solid matrix is in place, however, should not occur and would preclude the application of Paragraph 5(c).
    - **SPM in inks** are in principle derogated from the restriction on the basis of Paragraph 5(c) but some case-by-case assessment may be needed. For

example, markers for substrates such as glass, plastic and metal that use acrylic-based ink which creates a film, similarly to paint, may permanently incorporate SPM within a solid acrylic matrix. Equally, in analogy to the rationale elaborated in the guidance on substances in articles that any coating (or partial coating) of an article becomes an integral part of that article, any permanent application of SPM to the surface of a solid matrix, e.g., paper or card via a water-based ink, can be considered to be permanent incorporation into that solid matrix. The concept of permanence must be inherent to the intended end use. For example, polymer-encapsulated pigments in water-based inks that are absorbed on the paper surface (or other substrate that constitutes a solid matrix into which the SPM are incorporated) and permanently adhere to it (via an interfacial attachment mechanism, e.g. via valence forces, Van der Waals forces or other means of adhesion) once the ink is dry can be derogated under Paragraph 5(c). However, any end use of a paint or ink containing SPM that was clearly intended only for temporary marking of a substrate (e.g., dry-wipe, erasable or washable markers) would not be consistent with the conditions of Paragraph 5(c). Equally, any SPM in water-based inks that are not adsorbed on the paper surface (or other matrix) and do not permanently adhere to it once the ink dries cannot be considered as "permanently incorporated in a solid matrix" and Paragraph 5(c) does not apply – this could be the case, for example, of SPM-containing glitter in glitter gel pens, if the glitter pieces in the gel are too big to absorb on the paper and to permanently adhere to it once the ink (gel) is dried.

- Note that the particle in which the SPM is contained does not constitute a solid matrix for the purpose of Paragraph 5(c). If the contrary were true, the derogation would apply to all SPM contained in solid particles with dimensions < 5 mm, which are among the SPM primarily responsible for the identified risks and therefore targeted by the restriction.

Application of multiple derogations to the placing on the market of the same SPM

The **first scenario** discussed here is when the activities from actors at different stages of the supply chain may be covered by different derogations from the prohibition on the placing on the market affecting the same SPM. For example, an SPM manufacturer may be covered by the derogation in Paragraph 4(a) to supply SPM to an industrial 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 – see example in Text Box 10.

Text Box 10 – Example 1; Different derogations applying to the same SPM at different stages of the supply chain.

This is an illustrative example of different derogations applying to the placing on the market of the same SPM at separate stages of the supply chain:

- a polymer manufacturer benefits from the derogation in Paragraph 4(a) when selling film-forming polymers to a paint company that uses those polymers to formulate paint at their industrial plant;
- the paint company then benefits from the derogation in Paragraph 5(b) when placing the paint containing those film-forming polymers on the market for use by professionals/consumers (Paragraph 5(b) applies because film-forming polymers permanently stop being SPM during the intended end use of the paint);
- the polymer manufacturer benefitting from the derogation in Paragraph 4(a) has to comply with the IFUD obligations under Paragraphs 7 and 10 and the reporting requirements under Paragraph 11, while the paint company profiting from the derogation in Paragraph 5(b) has to comply with the IFUD obligations under Paragraph 8 and reporting requirements under Paragraph 12.

A **second scenario** is when the same actor in the supply chain places the SPM on the market at the same time for use at industrial sites and for use outside industrial sites. For example, an SPM manufacturer supplies the SPM to an industrial DU for use at industrial sites covered by the derogation in Paragraph 4(a) and, at the same time, places the same SPM to the market for professional use and the general public, covered by the derogations in Paragraph 5(a), 5(b) or 5(c). In this case, the actor in the supply chain placing on the market the same SPM both for use at industrial sites (under the derogation in Paragraph 4(a)) and for use by professionals and consumers outside industrial sites (under one of the derogations in Paragraph 5) needs to comply with the IFUD and reporting requirements stemming from both derogations, namely the IFUD and other information requirements laid down in Paragraph 7 and 8, and the reporting requirements laid down in Paragraph 11 and 12 – see example in Text Box 11.

Text Box 11 – Example 2; Multiple derogations applying when placing an SPM on the market at the same time for use at industrial sites and for use outside industrial sites.

Here is an illustrative example of both Paragraph 4 and Paragraph 5 derogations applying when an actor in the supply chain places the SPM on the market at the same time for use at industrial sites and outside industrial sites:

A polymer manufacturer places on the market synthetic solid paraffin (the SPM) as pellets for use in the formulation of candles. They benefit from the derogation:

- under Paragraph 4(a), to place the paraffin on the market for use by a DU in the formulation of candles at an industrial site;

- under Paragraph 5(b), to place the paraffin on the market for candle-making by professionals or consumers outside industrial sites; the derogation applies because during the intended end use the paraffin permanently stops being a SPM (as the paraffin pellets are melted to make a candle, so the paraffin is not contained in particles anymore);

The polymer manufacturer is placing the paraffin on the market at the same time for use at industrial sites and outside industrial sites. They therefore have to comply to the IFUD and other information requirements laid down in Paragraph 7 and 8, and the reporting requirements laid down in Paragraph 11 and 12.

A **third scenario** is when an actor in the supply chain places SPM on the market only for use at industrial sites and derogations under both Paragraph 4(a) and 5 may apply to that SPM placed on the market.

In this case, given that the SPM is only placed on the market for use at industrial sites, the applicable IFUD and reporting requirements are those stemming from the Paragraph 4(a) derogation – see example in Text Box 12.

If the opposite were true, and the requirements were to be cumulated, it would mean that obligations under Paragraph 7 and 11 (stemming from the derogation in Paragraph 4(a)) and Paragraph 8 and 12 (stemming from the derogation in Paragraph 5) would apply. However, IFUD under Paragraph 8 are targeted to professionals and the general public, so there would be no added value in adding them to a product only used at industrial sites. Similarly, the reporting obligations under Paragraph 12 concern estimated SPM emissions from products placed on the market for the first time to professional users and general public, which is not the case here. Consequently, only the IFUD and reporting requirements stemming from the derogation under Paragraph 4(a) apply in this case, i.e. the requirements laid down in Paragraph 7 and in Paragraph 11.

Text Box 12 – Example 3; Multiple derogations applying when placing an SPM on the market only for use at industrial sites.

This is an illustrative example of both Paragraph 4(a) and Paragraph 5 derogations applying when an actor in the supply chain places on the market the SPM for use at industrial sites.

A paraffin manufacturer places on the market synthetic solid paraffin (the SPM) as pellets for candle-making at industrial sites. Two derogations may appear to apply to the placing on the market of the paraffin:

- Paragraph 4(a), as the paraffin is placed on the market to be used at an industrial site;
- Paragraph 5(b), as the industrial use is the intended end use of the paraffin and, during that use, the paraffin permanently stops being a SPM (e.g. because the paraffine pellets melt during candle-making, so the paraffin is not contained in particles anymore);
- Although both derogations 4(a) and 5(b) would apply, given that the SPM is only used at industrial sites, the manufacturer placing that paraffin on the market has to comply to the

IFUD and other information requirements laid down in Paragraph 7, and the reporting requirements laid down in Paragraph 11.

A **fourth scenario** is when an actor in the supply chain places on the market a product containing SPM for a use other than at an industrial site, the product is covered by one of the product-specific derogations in Paragraph 4(b), (c), (d), (e) and (f) and contains SPM that would also be eligible to be placed on the market under a derogation in Paragraph 5. Non-exhaustive examples include:

- Medicines containing e.g. film-forming or swellable SPM, where Paragraphs 4(b) and 5(b) would apply;
- CE-marked fertilisers containing e.g. film-forming or swellable SPM, where Paragraphs 4(c) and 5(b) would apply;
- Food and feed (e.g. food and feed supplements) containing e.g. film-forming SPM, where Paragraphs 4(f) + 5(b) would apply;

In this scenario, the actor in the supply chain only needs to comply with the IFUD and reporting requirements stemming from the product-specific derogation under Paragraph 4(b), (c), (d), (e) and (f). Those derogations were introduced with the purpose to avoid overregulation on certain products covered by sectoral EU legislation. Such legislations already regulated (some) aspects covered by entry 78 such as some aspects related to information requirements, labelling or emissions to the environment and therefore it was not considered necessary to ask for IFUD or reporting requirements in all cases. Consequently, requiring those products to apply the IFUD and reporting requirements stemming from the use of the Paragraph 5 derogation would be contrary to the intended purpose, as it may result in overregulation.

Against this background, when an actor in the supply chain places on the market a product containing SPM covered by Paragraph 4(b), (c), (d), (e) and (f), but the product could appear to be also covered by Paragraph 5, the IFUD and reporting requirements apply as follows:

- Medicines containing e.g. film-forming or swellable SPM:
    - no IFUD requirements apply;
    - reporting requirements under Paragraph 12 apply;
- CE-marked fertilisers containing e.g. film-forming or swellable SPM:
    - no IFUD nor reporting requirements apply;
- Food additives and in vitro diagnostic devices:
    - IFUD under Paragraph 8 and reporting requirements under Paragraph 12 apply;
- Food and feed (e.g. food and feed supplements) containing e.g. film-forming polymers:
    - no IFUD nor reporting requirements apply.

Derogation for placing SPM on the market for research and development purposes

The use of SPM for research and development purposes (e.g. chemical grade reagents) is either not in the scope of the restriction or is derogated, depending on the type of research:

- the use of SPM for **scientific research & development** (i.e. any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year according to Article 3(23) REACH)) is out of the scope of the restriction: in accordance with Article 67 REACH, restrictions in Annex XVII REACH do not apply to the manufacture, placing on the market or use of a substance in scientific research and development (Art. 67 REACH).
- for the purpose of entry 78, the use of SPM for **product and process orientated research & development** is overall derogated under Paragraph 4(a), as it is a use of SPMs that usually takes place at industrial sites. In this case, IFUD and reporting obligations apply, in accordance with Paragraph 7 and 11, respectively[10].

7. Sector-specific transitional periods for the application of the prohibition of placing on the market

Paragraph 6 of entry 78 lists the SPM uses and the products containing SPM for which the prohibition of placing on the market does not apply at entry into force of the restriction but after a certain transitional period. The duration of the transitional period varies across uses, depending on the complexity of the product, the need for reformulation, the availability of suitable alternatives or the socio-economic costs associated with the prohibition of placing on the market.

The products containing SPM that are not granted a transitional period in Paragraph 6, cannot be placed on the market as of 17 October 2023 (date of entry into force of entry 78), unless the SPM in the product are derogated under Paragraphs 4, 5 or 16.

Uses and products granted (or not) a transitional period are discussed below.

Products containing microbeads and other products/uses not granted a transitional period

Products containing microbeads, i.e. SPM used as an abrasive to exfoliate, polish or clean, have not been granted a transitional period so their placing on the market is prohibited since the entry into force of the restriction on 17 October 2023.

Other examples of products containing SPM and uses of SPM that were not granted a transitional period include (not exhaustive):

[10] The intention of the regulators was to derogate the SPM used for product and process orientated research & development (PPORD) from the prohibition of placing on the market laid down in Paragraph 1 of entry 78. An explicit derogation for PPORD uses was not included in Entry 78 because it was considered redundant, as it was assumed that PPORD would systematically take place at industrial sites and the placing on the market of SPM used for PPORD would be derogated under Paragraph 4(a). However, experience from the practical implementation of the restriction shows a need to improve legal certainty concerning the derogation of SPM used for PPORD. To this end, Commission services is considering proposing a Correcting Act including an explicit derogation allowing the placing on the market of SPM used for PPORD.

- loose glitter, i.e. glitter on its own; (note that when glitter is used in applications granted a transitional period (e.g. as a cosmetic product or in cosmetic products; in detergents), the corresponding transitional period applies).
- toys
- products for art and crafts
- granular infill for uses other than on synthetic sport surfaces (the meaning of "synthetic sport surfaces" is clarified further down this Section)
- lubricants
- etc.

Note that only SPM on their own and SPM in products which are or contain substances/mixtures (as defined under REACH) are affected (see also Section 1 of this Narrative Part, and the ECHA Guidance on requirements for substances in articles to establish whether a product is a substance/mixture, an article or an integral part of an article, or a combination of an article and a mixture.

Fragrance encapsulation (Paragraph 6(a))

The transitional period for fragrance encapsulation was set at 6 years from the entry into force of the restriction, so SPM encapsulating fragrances cannot be placed on the market as of 17 October 2029.

Rinse-off cosmetic products (Paragraph 6(b))

Rinse-off cosmetic products containing SPM were granted a 4-year transitional period and cannot be placed on the market as of 17 October 2027 – except if:

- they contain microbeads, in which case the prohibition of placing on the market applies as of 17 October 2023;
- they contain SPM-encapsulated fragrances, in which case the prohibition of placing on the market applies as of 17 October 2029.

Make-up, lip and nail products (Paragraph 6(c))

The transitional period for make-up, lip and nail products was set at 12 years. Consequently, they cannot be placed on the market with SPM as of 17 October 2035, except if:

- they contain microbeads, in which case the prohibition of placing on the market applies as of 17 October 2023;
- they contain SPM-encapsulated fragrances, in which case the prohibition of placing on the market applies as of 17 October 2029;
- they are rinse-off cosmetic products, in which case the prohibition of placing on the market applies as of 17October 2027 (with exceptions, see subsection on "*Rinse-off cosmetic products*" above).

Make up products are defined in Paragraph 2(e) of entry 78. This definition was derived from the definition of a cosmetic product in the Cosmetic Product Regulation (Regulation (EC) 1223/2009) by excluding the parts of that definition not relevant for make-up products.

Although a 12-year transitional period may be necessary in some cases, companies who are **able to phase out the SPM in their products earlier** than 17 October 2035 should be encouraged to do so. For this reason, producers placing on the market make-up, lip and nail products still containing SPM after 8 years (out of 12) from the entry into force of the restriction, i.e. after 17 October 2031, are required to inform consumers of the presence of SPM in their product by adding the following statement on the label, packaging or leaflet of the product:

> "This product contains microplastics."

The statement uses the term "microplastics" (rather than "synthetic polymer microparticles") because it is a term the consumer is more likely to understand.

There is a 2-month transitional period to give suppliers at the end of the supply chain, e.g. retailers, the time to sell/dispose of non-compliant stocks. So, while suppliers should include the required statement on the label, packaging or leaflet of their products as of 17 October 2031, the prohibition to place products on the market without such a statement only applies as of 17 December 2031. After 17 December 2031, make-up, lip and nail products that contain SPM but do not include the required statement on the label, packaging or leaflet of the product need to be withdrawn from the market.

If the SPM, or the mixture containing them, is subject to classification and labelling requirements under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation), and suppliers choose to place the required statement on the label, the statement should be placed in the section of supplemental information of the CLP label, in accordance with Article 25(9) of the CLP Regulation.

Leave-on cosmetic products (Paragraph 6(d))

Leave-on cosmetic products containing SPM were granted a 6-year transitional period and cannot be placed on the market as of 17 October 2029 – except if:

- they contain microbeads, in which case the prohibition of placing on the market applies as of 17 October 2023;
- they are make-up, lip and nail products, for which the prohibition of placing on the market applies as of 17 October 2035 (with exceptions, see subsection on "*Make-up, lip and nail products*" above).

Leave-on cosmetic products that contain SPM-encapsulated fragrances also benefit from a 6-year transitional period and cannot be placed on the market as of 17 October 2029.

Detergents, waxes, polishes and air care products (Paragraph 6(e))

Detergents, waxes, polishes and air care products containing SPM were granted a 5-year transitional period and cannot be placed on the market as of 17 October 2028 – except for:

- Products containing microbeads, in which case the prohibition of placing on the market applies as of 17 October 2023;
- Products containing SPM--encapsulated fragrances, for which the prohibition of placing on the market applies as of 17 October 2029.

Medical and accessory devices (Paragraph 6(f))

Medical devices and accessory devices within the scope of Regulation (EU) 2017/745 that contain SPMs on their own or in mixtures (such as substance-based medical devices, e.g. devices referred to by the classification rule 21 or rule 4 in Annex VIII in Regulation (EU) 2017/745) were granted a 6-year transitional period and cannot be placed on the market if containing SPM as of 17 October 2029 – except for:

- Products containing microbeads, in which case the prohibition of placing on the market applies as of 17 October 2023;

Paragraph 6(f) does not apply to in vitro diagnostic medical devices and to accessories for such devices within the scope of Regulation (EU) 2017/74**6** because they are derogated from the prohibition on the placing on the market (Paragraph 4(e)) and therefore do not require a transitional period.

Non-CE marked fertilising products (Paragraph 6(g))

Fertilising products which are not in the scope of the Fertilising Product Regulation (Regulation (EU) 2019/1009), i.e. fertilising products that are authorised according to national legislation in the respective member state and are thus not CE-marked, were granted a 5-year transitional period and cannot be placed on the market if containing SPM as of 17 October 2028.
Paragraph 6(g) does not apply to the placing on the market of fertilising products within the scope of Regulation (EU) 2019/1009, i.e. CE-marked fertilising products, because these products are derogated from the prohibition on the placing on the market (Paragraph 4(c)) and therefore do not require a transitional period.

Plant protection products and biocidal products (Paragraph 6(h))

Plant protection products, seeds treated with those products, and biocidal products, were granted an 8-year transitional period and cannot be placed on the market if containing SPM as of 17 October 2031.

Products for agricultural and horticultural uses other than fertilising products, plant protection products and biocidal products (Paragraph 6(i))

Products for agricultural and horticultural uses that are not fertilising products, biocidal products or plant protection products, e.g. seeds coated with colorants or lubricants, were granted a 5-year transitional period and cannot be placed on the market if containing SPM as of 17 October 2028.

Granular infill for use on synthetic sport surfaces (Paragraph 6(j))

Granular infill containing SPM and used on synthetic sport surfaces was granted an 8-year transitional period and cannot be placed on the market SPM as of 17 October 2031.
A "synthetic sport surface" is a sport surface that includes at least one layer made of solid synthetic material (e.g. a synthetic rubber pad, synthetic turf, etc.), to which the granular infill is added. Playgrounds are not sport surfaces.

8. Information requirements, including instructions for use and disposal (IFUD)

For products for which the releases of SPM during their use can be prevented (or significantly minimised), the risk of possible SPM emissions is mitigated through mandatory instructions for use and disposal (IFUD) that explain to industrial downstream users and end users (professionals and the general public) how the SPM or the product containing them should be used, handled and disposed of so that SPM releases to the environment are avoided or minimised. The IFUD requirements are laid down in Paragraphs 7(a), 8 and 10 of entry 78. In addition to IFUD, entry 78 lays down information requirements (Paragraph 7(b), (c) and (d)) aiming at facilitating the reporting of estimated SPM emissions by industrial downstream users (see subsection "*Additional information to be provided in accordance with Paragraph 7*" in this Section, and Section 9).

If the SPM, or the mixture containing them, is subject to classification and labelling requirements under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation), and suppliers choose to place the required information in Paragraph 7, 8 or 9 on the label, that information should be placed in the section of supplemental information of the CLP label, in accordance with Article 25(9) of the CLP Regulation.

The term **"industrial downstream users"** is used in entry 78 to mean downstream users who use substances or mixtures in their industrial activities (for help identifying industrial activities, see ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12). The term **"downstream user"** is defined in Article 3(13) of REACH as individuals or companies (other than the manufacturer or the importer) established within the EU/EEA who utilise substances or mixtures in their industrial or professional activities. Distributors or consumers are not downstream users according to that definition.

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:

- Used at industrial sites;
- In food additives;
- In *in vitro* diagnostic devices;
- Contained by technical means
    - e.g. toner in printer cartridges, resin in chromatography columns or in water-filtering systems, water-retaining polymers in diapers, incontinence pads, or menstrual pads;
- Permanently modified at end use
    - e.g. film-forming polymers in paints, swellable polymers in diapers;
- Permanently incorporated in a solid matrix at end use
    - e.g. fibre-like particles in concrete, glitter in paint.

IFUD are not required for SPM, and products containing them, derogated under Paragraph 4(b), (c) and (f). See subsection "*Application of multiple derogations to the placing on the market of the same SPM*", scenario 4, in Section 8 above.

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. In addition, IFUD should minimise emissions while being feasible and within the capacity for the target users to achieve in practice – particularly when targeted to consumers and professional users. If emission minimisation can only be achieved by means of IFUD so complex/stringent that it is unlikely that a target user would be able to implement them in practice, then the supplier should consider not placing the SPM on the market for that end use as the derogation may not apply.

To increase the IFUD effectiveness, it is important to draft the IFUD with the right user in mind:

- the IFUD 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 IFUD 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.

The IFUD have to be inserted as clearly visible, legible and indelible text or pictograms. Pictograms can replace the text, provided they convey the IFUD as effectively. The presence of both text and pictograms is permitted but not required. It is for Member State authorities to decide whether the IFUD – provided as text or pictogram(s) – are appropriate to prevent or

minimise SPM releases to the environment. Note that Member States' authorities do not pre-approve products or product information (including pictograms).

The text or pictograms can be placed on the label, the packaging, or the package leaflet of the products containing SPM or on the safety data sheet (when available).

If the product already comes with generic IFUD that effectively prevent or minimise SPM emissions (even if they are not specifically conceived for SPM), it is acceptable to keep the existing instructions, including when they are in the form of pictograms. The addition of SPM-specific instructions are however necessary if the existing instructions, including pictograms, are not adequate to prevent SPM emissions.

- An example is that of the instructions for disposal of a sealed spray can of paint containing film-forming SPM derogated under 5(b), where the spray can comes with instructions and/or pictogram(s) explaining how to safely dispose of the can in accordance with other applicable legislation, e.g. (non-exhaustive) a statement or a pictogram indicating to dispose of the can in a bin, without opening it. Considering that the consumer has no access to the product in the sealed can and any (residual) SPM within, the obligation under Paragraph 8 concerning disposal instructions can be fulfilled by the existing instructions/pictograms present on the packaging, label or leaflet. No SPM-specific disposal instructions are necessary (but SPM-specific instructions for use may still be needed, if the existing ones are not specific enough to prevent SPM emissions).

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 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, e.g. (not exhaustive):

- an extended, more detailed version of the IFUD which includes, for example, drawings and graphic instructions;
- more details about the pictogram developed to comply with the requirements of the restriction;
- educational videos or brochures on how to use/store/handle/apply the product (including the cleaning of tools) and/or remove the applied product and handle SPM (re)formed when the product is removed, and/or dispose of the 'empty' container/packaging in a way that is safe for the environment.

The derogations under Paragraph 5 are primarily intended to cover uses of SPM in (non-industrial) professional or consumer settings.

In the case of 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. The reason is that, since the 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.

In the case of products containing SPM **derogated under Paragraph 5(b)**, IFUD should instruct how to prevent SPM emissions when using the product, including when cleaning tools, and disposing of it, including the appropriate disposal of the "unconsumed" product in the container/packaging. IFUD do not need to address (but can) how to handle the product once applied/used, as the applied product does not contain SPM (SPM derogated under Paragraph 5(b) stop being SPM during use). Consideration should also be given to address how to handle the product so that the SPM are not (re)formed and to handle the SPM that may be (re)formed.

In the case of products containing SPM **derogated under Paragraph 5(c)**, IFUD should address how to prevent SPM releases during the intended end use of the product (e.g. during the preparation, application and curing/setting of the solid matrix).

Given the many different products which may contain derogated SPM, and the variety of their uses, it is not possible for this guidance to provide a single text or pictogram that would be appropriate for all derogated products and uses. As a general rule, any IFUD that effectively prevent derogated SPM in a product, including product residues in "empty" containers/packaging, from being released to the environment can be considered appropriate. For example, appropriate IFUD could include instructions to avoid disposal of unused material to drains and watercourses and to clean up areas thoroughly after use.

Some examples of possible IFUD for SPM derogated under Paragraph 5(b), such as film-forming SPM in nail polish, are provided below (non-exhaustive):

- 'Do Not Pour Product Down the Drain'; or
- 'Do Not Rinse the Container Before Disposal'

Here is a possible example of a pictograms expressing the same concept:

These are indicative examples and only Member State authorities can assess on a case-by-case whether the indicative sentences or pictogram above would be sufficient/appropriate. It is the

supplier responsibility to choose sentences or pictograms that are appropriate to comply with the IFUD requirements based on their knowledge about how the product they are placing on the market is used. Note that Member State authorities do not pre-approve products or product information, including pictograms.

The transitional period for the application of the IFUD is 24 months for all uses except *in vitro* diagnostic devices. The transitional period for IFUD requirements for *in vitro* diagnostic devices is longer – 36 months – to allow enough time for regulatory approval of *in vitro* diagnostic devices in case manufacturers have to change the existing leaflet/packaging to include IFUD for SPM.

IFUD obligations for products containing SPM for which the placing on the market is derogated under Paragraph 4 or 5 are explicitly laid down in Paragraphs 7 or 8 of entry 78. The IFUD obligations in Paragraphs 7 or 8 apply as of 17 October 2025 to products for which the placing on the market is derogated under Paragraphs 4(a), 4(d) and 5 and as of 17 October 2026 to products for which the placing on the market is derogated under Paragraphs 4(e), regardless of whether a transitional period for the prohibition of placing on the market under Paragraph 6 applies to that type of products. For example, considering a nail polish that contains film-forming SPM (for which the placing on the market is derogated under Paragraph 5(b)), the IFUD obligations apply as of from 17 October 2025 (and not 17 October 2033).

Additional information to be provided in accordance with Paragraph 7

In case of the use of SPM at industrial sites derogated under Paragraph 4(a), in addition to appropriate IFUD, suppliers of SPM are required to provide additional information on the derogated SPM to industrial downstream users and other suppliers:

1. The generic identity (e.g. polyethylene terephthalate (PET)) of the polymer(s) contained in the substance or mixture that is placed on the market.
2. The quantity or the concentration of SPM in the product; this can be expressed, for example, as polymer concentration, e.g. 40% w/w of polymer X in the product; or as absolute weight of the polymer in the product, e.g. 16 g of polymer X per product bottle of 40 ml;
    - NB: providing precise concentration information to downstream users is preferable. However, information may be provided as concentration range where necessary to protect commercial interests. As downstream users will need to use the upper bound of any range for reporting requirements (to avoid underestimating the polymer concentration of SPM in their products or the magnitude of polymer releases from SPM from their sites), the range provided should be realistic and limited to what is required to maintain confidentiality.
3. A specific 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”);

The information should be sufficiently detailed that industrial downstream users and other suppliers are able to estimate their own SPM emissions and, where required, the SPM emissions further down the supply chain until end use (by professionals or general public), in order to comply with their reporting obligations under Paragraphs 11 and 12. This information complements the existing REACH requirements for suppliers described in Article 31(9c) (when the compilation of an SDS is required by Article 31), and Article 32(1c) (when the compilation of an SDS is not required by Article 31).

The information can be provided on a safety data sheet (SDS), the product package, the package leaflet, or on the product label itself. 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. Section 15 of the SDS for 'Regulatory Information' may be the appropriate place to identify that a substance or mixture is subject to the restriction and provide sufficient information on the SPM composition to allow downstream users to comply with the reporting requirements. The transitional period for the application of information requirements under Paragraphs 7(b), (c) and (d) is 24 months, i.e. the information should be included in products containing derogated SPM as of 17 October 2025.

9. Reporting of estimated emissions

Reporting requirements apply to:

- Manufacturers and industrial downstream users of SPM derogated under Paragraph 4(a) (reporting requirements in Paragraph 11); and
- suppliers of products (i.e. SPM on their own or in mixtures) for which the placing on the market is derogated under Paragraph 4, points (b), (d) and (e), and Paragraph 5, that place the products on the market for the first time to professional users and the general public (reporting requirements in Paragraph 12);

The supply chain actors mentioned above have to **report the estimated SPM emissions from using those SPM/products** to ECHA by 31 May of each year.

The aim is to monitor the effectiveness of the IFUD as regards the derogated uses and of the restriction in general. The information gathered will be collated by ECHA and made available to the MS and the Commission to potentially identify uses where further risk management is needed or uses where releases are low over time, in accordance with Paragraph 13.

The information to be reported includes:

- A description of the use(s) of the SPM in the previous calendar year;
- Generic information on the identity of the polymers used;
- An estimate of the quantity of SPM released in the previous calendar year; For example, manufacturers/suppliers would report by 31 May 2026 the estimated emissions incurred between January and December 2025;
- For each use, the applicable derogation(s) in Paragraphs 4 or 5.

Regarding the obligation to report **generic information on the identity of the polymer**(s) used, reporting of polymer identity is envisaged via a system with pick lists, so that stakeholders can comply with their reporting obligations by using the information in suppliers' safety data sheet, for example, or the information provided by suppliers under Paragraph 7(d). Providing precise information on the identity of the polymer will not be necessary for reporting.

Reporting **a description of the use(s) of the SPM** in the previous calendar year should be done without disclosing confidential business information. For reporting description of use, the existing system outlined in ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12 could be used. Alternatively, use descriptions could also be developed and adopted by industry sectors. Finally, it may be possible to standardise use descriptions as part of the development of the reporting system and allow the use of pick-lists during reporting, similarly to the reporting of polymer identity.

With regard to reporting the **estimated quantity of SPM released** to the environment in the previous calendar year, the standard methodologies for exposure assessment of chemicals, e.g. including the use of default values established for environmental release categories (ERCs) or in OECD emission scenario documents, are expected to be sufficient to satisfy the reporting requirements in the absence of refined approaches. Refined default-based approaches for specific uses/sectors, such as those used in REACH specific environmental release categories (spERCs), can also be applied to meet the reporting obligation. Indeed, whenever spERCs are periodically reviewed and updated based on the adoption of best-practices, the latest consumer/professional behaviour and the effectiveness of the instructions and labelling, spERC approaches to estimate releases may be particularly useful to provide information on minimisation of releases for a particular sector over time. Downstream users using Paragraph 7(c) information provided by upstream SPM suppliers as a concentration range will need to use the upper bound of the range when estimating SPM emissions (to avoid underestimating the SPM concentration in their products or the magnitude of SPM releases from their sites).

For **SPM** for which the placing on the market is **derogated under Paragraph 4 or 5**, the reporting should consider, among other things, the possible SPM releases (e.g. down the drain or the water closet, etc.) occurring during the intended end use even in the presence of appropriate instructions for use and disposal, in particular:

- For the derogation in **Paragraph 5(a)**, the releases occurring in case of breakage of the technical means used to contain the SPM.
- For the derogation in **Paragraph 5(b)**, the possible releases occurring before SPM stop being SPM, e.g. during washing of tools, cleaning of work surfaces, disposal of unconsumed product, etc.
- For the derogation in **Paragraph 5(c)**, the likely releases of SPM prior to incorporation in the solid matrix e.g. during the preparation, application and curing/setting of a solid matrix, from product packaging or inappropriate disposal, as well as during the removal of the solid matrix.

The general principles for who should report, and which estimated SPM emissions should be reported, are the following:

a. Manufacturers and industrial downstream users of SPM derogated under Paragraph 4(a) have to estimate and report their own SPM emissions, i.e., the emissions incurred in the past calendar year during their own operations, including emissions during transport (even when transport is performed by third-party transporter(s)) (Paragraph 11); For example, they would report by 31 May 2026 the estimated emissions incurred between January and December 2025.
b. Supply chain actors are responsible for reporting the relevant information for their own operations.
c. In the case of Paragraph 12, in order to ensure that all emissions along the supply chain are monitored and reported, without risking double reporting or adding undue burden on end users, the suppliers (manufacturers, importers, downstream users, as appropriate) of products containing derogated SPM that place those products on the market **for the first time to professional users or the general public** have to estimate and report:
    - their own SPM emissions, including during transport (even when performed by third-party transporter(s));
    - the downstream SPM emissions, i.e. the emissions occurring downstream in the supply chain all the way to the end user, from the moment the product is placed on the market to professional users and the general public to the moment it is disposed of after end use. These can be sector-specific release estimates, such as those described by spERCs.
d. Importers of SPM, and of products containing SPM, that are derogated because placed on the market for use at industrial sites are not required to report their own estimated SPM emissions, in accordance with Paragraph 11;
e. By contrast, importers of derogated SPM, and of products containing derogated SPM that place those products on the market for the first time to professional users and the general public are required to report their own estimated SPM emissions, including during transport, plus the estimated downstream SPM emissions, in accordance with Paragraph 12.
f. When importers of products containing SPM estimate and report their own SPM emissions, they should estimate emissions generated as of the moment the product containing SPM enters the custom territory of the Union.
g. Distributors, including retailers, of products for professional use and the general public, professional end users and consumers do not report SPM emissions to ECHA, even if they undertake further formulation – e.g. mixing of custom paint colours. This is because distributors (including retailers), by definition, receive the product from a third party, so when the distributor receives it, the product has already been placed on the market. It is the industrial actor placing the product on the market for the first time to professionals or the general public that has to comply with the reporting requirement.

h. Products containing SPM which are directly exported and not placed on market, are not subject to the reporting requirements.

Text Box 13 – Emissions during transport

It is important that the data reported to ECHA include estimations of emissions/losses during transport, including loading and unloading activities, as these activities are an important source of emissions.

Case 1: *How to report the estimated SPM emissions during transport when SPM, or products containing them, are* ***moved between supplier A and recipient B within the EU.***

The emissions have to be reported by the actor (A or B) who is liable for the product at the time the emissions take place, based on contractual agreements between supplier A and recipient B. For example:

- Supplier A and recipient B agree that supplier A delivers a SPM-containing mixture (including by means of one or more third-party transporter(s)) to recipient B and remains liable for that mixture until recipient B receives it. In that case**:**
  - Supplier A estimates and reports to ECHA the emissions during pre-transport and transport operations, including (but not limited to) handling and storage, loading and transport itself (including emissions occurring when the mixture is with one or more third-party transporter(s));
  - Recipient B reports to ECHA the post-transport emissions, including (but not limited to) emission during unloading and subsequent handling and storage.

Case 2: *How to report the estimated SPM emissions during transport when SPM, or products containing them, are* ***moved between different sites belonging to supplier A within the EU.***

The estimated SPM emissions have to be reported to ECHA by supplier A, either per site (one submission per individual site) or combined (one submission for multiple sites):

- Supplier A reports estimated emissions during pre-transport, transport and post-transport operations, including pre-transport handling and storage, loading, transport itself, unloading and post-transport handling and storage.

Case 3: *How to report the estimated SPM emissions during transport when products containing SPM, are* ***moved between non-EU supplier A and EU importer B to be placed on the EU market for the first time*** *to professional users and the general public.*

Non-EU supplier A does not report to ECHA (because entry 78 only applies in the EU/EEA). EU importer B, placing the product on the EU market for the first time to professional users and the general public, reports the estimated emissions that occur while they are liable for the product (based on contractual agreements between non-EU supplier A and EU importer B) and, at the earliest, as of the moment the product containing the SPM enters the custom territory of the EU. EU importer B also reports the estimated SPM emissions occurring

downstream in the supply chain from the moment the product is placed on the market in the EU to professional users and the general public to the moment it is disposed of after end use.

Example 1:

- Non-EU supplier A and EU importer B agree that non-EU supplier A delivers a SPM-containing mixture (including by means of one or more third-party transporter(s)) to EU importer B and remains liable for that mixture until EU importer B receives it. EU importer B then places the imported mixture on the EU market for the first time to professional users and consumers. In that case:
  - Non-EU supplier A does not report to ECHA;
  - EU importer B reports the estimated SPM emissions starting from the moment they receive the mixture, including (but not limited to) emission during unloading and subsequent handling and storage. EU importer B also reports the estimated downstream SPM emissions, i.e. the SPM emissions occurring from the moment they place the mixture on the market in the EU to professional users and the general public to the moment the mixture is used and disposed of by the end user.

Example 2:

- Non-EU supplier A and EU importer B agree that non-EU supplier A supplies a SPM-containing mixture to EU importer B and EU importer B is responsible for delivery of the mixture into the EU (including by means of one or more third-party transporter(s)) and is liable for that mixture from the moment it leaves the supplier A premises located outside the EU. EU importer B then places the imported mixture on the EU market for the first time to professional users and consumers. In that case:
  - Non-EU supplier A does not report to ECHA;
  - EU importer B reports the estimated transport SPM emissions as of the moment the SPM-containing mixture the enters the custom territory of the EU, including (but not limited to) emissions during transport taking place in the EU custom territory, custom clearance, unloading and subsequent handling and storage. They also report the estimated downstream SPM emissions occurring after they place the imported mixture on the EU market to professional users and consumers.

The reporting is envisaged to take place through a dedicated, IUCLID-based online system hosted by ECHA. The information will be reported using a prescribed electronic format. Instructions on how to submit the required information will be made available on the ECHA website once the reporting interface is operational, which is expected by the end of 2025 at the latest.

ECHA will not provide a methodology for estimating the releases. Given the very different products and uses concerned, it is considered more appropriate to leave the choice of the method to estimate emissions to the concerned industrial sectors, which are encouraged to develop sector-specific spERCs.

The transitional periods for the application of reporting requirements under Paragraphs 11 and 12 are:

- 24 months, for manufacturers and industrial downstream users of SPM in pellets, flakes, and powders used as feedstock in plastic manufacturing at industrial sites;
- 36 months, for other (non-pellets/flakes/powders) industrial downstream users and all suppliers of products containing SPM.

10. Information to competent authorities

The restriction applies to SPM on their own or intentionally present in mixtures to confer a sought-after characteristic. To verify whether there are SPM in the product and whether their presence is intentional, it is necessary that enforcement authorities know the exact identity and function of the solid polymers included in the product. For this reason, Paragraph 14 lays down an obligation for manufacturers, importers and industrial downstream users to disclose to enforcement authorities, upon request:

- the exact **identity** of polymers in the scope of this restriction contained in their product; and
- the **function** of those polymers in the product

The exact information that needs to be provided, upon request, to enforcement authorities to unequivocally identify polymers is listed in points 2.1 to 2.2.3 and points 2.3.5, 2.3.6 and 2.3.7 of Annex VI to REACH:

- 2.1. Name or other identifier of each substance
- 2.1.1. Name(s) in the IUPAC nomenclature or other international chemical name(s)
- 2.1.2. Other names (usual name, trade name, abbreviation)
- 2.1.3. EINECS or ELINCs number (if available and appropriate)
- 2.1.4. CAS name and CAS number (if available)
- 2.1.5. Other identity code (if available)
- 2.2. Information related to molecular and structural formula of each substance
- 2.2.1. Molecular and structural formula (including SMILES notation, if available)
- 2.2.2. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)
- 2.2.3. Molecular weight or molecular weight range
- 2.3.5. Spectral data (e.g. ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)
- 2.3.6. High-pressure liquid chromatogram, gas chromatogram
- 2.3.7. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced.

Industrial downstream users that do not have the required information have to request it from their suppliers within 7 days from the receipt of the request from the competent authorities. They also need to inform the authorities of the request made without delay.

The suppliers have 30 days to provide the requested information to the industrial downstream user. Suppliers that do not wish to share the requested information with industrial downstream users – for example to protect commercially confidential information – can provide it directly to the enforcement authority requesting it. It is envisaged that, for this purpose, suppliers may be able to use ECHA's existing infrastructure for exchanging confidential information with authorities. If the supplier decides to provide the information directly to the authority, it needs to inform of this the industrial downstream user concerned without delay.

If the supplier provides the information to the industrial downstream user, the industrial downstream user needs to forward that information to the competent authorities without delay.

Furthermore, Paragraph 15 requires manufacturers, importers and industrial downstream users claiming that certain polymers in their products do not meet the definition of SPM on grounds of degradability or solubility to provide proof proving those properties to competent authorities upon their request, without delay. For the purpose of entry 78, degradability or solubility have to be proven in accordance with Appendix 15 or 16 to Annex XVII of REACH, respectively.

Finally, in accordance with Paragraph 13, the Agency will make the information reported under Paragraphs 11 and 12 available to the Member States authorities.

11. Products already on the market at entry into force

Paragraph 16 exempts from the prohibition of placing on the market SPM on their own or in products (substances, mixtures, combination of articles and mixtures) that were already on the market when the restriction entered into force on 17 October 2023, e.g. SPM and products containing them that, after being placed on the market, are in warehouses or on the shelves. This derogation also applies to second-hand products. This is to prevent unnecessary product recalls and reduce waste. The derogation does not apply for uses of SPM that are granted a transitional period in Paragraph 6.

Imports, i.e. products that are physically introduced into the customs territory of the Union, are considered as placed on the market. For products produced in the EU, they are considered placed on the market when supplied or made available, whether in return for payment or free of charge, to a third party (Article 3(12) REACH).

In summary:

- SPM and SPM-containing products (substances, mixtures, combination of articles and mixtures) that have been placed on the market before 17 October 2023 (for uses other than those laid down in Paragraph 6) do not need to be recalled or withdrawn from the market and can continue being sold, in accordance with Paragraph 16. This would be the case, for

example, of finished products already imported or supplied to downstream users, distributors or retailers. Note that:

  - SPM and SPM-containing products (substances, mixtures, combination of articles and mixtures) already on the market on 17 October 2023, e.g. large bags of SPM-containing glitter in importers', downstream users' or distributors' stocks, can continue being placed on the market and used (e.g. repackaged, used in the production of other products, etc) until stocks run out.] in order to benefit from the derogation in Paragraph 16 and continue to be sold, imported products not benefiting from a transitional period under Paragraph 6 need to arrive on the customs territory of the EU before 17 October 2023.

- The derogation laid down in Paragraph 16 is limited to SPM for which the placing on the market is banned at entry into force (17 October 2023). SPM in products that have been granted a transitional period in Paragraph 6 do not need the derogation laid down in Paragraph 16, as the transitional period grants suppliers the necessary time to progressively phase out the non-compliant products.