REACH restriction of synthetic polymer microparticles

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

– Explanatory Guide –

Version 1

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Contents

Part II - Questions and Answers

Part II of this document is the question-and-answer (Q&A) part. All questions and their answers refer to entry 78 of Annex XVII of REACH, restricting synthetic polymer microparticles (SPM). These questions have been submitted by stakeholders (in some cases the wording of the questions received has been revised for clarity, or several similar questions were combined) and the responses have been developed for the purpose of this Q&A to provide a clearer understanding of the legal text of entry 78. The questions have been organised in 19 Sections covering specific provisions in the restriction (e.g., prohibition of placing on the market, definitions, etc.) or products, e.g. glitter, cosmetic products, etc.

Paragraph numbers refer to Paragraphs in the right-hand column of entry 78, unless otherwise specified.

1. General

This Section includes general questions about entry 78 of Annex XVII of REACH, covering issues such as polymer definition, entry into force of the restriction, how to distinguish a substance, a mixture or an article under REACH, and other general questions.

1.1. Are polymers covered by REACH? Can they be restricted?

Polymers are regarded as substances under REACH and are covered by the REACH Regulation. They are exempted from registration and evaluation provisions (Article 2(9) of REACH) but are subject to other REACH provisions, including restrictions (Title VIII).

Note that, according to REACH Article 6(3), monomer substances must be registered, in certain circumstances.

1.2. How do I assess whether my substance is (or is not) a polymer under REACH?

In accordance with REACH Article 3(5), a polymer is defined as 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 other monomer unit or other reactant;
(b) less than a simple weight majority of molecules of the same molecular weight.

In practice:
(a) Over 50 percent of the weight for that substance consists of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or another reactant; and
(b) The amount of molecules presenting the same molecular weight must be less than 50 percent of the weight of the substance.

Therefore, it is necessary to know the chemical composition of the substance and the details of the relevant manufacturing process (polymer-forming reaction) to identify all polymeric and non-polymeric molecules that comprise the substance. In addition, the molecular weight distribution of the above molecules in the substance needs to be known.

It should be noted that a well-defined mono-constituent substance cannot be a polymer since a substance needs to contain polymer molecules with a certain molecular weight distribution to be considered a polymer. See more details in the ECHA Guidance for monomers and polymers available from the ECHA website.

1.3. Can Member States keep existing stricter national provisions?

Commission Regulation 2023/2055 (introducing entry 78 into Annex XVII REACH) applies as of 17 October 2023 to the entire EU territory. It is directly applicable and no transposition into national legislation is necessary. Member States have to ensure that their national legislation is not in conflict with the restriction. In particular, they cannot maintain existing stricter measures addressing the same risk as that targeted by the restriction other than in accordance with Article 114(4) TFEU.

1.4. When did the restriction on placing SPM on the market come into effect?

The placing on the market of SPM on their own, or in mixtures where the SPM are present to confer a sought-after characteristic in a concentration equal or greater than 0.01 % by weight, is banned as of 17 October 2023, unless the SPM are derogated under Paragraphs 4, 5 or 16 or products are granted a transitional period under Paragraph 6 of the restriction. (For more information on what is meant by the term “sought-after characteristic”, see Part I, Section 5, and Part II, Q&A3.1.)

Examples of products for which the placing on the market is banned as of 17 October 2023 include cosmetic products or household cleaning products that contain microbeads (SPM for use as an abrasive, i.e. to exfoliate, polish or clean); and plastic glitter on its own (‘loose’ plastic glitter), for uses not listed in Paragraph 6 or derogated under Paragraph 4 or 5.

SPM and products containing SPM that were already placed on the market before 17 October 2023, do not need to be recalled or withdrawn from the market and can continue to be placed on the market, re-packaged and, in general, passed along supply chains until existing stocks run out (as provided in Paragraph 16).
This would be the case, for example, for SPM-containing household cleaning products or cosmetic products that are already placed on the market and in the warehouses of distributors/importers or on the shelves at retailers on 17 October 2023.
Certain uses benefit from transitional arrangements during which it is still permitted to place SPM on the market (Paragraph 6). However, Paragraph 16 does not apply to products with a transitional period under Paragraph 6. These products cannot continue to be placed on the market beyond the date provided in Paragraph 6 even if they had been placed on the market before 17 October 2023.

In addition, it is still permitted to place certain SPM on the market, on their own or in certain products, depending on how they are used. These derogations are provided in Paragraphs 4 and 5 of the restriction. Placing SPM on the market for a derogated use is, in most cases, subject to requirements to provide information to users, detailed in Paragraphs 7, 8 and 9, and reporting requirements, detailed in Paragraphs 11 and 12.

1.5. Why did the ban on placing on the market of glitter enter into force only a few days after the announcement of the restriction?

As a general rule, a Commission Regulation enters into force 20 days after publication in the Official Journal of the European Union (OJEU), unless another date is specified as stated in Article 297 of the Treaty of Functioning of the European Union (TFEU).

The Commission proposed longer transition periods for the application of the restriction to specific cases where information, including from the call for evidence and the consultations on the Annex XV dossier and the SEAC draft opinion, indicated that the affected parties needed more time to substitute SPM and comply with the new rules because of the lack of suitable and available alternative materials. Alternatives to synthetic polymer glitter (such as mineral silicates) as well as degradable polymer glitter are already commercially available, so a longer transition period was not considered necessary.

1.6. Are there any additional obligations for online sales?

Online sales within the EU must comply with the text of the restriction. See Part III, Annex 2 for additional guidance on identifying responsibilities along the supply chain.

1.7. Can we test the physical state (i.e. whether they are solid or liquid) of the polymers in our products in our quality control laboratory even if it is not accredited to ISO 17025 or certified to GLP?

ISO 17025 accreditation or GLP compliance (or equivalent) is only needed for laboratories undertaking degradability and solubility testing of polymers according to Appendix 15 and 16, respectively.

1.8. To determine compliance with the conditions of the restriction, can a company be satisfied with a "non-microplastic" upstream statement, or must it receive an assessment against specific criteria (e.g. liquid, soluble, biodegradable, natural, present in a concentration <0.01%)?

It is for the company to determine if they are satisfied with the supplier’s declaration. The company remains responsible for their own compliance with the restriction. Only where manufacturers, importers or industrial downstream users (DU) claim that the conditions for the degradability and solubility derogations are met, they need to have information proving those claims available (e.g. product data sheet, safety data sheet, etc.). Please refer to Paragraph 15. See also Q&A 1.10 for additional information.

1.9. Does this restriction permit the placing on the market, including import, of glitter or other products containing SPM, for sale to companies that are engaged in small-scale craft production?

No, unless the small-scale craft production takes place at an industrial site (the placing on the market of SPM for use at industrial sites is permanently derogated under Paragraph 4(a)). Usually, small-scale craft production does not take place at industrial sites but it is rather considered a professional use. Placing SPM on the market for consumer and professional uses is only permitted if one of the derogations in Paragraph 4, 5 or 16 applies or the use is granted a transitional period (Paragraph 6).

Examples of uses at industrial sites and of professional uses can be found in Part I, Section 6. Further information on determining what is a use at an industrial site and what is a professional use can be found in Part I, Section 6 and Q&A 6.2 in this document, and in ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12 on Use Description. The latter includes a weight of evidence method (table R.12-6 in Appendix R.12.3) that can help stakeholders differentiating between uses at industrial site and use by professional workers outside industrial sites, as noted in Part I, Section 6 of this document.

Placing on the market for use at industrial sites is subject to the information requirements in Paragraph 7 and the reporting requirements in Paragraph 11.

See also Q&A 1.11 and 1.12 and Part III, Annex 2 for additional information.

1.10. Are operators required to check the final product for the presence of SPM or are they covered by a declaration of SPM absence from the suppliers of raw materials?

Operators are responsible for placing on the market products which comply with EU legislation. How to ensure compliance is left to the operator's discretion. Note that enforcement is a national competence, so it is for Member States' enforcement authorities to decide whether the proof of compliance provided is adequate.
Note that Member States' enforcement authorities do not pre-approve products or product information.

Appendices 15 and 16 of the restriction provides the requirements to claim that products are exempt on the basis of degradability and solubility. See also Q&A 1.8.

1.11. Does the restriction apply to artists, small scale producers, or micro business such as handmade crafters, who may sell on online marketplaces or at craft fairs?

The restriction applies across the supply chain, including to small producers or artists selling their products at craft fairs or online. Derogations may apply, depending on the polymers/products concerned. See Part III, Annex 2 for additional information.

1.12. Can craft companies repackage products containing SPM, e.g. glitter for resale in e.g. art kits?

Repackaging of (products containing) SPM is a downstream use. Placing on the market of products containing SPM, e.g. a large bag of glitter, for later repackaging by craft companies is allowed provided the repackaging takes place at an industrial site, since placing on the market for use at industrial sites is derogated under Paragraph 4(a).

The placing on the market of products containing SPM for a repackaging that does not take place in an industrial setting is not allowed, unless one of the derogations in Paragraphs 4, 5 or 16 apply to the SPM in the product, or the product is granted a transitional period in Paragraph 6.

If the repackaged product containing SPM (e.g. a small bag of glitter) is then included into a new product, e.g. an art kit, the new product can be placed on the market only if one of the derogations in Paragraphs 4, 5 or 16 apply to the SPM in the product, or the product is granted a transitional period in Paragraph 6. See Part I, Section 11 and Q&A 12.1 for cases derogated under Paragraph 16; see Q&A 17.1 and 18.8 for examples of uses derogated under Paragraph 5.

IFUD and reporting obligations apply to (products containing) SPM placed on the market for uses derogated under Paragraph 4 and 5. Please see Part I, Sections 5 and 11 for additional information.

2. Definition of "synthetic polymer microparticles" and scope of the restriction

This Section includes questions on the definition of an SPM in entry 78, how to identify if a polymer is an SPM, and the overall scope of the restriction.

2.1. Where can I find a definition of "SPM"?

"SPM" are defined in the left-hand column of entry 78, as follows:

"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 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.

Further explanations can be found in Part I, Section 2, of this Explanatory Guide.

2.2. What is the hierarchy of applying the conditions included in the SPM definition?

There is no hierarchy for the conditions of the SPM definition listed in the left-hand column of entry 78. Conditions a) and b) must be met simultaneously (but only one between (b)(i) and (b)(ii) needs to apply) for polymers to be considered as SPM.

See also Part I, Section 2, and Part III, Annex 1 of this Explanatory Guide.

2.3. Is the definition of "microplastics" harmonised across the EU and European Economic Area (EEA)?

Entry 78 does not define the term "microplastic". Instead, it defines what SPM are for the purpose of entry 78 of Annex XVII of the REACH regulation, which is harmonised and applies across the EU and, once incorporated in the EEA agreement, the EEA. Definitions of particles that could be regarded as "microplastics" might be provided in other EU legislation (such as the definition of "plastic pellets" included in the proposal for a Regulation on preventing pellet losses to reduce microplastic pollution). Other organisations may develop other definitions for their specific purposes.

2.4. Are all polymers SPM? How do I know if the polymers in my product should be considered as SPM?

No, not all polymers are SPM. Only polymers which fulfil all of the conditions listed in the left-hand column of entry 78 are to be regarded as SPM.

Natural polymers that have not been chemically modified, degradable polymers (according to Appendix 15), polymers with water solubility >2 g/L (according to Appendix 16) or polymers that do not contain carbon atoms in their structure are not SPM, irrespective of their physical state, whether they are present in particles or the dimensions of those particles.

Part I, Section 2, which links to Part III, Annex 1, provides the criteria and a decision tree to help identify SPM.

2.5. If a substance is registered under REACH it should, by definition, not be a polymer. Therefore, can registered substances be considered as being out of the scope of the restriction?

It is true that polymers do not have to be registered under REACH. However, the fact that a substance has been registered does not automatically mean that it is not a polymer. Some registered substances have been found to be polymers after review and their registrations annulled. Please note that it is the responsibility of the Registrant to assess whether their substance fulfils the polymer definition or not.

2.6. Are polymers in emulsions to be regarded as SPM?

An emulsion is a liquid-liquid mixture, so any polymer in it would be liquid. If a polymer is not solid, it cannot be an SPM (Entry 78 defines SPM as solid polymers).

2.7. If a polymer is dissolved in oil, is it an SPM?

If the polymer is not contained in or not coating a particle, it does not fulfil the SPM definition. The type of solvent is not an element of the definition.

However, if a polymer is a solid dispersed in oil (or any other fluid), the polymer may fulfil the SPM definition (if the other SPM conditions are met).

The physical state of the polymer as placed on the market is decisive for understanding whether the polymer is an SPM. The physical state may change with each operator in a supply chain, so each operator needs to individually consider the compliance of their product.

2.8. Are particles coated or encapsulated with polymers considered to be SPM?

Yes, they would be considered as SPM as long as the other conditions of the SPM definition are met.

2.9. Do single molecules (which can be quite large) fall under the SPM definition?

Single molecules are not considered to be particles (Paragraph 2(a)) and would, therefore, not be SPM. In addition, a single molecule cannot fulfil the definition of “polymer” in Article 3(5) of REACH and therefore cannot be an SPM.

2.10. Synthetic polymers in a mixture might be contained in particles or build a continuous surface coating on particles with different characteristics at different stages of a product life cycle, e.g. (i) during formulation of a product, (ii) in the product as placed on the market and (iii) during the use of the product. When should the presence of SPM be assessed?

The restriction applies when the mixture that is placed on the market contains SPM. Consequently, it is critical to verify whether a mixture contains SPM when it is placed on the market (for either an industrial, professional or consumer use). Mixtures that do not contain SPM (or contain them in a concentration < 0.01% w/w) when placed on the market are not in the scope of the restriction.

That said, it is recommended that the presence of SPM in a mixture is checked and managed throughout all relevant parts of the mixture's lifecycle, including any industrial formulation stages that take place prior to the production of the final product that is placed on the market.

Placing a mixture containing SPM on the market is still allowed where derogations apply (e.g. placing on the market for use at an industrial site). However, most derogated products must comply with the information requirements (set out in Paragraph 7 and 8) so that users have sufficient information to ensure that releases of SPM are prevented or minimised during the use of the mixture.

In addition, the intended end use of SPM by a consumer or a professional user is relevant for determining whether the derogations laid down in Paragraphs 5(a), 5(b) or 5(c) apply, i.e. if SPM are contained by technical means during end use, if SPM permanently change their properties during end use and stop being SPM (because e.g. they stop being contained in particles when they coalesce to create a film) or if SPM are permanently contained in a solid matrix at end use.

Please see Part III, Annex 2 for more information on obligations along the supply chain and Annex 3 for specific examples of mixtures in toys and decorations.

2.11. How should particle size be measured?

Particle size can be measured according to various ISO standards e.g. ISO 14644-1:2015 and ISO 21501-4:2018. Techniques used for the characterisation of nanomaterials could be useful for very small particles, e.g. dynamic light scattering (DLS) or field flow fractionation (FFF).

In a given test sample, the particle size measured will have a certain size distribution (i.e. the size will vary across a certain size range) and there may be particles present with sizes both above and below the 5 mm size cut-off (15 mm for particles with a length to diameter ratio > 3). To assess the distribution, it is recommended to use a mean value obtained from several batches over time. The key parameter to be measured in order to determine whether the polymers contained in or coating the particles in the batch are SPM is the weight of the particles below 5 mm (or 15 mm, for particles with a length to diameter ratio > 3), rather than their number. If the weight of the particles with all dimensions equal or smaller than 5 mm (or 15 mm) is equal to or more than 1% of the total weight of all the particles under consideration, then the polymers contained in or coating all the particles in the batch are SPM (as long as the other conditions of the SPM definition are met).

While the temporary lower size limit laid down in Paragraph 3 of entry 78 applies, it is acceptable to only consider the weight of particles with dimensions between 0.1 µm and 5 mm (or with length between 0.3 µm and 15 mm, for particles with a length to diameter ratio > 3) when verifying if at least 1% of the polymer particles fulfils the size requirements. See part I, Section 2 for more information on how the temporary lower size limit should be applied.

If the temporary lower size limit is applied, documentation should be available showing that it was not feasible to detect particles smaller than the above-mentioned size limits, e.g. a letter from a laboratory or a contract research organisation.

2.12. Can natural cellulose fibres meet the definition of SPM?

As indicated in the left column of entry 78, polymers are not SPM if they are the result of a polymerisation process that has taken place in nature, independently of the process through which they have been extracted (i.e. they are 'natural polymers' according to the ECHA Guidance for monomers and polymers), and are not chemically modified substances. Consequently, natural cellulose fibres that have not been chemically modified are not SPM.

Article 3(40) of REACH defines a "not chemically modified substance" as 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.

Examples of natural polymers include cellulose, DNA and RNA, silk, proteins and peptides, natural rubber, etc. Chemically modified polymers have undergone modification to include new or additional reactive groups (e.g. amines, hydroxyl groups, carboxylic acids). Examples include polymers such as vulcanized rubber.

For more information on natural polymers and chemically modified natural polymer, see Section 3.2.1.3 of ECHA Guidance for monomers and polymers. For general information on "not chemically modified substances", see ECHA Guidance for Annex V - Exemptions from the obligation to register.

2.13. Is lignin (including Kraft lignin, isolated lignin, etc.) considered to be a natural polymer which is not chemically modified?

Lignin extracted from wood is a natural polymer. Lignin can be regarded as being "not chemically modified" if, after being extracted and isolated, it has not undergone modification to include new or additional reactive groups. Please see Article 3(40) of REACH for the definition of "chemically modified". See also Q&A 2.12 above.

2.14. If a synthetic polymer also occurs in nature, can it be considered a "natural polymer" and therefore out of scope?

No. A polymer which results from a polymerisation process that has not taken place in nature but in a laboratory, research or industrial facility is not considered as a 'natural polymer' even if its chemical structure mimics that of a polymer which exists in nature. Such polymer is to be regarded as a synthetic polymer and would be in the scope of entry 78, provided the other conditions of the SPM definition are fulfilled.

The approach of treating apparently identical natural and industrial substances differently (as their properties may differ) is an established practice under REACH. For example, different registration requirements apply when the same substance is produced in nature

and extracted (exempted from registration, with some exceptions) or is industrially manufactured (registration is required). A common case is NaCl – better known as table salt, a substance which is structurally far simpler than a polymer – which is exempted from REACH registration when extracted from salt pans but requires registration when industrially manufactured.

2.15. Can a polymer produced using industrial fermentation be considered as a natural polymer and therefore out of scope?

No. A polymer which results from a polymerisation process that takes place in a laboratory, research or industrial facility is to be regarded as a synthetic polymer, even if its chemical structure mimics that of a polymer which exists in nature.

2.16. Are polymers synthesised by emulsion polymerisation and dispersed in an aqueous solution to be regarded as SPM?

Those polymers would be regarded as SPM if they fulfil the SPM definition, which refers, among other things, to the presence of solid particles with specific properties (e.g. dimensions, polymer concentration, etc.) The type of polymerisation process is not a determining factor in the SPM definition (except for polymers resulting from a polymerisation process that has taken place in nature, which are out of scope of entry 78).

2.17. Are degradable polymers 'excluded' from the scope of entry 78 or rather ‘derogated’ from the ban on placing on the market in Paragraph 1 of the entry?

Polymers that pass the appropriate tests laid down in Appendix 15 of Annex XVII of REACH are to be regarded as ‘degradable’ for the purpose of entry 78. As such, they are not covered by the definition of SPM and they are excluded from the scope of entry 78. Products containing degradable polymers are not subject to instructions for use and disposal (IFUD) or reporting requirements. However, manufacturers, importers and industrial DU of products containing polymers that are claimed to be degradable shall provide, without delay, information proving that those polymers are degradable in accordance with Appendix 15, as applicable, to competent authorities upon request (Paragraph 15 of the restriction).

2.18. Are water-soluble polymers excluded from the scope of the restriction?

Yes, polymers with solubility >2 g/L, as measured in accordance with Appendix 16 of Annex XVII of REACH, are excluded from the scope of entry 78.

However, manufacturers, importers and industrial downstream users of products containing polymers that are claimed to be soluble shall provide, without delay, information proving that those polymers are soluble in accordance with Appendix 16, as applicable, to competent authorities upon request (Paragraph 15 of the entry).

2.19. In case of solid dosage forms of pharmaceutical products, e.g. tablets, pills, granules, is the whole tablet to be considered a particle? Or is the tablet a mixture that contains SPM?

A tablet, pill or granule is to be regarded as a particle, as it meets the particle definition in Paragraph 2(a). It does not matter whether the tablet, pill or granule is a solid mixture (solid mixtures can be particles, the two terms are not mutually exclusive).

Synthetic solid polymers contained in or coating a tablet/pill/granule can be regarded as SPM if all the conditions in the left column of entry 78 are met (including the conditions to be fulfilled by the particle, i.e. the tablet/pill/granule). See also Part I, Section 2 of this document.

Pharmaceutical products for human and veterinary use are derogated (Paragraph 4(b)) from the prohibition on placing on the market under Paragraph 1 but are subject to reporting requirements under Paragraph 12.

2.20. Are non-woven fabrics covered under the scope of the restriction?

Man-made non-woven fabric is considered as an article and is therefore not within the scope of the restriction. For more information on non-woven fibres and fabric, see ECHA guidance for requirements for substances in articles.

2.21. Are recycled polyolefin granules covered under the scope of the restriction?

Recycled polyolefin granules that meet the definition of SPM or that contain SPM are within the scope of the restriction. Consequently, their placing on the market is allowed if one of the derogations in Paragraph 4, 5 or 16 applies or, for a use granted a transitional period in Paragraph 6, until the end of that transitional period. Information requirements (Paragraph 7-10) and reporting requirements (Paragraph 11 and/or 12) may apply.

2.22. Is my item within the scope of the restriction?

When considering whether a given item is in scope of the restriction it is first necessary to consider whether it is an SPM on its own, a mixture containing SPM, an article (including an article with a mixture that is an integral part of it), or a combination of a mixture and an article. Articles are not within the scope of the restriction. Once it has been established if a substance or a mixture is, or contains, SPM, it will then be necessary to consider other elements of the restriction such as derogated uses or transitional periods.

Please refer to Part I, Sections 1 and 2 of this Explanatory Guide and to the ECHA Guidance on requirements for substances in articles to determine whether the product is considered an article or a substance/mixture as well as to assess whether any SPM-containing substance/mixture is to be regarded as an integral part of an article. In addition, Part III, Annex 3 provides an assessment on some specific examples.

2.23. Which solid and liquid mixtures containing SPM are within the scope of the restriction?

Any mixture containing SPM, in concentration equal or above 0.01% by weight, that convey a ‘sought-after characteristic’ is within the scope of the restriction. A mixture

containing SPM that are not present intentionally and do not confer a sought-after characteristic to the mixture is not within the scope. A mixture that does not contain SPM when placed on the market, or contains them in a concentration equal or lower than 0.01% w/w, is not within the scope. For more information, see Part I, Sections 2 and 5, and Part III, Annex I and III.

2.24. Are natural oils (e.g. rapeseed oil) considered as natural polymers? Are they out of the scope of the restriction?

Oils that only contain solid polymers which are the result of a polymerisation process that has taken place in nature, independently of the process through which they have been extracted, are excluded from the scope of the restriction, provided that those polymers have not been subsequently chemically modified (i.e. they are not chemically modified substances in accordance with Article 3(40) REACH). If the polymers in the oil meet the conditions listed in Paragraph 2(d), they are considered to be liquid and therefore those polymers are excluded from the scope of the restriction.

2.25. Are garments with SPM-containing glitter affixed on their surface in the scope of the restriction?

Garments with SPM-containing glitter affixed on their surface are excluded from the scope of the restriction. Although SPM-containing glitter is considered a substance or a mixture, when the glitter is affixed to an article, it is considered an integral part of that article (and the restriction does not apply to articles). For more information, please refer to Part II, Section 19, and to Part III Annex 3 of this Explanatory Guide for specific examples.

2.26. Do all products containing SPM need to comply with the restriction? Or does the restriction only apply to SPM in the products listed in Paragraph 6?

The restriction is not limited to products listed in Paragraph 6. The requirement applies to SPM as defined in the left-hand column of entry 78, on their own or present in mixtures to confer a ‘sought-after characteristic’, in a concentration equal to or greater than 0.01% by weight. Nevertheless, several derogations from the scope are provided in Paragraphs 4 and 5 and, for the products listed in Paragraph 6, the prohibition of placing on the market applies only from the date specified in that Paragraph.

For more information on what is meant by the term “sought-after characteristic”, see Part I, Section 5, and Q&A 3.1 below.

2.27. If particles or mixtures contain two or more synthetic solid polymers, should the concentration of the different polymers be added up when assessing whether concentration limits set out in the SPM definition (left-hand column) and in Paragraph 1 are met?

Yes, the combined concentration of all relevant polymers should be considered when verifying whether the concentration limits set out in the left-hand column and Paragraph 1 of the restriction are met, for example:

a) Where a particle contains two or more synthetic solid polymers, and the sum of the different polymer concentrations is at least equal to 1% by weight of the particle, then the polymers in the particle are SPM (provided that at least 1% of the particles fulfil the SPM dimension conditions and the polymers meet the other conditions to be considered SPM, i.e. they are solid, synthetic, organic, non-degradable, and have a solubility < 2g/L).

b) Where a mixture contains two or more SPM, the ban on placing on the market (Paragraph 1) applies if the combined weight of all the different SPM types is greater than 0.01% of the total weight of the mixture.

2.28. Do SPM in or on food contact materials and articles (e.g., SPM in food contact coatings and food contact printing inks on food contact articles made of e.g., metal alloys, plastics, or in/on paper and cardboard food) falling under the food contact materials framework regulation (EG) 1935/2004 also have to comply with the restriction on SPM imposed by Regulation (EU) 2023/2055?

SPM in food contact materials (FCM) that are substances or mixtures (if any), as well as SPM in substances/mixtures used to produce FCM are in the scope of entry 78. Food contact printing inks on food contact articles are out of scope of the restriction as they are considered to be an integral part of the food contact article, and articles are outside the scope of entry 78. Production of an article, including food contact articles, using SPM at industrial sites would be derogated from the prohibition on placing on the market based on Paragraph 4(a) but information and reporting requirements in Paragraphs 7, 10 and 11 would apply.

Part I, Sections 1 and 2 of this Explanatory Guide present additional information on how to determine whether an item is in the scope of the restriction. In addition, please refer to the ECHA guidance on requirements for substances in articles to determine whether the item in question is considered an article or a mixture, and to assess whether a mixture is to be regarded as an integral part of an article or not.

2.29. Is glitter considered to be a substance or a mixture under REACH and therefore in the scope of the restriction?

Article 3(2) of the REACH regulation defines mixture as “a mixture or solution composed of two or more substances”. Glitter is considered as a substance or a mixture (depending on its composition) under REACH and, if it contains SPM, it is within the scope of the restriction. See also Q&A 17.1 in this Part of the Explanatory Guide.

2.30. Are articles in the scope of the restriction? Do articles under REACH have a minimum size?

Paragraph 1 (prohibition of placing on the market) does not apply to articles, or to SPM which are integral parts of articles.

The definition of "article" in Article 3(3) of the REACH regulation applies regardless of the size of an object. Article 3(3) defines an article as 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.

The general principle therefore is:

- if the shape, surface or design of an object determines its function more than its composition = article
- if composition is equally or more important to determine the function of the object than shape, surface or design = mixture or substance

Please refer to ECHA guidance on requirements for substances in articles for information on how to determine whether an object is an article, a substance/mixture or a combination of an article and a substance/mixture. Examples of borderline cases can be found in the ECHA Catalogue of borderline cases between articles and substances/mixtures, and in Part III, Annex 3 of this Explanatory Guide.

2.31. Are SPM used in scientific research and development or product and process-oriented research and development (PPORD), e.g., chemical grade reagents, in the scope of entry 78?

According to Art. 67 of REACH, restrictions in Annex XVII of REACH do not apply to the manufacture, placing on the market or use of a substance in scientific research and development (as defined in Article 3(23) of REACH).

The restriction in principle applies to PPORD (defined in REACH Article 3(22)). However, for the purpose of entry 78, the use of SPM (such as chemical reagents) for PPORD is overall derogated under Paragraph 4(a) as it is considered a use of SPM that usually takes place at industrial sites. The placing on the market of SPM for PPORD use is therefore allowed. This derogation is subject to information requirements (Paragraph 7) and reporting requirements (Paragraph 11).

See more details on PPORD in the ECHA Guidance on Scientific Research and Development and Product and Process Orientated Research and Development.

2.32. Could you clarify the relationship between the concentration limits of 1% by weight in the definition of SPM in the left-hand column of entry 78 and the concentration limit of 0.01% by weight in Paragraph 1)?

The left-hand column of entry 78 defines the conditions that polymers need to meet to be considered SPM and, therefore, within the scope of the restriction. These conditions include, among other things, that polymers are:

a) contained in particles and constitute at least 1% by weight of those particles; or build a continuous surface coating on particles; and

b) at least 1% by weight of the particles referred to in point (a) need to be either ≤5 mm in size or, if their length to diameter ratio is greater than 3 (e.g. fibres), be ≤15 mm in length.

In short, the concentration limits in the left-hand column of entry 78 are used, together with other conditions, to identify whether a polymer is an SPM. Note that polymers that are inorganic, natural, degradable or soluble in water, are excluded from the scope of the restriction and are not to be considered when determining whether the polymers contained in the particle constitute at least 1% by weight of that particle.

In contrast, the concentration limit of 0.01% by weight in Paragraph 1 specifies the concentration of SPM, present to confer a sought-after characteristic, that must not be reached in mixtures when placed on the market. It is set at a low concentration (0.01% by weight) to avoid the intentional use of SPM to confer a sought-after characteristic to the mixture. The concentration limit of 0.01 % corresponds to the lowest concentration level reported where SPM could still have an influence on the function of a product.

For additional information and practical examples of when a solid polymer can be considered an SPM and therefore within the scope of the restriction, and how to apply Paragraph 1, refer to Part I, Section 2, Part I, Section 5 and Annex 1, Tier 3 of this Explanatory Guide.

2.33. Is an article with a mixture that constitutes an integral part of it affected by the restriction, if that mixture contains SPM?

Articles are outside of the scope of Entry 78. This includes mixtures that are considered as integral part of them.

Please refer to ECHA guidance on requirements for substances in articles for information on how to determine whether an object is an article with a substance/mixture that constitutes an integral part of it, or a combination of an article and a substance/mixture (see, in particular, Appendix 3, and example 5, of the ECHA guidance).

2.34. What are unintentional SPM?

Unintentional SPM for the purpose of this entry are those that are not intentionally present in a mixture to provide a ‘sought-after’ characteristic. The restriction does not apply to the placing on the market of SPM that are unintentionally present in mixtures. For example, SPM present in a mixture unintentionally, i.e. because of the breakdown/abrasion of product packaging, are unintentional SPM and not in the scope of Paragraph 1 of entry 78, nor subject to IFUD and reporting requirements.

See also Q&A 3.1 and 3.2.

2.35. If a polymer forms a solid polymeric coating on the surface of an inorganic particle < 5 mm, such as sand, does it fall into the scope of the microplastic restriction?

If the polymer coating the sand is synthetic or chemically modified (see Art. 3(40) of REACH and Q2.13), organic, non-degradable (in accordance with Appendix 15 of Annex XVII of REACH) and has a solubility < 2g/L (in accordance with Appendix 15 of Annex XVII of REACH), then that polymer is an SPM and within the scope of the restriction.

2.36. How should the term "continuous surface coating" in the first column of entry 78 be understood?

Although there is no definition for the term "continuous surface coating" in entry 78, it means that 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 surface coating does not necessarily cover the entire surface completely and the presence of small gaps in the coating is possible. For more information, see Part I, Section 2 of this Explanatory Guide.

2.37. Does the restriction apply to medicinal products, medical devices and biocides?

The restriction on the placing on the market applies to medical and accessory devices within the scope of Regulation (EU) 2017/745 that contain SPM on their own or in mixtures, unless derogated under Paragraphs 4, 5 or 16. The restriction mainly affects the so called 'substance-based medical devices', e.g. medical and accessory devices referred to by the classification rule 21 or rule 4 in Annex VIII in Regulation (EU) 2017/745. These devices benefit from the transitional period in Paragraph 6(f) and can be placed on the market until 17 October 2029, unless they contain microbeads (i.e. SPM for use as an abrasive, namely to exfoliate, polish or clean), in which case they are prohibited from being placed on the market since 17 October 2023.

The restriction on the placing on the market also applies to biocidal products that contain SPM on their own or in mixtures. Biocidal products benefit from a transitional period in Paragraph 6(h) and can be placed on the market until 17 October 2031.

The restriction on the placing on the market does not apply to medicinal products within the scope of Directive 2001/83/EC and Regulation (EU) 2019/6 (Paragraph 4(b)) – see Section 6, Part I of this Guide. These products are however subject to the reporting requirements in Paragraph 12. Moreover, the restriction does not apply to *in vitro* diagnostic devices (including accessory devices) within the scope of Regulation (EU) 2017/746 (Paragraph 4(e). However, *in vitro* diagnostic devices are subject to information (Paragraphs 8 and 10) and reporting requirements (Paragraph 12).

2.38. Under what circumstances would a seed coating formulation fall within the scope of the restriction.?

The solid polymer(s) in the seed coating would be considered as SPM (and therefore covered under the restriction) if:

- at least 1% (by weight) of the seeds in the batch measure <5 mm in all dimensions;

- the polymer(s) in the coating is(are) synthetic or chemically modified (see Art. 3(40) of REACH and Q2.13), organic, non-degradable (in accordance with Appendix 15 of Annex XVII of REACH) and has(have) a solubility < 2g/L (in accordance with Appendix 15 of Annex XVII of REACH).

In accordance with Paragraph 6(h), seeds coated with plant protection products containing SPM benefit from an 8-year transitional period and can be placed on the market until 17 October 2031. Other coated seeds used in agriculture and horticulture benefit from a 5-year transitional period under Paragraph 6(i) and can be placed on the market until 17 October 2028.

The placing on the market of SPM for use at industrial sites, e.g. for the formulation and application of seed coating at an industrial site, is allowed (derogation under Paragraph 4(a)) but IFUD and reporting requirements apply.

2.39. What products for agricultural and horticultural applications/uses are included in the scope of the restriction?

The restriction on the placing of the market applies to SPM in agricultural and horticultural products such as:

- non-CE marked fertilising products (e.g., where SPM are used as coating agents or to increase the water retention capacity or the wettability of the product), as of 17 October 2028 (Paragraph 6(g));
- plant protection products, as of 17 October 2031 (Paragraph 6(h));
- biocides, as of 17 October 2031 (Paragraph 6(h));
- treated/coated seeds, as of 17 October 2031 (Paragraph 6(h)) if coated with plant protection products, or 17 October 2028 (Paragraph 6(i)) if coated/treated with other substances/mixtures;
- technical additives, anti-caking or anti-dusting agents, colorants, etc, as of 17 October 2028 (Paragraph 6(i)).

The restriction does not apply to the placing on the market of SPM in CE-marked fertilisers as such products are regulated under the Fertilising Products Regulation (Regulation (EU) 2019/1009).

3. Paragraph 1 – Prohibition of placing on the market

The questions in this Section aim to clarify how the prohibition in Paragraph 1 is applied. This Section is complemented by product-specific questions in Sections 15 to 19.

3.1. What is meant by the term “sought-after characteristic”?

The wording intends to convey that, in case of SPM present in mixtures, the restriction on the placing on the market applies when the SPM are present or added to the mixture (product) intentionally, for the purpose of providing a sought-after property to the mixture

(product), such as a given colour (e.g. encapsulated pigments), texture, water absorption, fluidity, volume (e.g. fillers), etc. An SPM that is present only as an unintentional impurity, for example, because of the degradation of larger polymer particles or objects, should **not** be considered to be present to confer a 'sought after characteristic'.

For more information on what is meant by the term "sought-after characteristic", see Part I, Section 5.

3.2. Does a polymer fall within the scope of Paragraph 1 of entry 78 if it does not constitute an SPM when it is added to the mixture (product) but becomes an SPM when the mixture (product) is used?

No. Polymers that are not SPM but that unintentionally become SPM during use or disposal of a product (e.g. from wear and tear, or the breakdown of larger plastic particles or objects) are not in the scope of Paragraph 1 of entry 78.

3.3. What is "placing on the market"? What is the difference between "placed on the market" in Paragraph 1 and "placed on the market for the first time" in Paragraph 12?

Placing on the market is defined in Article 3(12) of REACH as "supplying or making available, whether in return for payment or free of charge, to a third party". It includes for example (not exhaustive) supplying, selling, renting, etc. Products in distributor's stocks, products that have left the distributor's facilities and product on retailer's shelves are all examples of products placed on the market.

The expression "placing on the market for the first time" is specifically used in Entry 78 in relation to the reporting requirements in Paragraph 12, where it identifies the first time in the supply chain that a product containing derogated SPM is placed on the market for use by the general public or professionals (to distinguish it from previous steps in the supply chain where the product, or the derogated SPM present in it, would have been placed on the market for use at industrial sites).

Paragraph 12 requires that the first supplier (i.e. the first manufacturer, importer, or DU) in the supply chain that places a product containing derogated SPM on the market for use by the general public or professionals (rather than for use at industrial sites) estimates and reports to ECHA their own SPM emissions, including during transport, plus the downstream SPM emissions from the moment the product is placed on the market for use by the general public or professionals to the moment it is disposed of after end use. This obligation, which applies for products containing SPM derogated under Paragraph 4, points (b), (d) and (e), and Paragraph 5, is intended to avoid double reporting of estimated SPM emissions when multiple suppliers (particularly distributors) are involved in the supply chain of a product. It also intends to avoid placing reporting obligations on distributors, retailers and end users.

3.4. Can loose plastic fibres for model making and products that contain these fibres continue to be placed on the market?

Loose fibre-like particles are in the scope of the restriction if:

1. they contain at least 1% of, or are coated by, solid polymers that are synthetic (or chemically modified natural polymers), organic, non-degradable and have a solubility < 2 g/L; and
2. At least 1% of the fibre-like particles containing those solid polymers are less than 15 mm long and have a length to diameter ratio greater than 3.

Fibre-like particles in the scope of the restriction can only continue to be placed on the market, on their own (i.e. loose) or in mixtures, for use at industrial sites (under derogation 4(a)) or if their intended end use is covered by one of the derogations under Paragraph 5. In those cases, they are subject to IFUD and reporting requirements in Paragraph 7-8 and 11-12, respectively. Articles containing these fibres may continue to be placed on the market if those fibres are considered to be an integral part of the article. See the ECHA Guidance on requirements for substances in articles for further guidance.

4. Paragraph 2 – Definitions

This Section includes questions on the definitions of specific terms and expressions provided in Paragraph 2.

4.1. Are amorphous polymers with a glass transition temperature below 20°C to be considered solid or liquid?

The glass transition temperature is not used as a criterion to determine whether a polymer is solid or liquid for the purpose of entry 78. Paragraph 2(b) of entry 78 defines a solid as "a substance or mixture other than a liquid or a gas", in line with the definition used in the "Globally Harmonized System of Classification and Labelling of Chemicals" (GHS). The terms "liquid" and "gas" are defined in Paragraph 2(d) and 2(c), respectively.

For a substance or a mixture which does not exhibit a specific melting point, the solid *vs* liquid status can be determined either via the ASTM D 4359-90 test or via the fluidity test (penetrometer test) described in section 2.3.4 of Part 2 of Annex A to the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).

4.2. Are semi-solid polymers included in the scope of the proposed restriction?

The term 'semi-solid' is not used nor defined in entry 78. Therefore, the term 'semi-solid' is not a relevant parameter.

To understand whether a 'semi-solid' polymer is in the scope of entry 78, it is necessary to assess whether that polymer fulfils the definition of 'solid' under Paragraph 2(b) (since only solid polymers are in the scope of entry 78). A 'solid' is a substance or mixture other than a liquid (as defined under Paragraph 2(d)) or a gas (as defined under Paragraph 2(c)).

Certain polymers that are commonly referred to as “semi-solid” may be solid according to the definition in Paragraph 2(b).

4.3. What cosmetic products are considered make-up, for the purpose of the restriction?

The definition of make-up introduced in Paragraph 2(e) for the purpose of the restriction is: "any substance or mixture intended to be placed in contact with specific external parts of the human body, namely the epidermis, eyebrows and eye lashes, with a view to, exclusively or mainly, changing their appearance".

A case-by-case evaluation is necessary to conclude whether a cosmetic product is "make up". The evaluation will depend on how the product is presented and what the main purpose of the product is. For example, if the presentation of a cosmetic product makes clear that the product aims at changing the appearance, the product could be considered make-up.

4.4. What is the definition of ‘air care products’ for the purposes of the restriction?

Entry 78 does not include a definition of air care products. However, examples of air care products are listed in footnote 78, page 131 of the final RAC/SEAC Opinion supporting the restriction: aerosol, electric, gel and liquid air fresheners; scented candles; and car air fresheners..

4.5. Are all "gas" and "liquid" polymers out of scope of the restriction? What proof needs to be submitted to enforcement authorities to prove that the physical state of a polymer is "gas" or "liquid"? Is the information in the SDS or a statement from the supplier sufficient or companies have to re-test their formulations for compliance with the regulation?

Only solid polymers (with certain characteristics) are in the scope of the restriction. All gaseous (if existing) and liquid polymers are excluded.

Information on the physical properties of the polymers in the product does not have to be systematically submitted to authorities but this information should be available in case of control by enforcement authorities, in particular when the company claims that the polymers in the product are outside the scope of the restriction because they are not solid. REACH does not require certificates of conformity. Individual companies remain responsible for ensuring compliance of their products with the restriction, which may mean re-testing of products to ensure that their physical properties are consistent with the definitions of liquid or gas provided in entry 78

5. Paragraph 3 – Temporary lower size limit

This question concerns the temporary lower size limit as defined in Paragraph 3.

5.1. Will Paragraph 3 of entry 78 be updated and the temporary lower limit lowered to take into account scientific developments?

It is not necessary to amend Paragraph 3 of the restriction to reflect scientific progress in analytical techniques in order for that Paragraph to stop applying. The reference in

Paragraph 3 is dynamic, so the exception in this Paragraph will no longer apply as soon as new methods are developed that allow the reliable detection and quantification of particles below 100 nm (or 300 nm, of particles with length to diameter ratio > 3). If the exception in Paragraph 3 stops applying, all particles with dimensions ≤ 5 mm (or length ≤ 15 mm, if length to diameter ratio > 3) should be considered when applying the SPM conditions in the left-hand column of entry 78.

To ensure 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 reported in future updates of this Explanatory Guide.

However, should there be the need of setting a new temporary lower limit, then it will be necessary to amend Paragraph 3 accordingly.

6. Paragraph 4 – Derogations for certain uses and products

These questions concern how the derogation from the prohibition of placing SPM on the market applies to uses and products laid down in Paragraph 4.

6.1. When does Paragraph 1 apply for uses of SPM that are not specifically mentioned in Paragraph 6? Is the placing on the market of SPM for these uses prohibited from the entry into force of the restriction?

The placing on the market of SPM is prohibited as of 17 October 2023, unless the SPM (or the product containing them) benefit from a derogation under Paragraphs 4, 5 or 16 or are granted a transitional period in Paragraph 6 of the restriction.

SPM benefitting from the derogations under Paragraphs 4 and 5 are subject to IFUD requirements (for suppliers) and reporting obligations (for manufacturers, certain importers, and DU). Please refer to Paragraphs 7, 8, 10 and 11 and/or 12, and see Part I, Section 8 and 9 of this Explanatory Guide for additional information, including on from when these requirements will apply for uses benefiting from a derogation or granted a transitional period.

6.2. How do I identify a “use at industrial sites” for applying the derogation in Paragraph 4(a)?

ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12 on Use Description, helps in distinguishing between uses at industrial sites and professional uses outside industrial sites. It includes a weight of evidence method to decide whether a use takes place at an industrial site or outside an industrial site (see, in particular, the criteria set in table R.12-6 in Appendix R.12.3).

Further information and examples of uses at industrial sites are also provided in Part I, Section 6 of this guide.

Paragraph 4(a) derogates uses of SPM at industrial sites from the general prohibition under Paragraph 1. It does not apply to SPM for professional uses outside industrial sites. Placing

on the market of SPM (on their own or in a mixture in a concentration ≥0.01% w/w) for professional uses (not at an industrial site) or consumer uses is only permitted for SPM derogated under Paragraph 4 (other than 4(a)), 5 or 16, or in products granted a transitional period under Paragraph 6.

Please refer to the decision trees in Part III, Annex 1 and flow charts in Part III, Annex 2 on obligations along the supply chain.

6.3. Are medical devices derogated from the restriction?

In vitro diagnostic devices, including accessory devices, within the scope of Regulation (EU) 2017/746 are derogated from the ban on placing on the market (Paragraph 1) under Paragraph 4(e). However, the ban on placing on the market applies to medical or accessory devices within the scope of Regulation (EU) 2017/745 after a 6-year transitional period, i.e. as of 17 October 2029 (unless they contain microbeads in which case their placing on the market is an as of 17 October 2023, cf Paragraph 6(f)).

The restriction applies to the placing on the market of medical devices within the scope of Regulation (EU) 2017/745 that are substances, or mixtures, or a combination of an article and a substance/mixture. Thus, the restriction will predominantly affect '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. See also Q&A 2.37 and 6.7, and Part I, Section 7 of this Explanatory Guide.

Certain medical devices that use SPM, such as polymeric filters (ion exchange resins), adsorbers and absorber granulates for blood treatment may be derogated under Paragraph 5(a) (for ion exchange resins) or Paragraph 5(b) (adsorbers that swell) if they comply with the conditions laid down in those Paragraphs.

Note that suppliers of medical devices containing derogated SPM are subject to information requirements outlined in Paragraph 8 and 10 and to reporting requirements outlined in Paragraphs 11 (for industrial downstream uses) and/or 12 (for professional and consumer end uses). Part I, Section 8 and 9 of this Explanatory Guide contains additional information on IFUD and reporting requirements.

6.4. Does Paragraph 4(d) derogate food additives from the restriction? Similarly, does Paragraph 4(f) derogate all foodstuffs except food additives? What information (e.g. IFUD) must suppliers of food additives communicate to their DUs and in what format?

Paragraph 4(d) derogates food additives containing SPM from the prohibition on placing on the market in Paragraph 1. However, from 17 October 2025, suppliers of food additives containing SPM are subject to IFUD requirements in accordance with Paragraphs 8 and 10. In addition, from 31 May 2027, industrial DU using SPM to manufacture food additives at industrial sites and suppliers of food additives containing SPM are subject to reporting requirements according to Paragraph 11 and 12 of the restriction, respectively.

However, information requirements and reporting requirements are not applicable to foods in scope of Paragraph 4(f). This means that once an SPM-containing additive has been added to food, there are no further obligations under the restriction.

See Part I, Section 8 and 9 of this Explanatory Guide for additional information on IFUD and reporting requirements.

6.5. What is the difference between derogations 4(a) and 5(b)? Can examples be provided?

The derogation under Paragraph 4(a) enables suppliers to place SPM on the market for any use at industrial sites. When using this derogation to place SPM on the market, suppliers have to provide the information specified in Paragraph 7, including IFUD. Manufacturers and industrial DUs of SPM for which the placing on the market is derogated under Paragraph 4(a) are required to undertake annual reporting of estimated SPM emissions to ECHA as per Paragraph 11 (by 31 May of each year starting from 2026 (SPM in pellets, flakes, and powders used as feedstock in plastic manufacturing) or 2027 (other SPM)). As part of the reporting obligations, they also have to provide a description of the SPM uses, generic information on the identity of the polymer, and a reference to the applicable derogation(s).

The derogation under Paragraph 5(b) permits placing SPM on the market for a specific intended end use, where the polymers physical properties permanently change as part of that intended use and the polymers stop being SPM (e.g. film-forming polymers in paints that, when the paint is applied, coalesce to form a film and are no longer contained in particles; PET in pellets melted during the production of plastic bottles). Products must be accompanied by IFUD as per Paragraph 8 (effective from 17 October 2025). Moreover, the initial supplier placing the product on the market for the first time to professional users or the general public must undertake annual reporting to ECHA as per Paragraph 12 (by 31 May of each year starting from 2027).

Multiple derogations can apply at the same time, such as derogations under Paragraphs 4(a) and 5(b) applying to the placing on the market of the same SPM.

The information and reporting requirements applicable when multiple derogations apply are discussed in Part I, Section 6 of this Explanatory Guide.

6.6. If a company uses SPM to manufacture or formulate a fertiliser at an industrial site, and then places the resulting fertiliser containing SPM on the market, what are their reporting or labelling obligations and what are their deadlines?

A company that uses SPM at industrial sites to manufacture or formulate a fertiliser must meet the reporting obligation in Paragraph 11 by 31 May 2027 (for uses that took place in 2026) and yearly thereafter. This reporting obligation is independent of whether the manufactured or formulated product containing SPM is subsequently placed on the market.

As regards the placing on the market of the manufactured or formulated fertiliser, it is to note that the placing on the market of fertilising products that fall within the scope of the

EU Fertilising Products Regulation (FPR), i.e. the so-called CE-marked fertilising products is not prohibited (derogation under Paragraph 4(c)) and not subject to information or reporting obligations.

Fertilising products that do not fall within the scope of the FPR, i.e. non-CE marked fertilising products that contain SPM, can only be placed on the market until 17 October 2028 (Paragraph 6(g)) unless derogations under Paragraphs 4 or 5 apply to the SPM (in which case, information (including IFUD) obligations under Paragraphs 7 or 8, and 10, and reporting obligations under Paragraph 11 or 12 may apply, see Sections Part I, Sections 8 and 9).

However, if the fertiliser contains polymers that are degradable (as per Appendix 15 to Annex XVII of REACH) or soluble (as per Appendix 16), then the product is out of the scope of the restriction and can continue to be placed on the market after 17 October 2028.

See also Q&A 2.39.

6.7. If a company uses SPM to produce a medical device at an industrial site, and then places the resulting medical device containing SPM on the market, what are their reporting or labelling obligations and what are their deadlines?

A company that uses SPM to manufacture such devices at industrial sites is subject to the reporting obligation in Paragraph 11 from 31 May 2027 (for uses between January and December 2026) and yearly after. This reporting obligation is independent of whether the manufactured or formulated product containing SPM is subsequently placed on the market.

As regards the produced medical device, the restriction applies to the placing on the market of medical and accessory devices within the scope of Regulation (EU) 2017/745 that contain SPM on their own or in mixtures, unless derogated under Paragraphs 4 or 5, as of 17 October 2029 (Paragraph 6(f)), unless they contain microbeads (i.e. SPM for use as an abrasive, namely to exfoliate, polish or clean), in which case they have been prohibited from being placed on the market since 17 October 2023.

A company placing on the market a medical device, including in vitro medical devices, containing SPM derogated under Paragraph 4(e) or 5, must provide instructions for use and disposal with the device by 17 October 2025 and 17 October 2026 respectively (see Paragraph 8). If the company is the first supplier in the supply chain to place on the market the medical device to professional users or to the general public, then it is subject to the reporting obligations in Paragraph 12 from 31 May 2027 (for uses and emissions between January and December 2026) and yearly after.

See also Q&A 2.37 and 6.3.

6.8. With regards to pharmaceutical ingredients, what information must manufacturers communicate to their DUs (e.g. IFUD and/or degradability and solubility data) and in what format?

Some pharmaceutical ingredients may be SPM. Pharmaceutical ingredients placed on the market in medicinal and veterinary medicinal products are derogated under Paragraph 4(b). Suppliers of medicinal products containing SPM derogated under Paragraph 4(b), are not subject to IFUD requirements under Paragraphs 7 or 8 of entry 78 but, from 31 May 2027, they are subject to reporting requirements according to Paragraph 12 of the entry.

Pharmaceutical ingredients that are not yet included in medicinal products cannot benefit from the derogation under Paragraph 4(b). However, if they are used at industrial sites (e.g. in the formulation of the medicinal product), they can benefit from the derogation under Paragraph 4(a). In this case, manufacturers and industrial downstream users of pharmaceutical ingredients that are SPM are subject to the information requirements in Paragraph 7 as of 17 October 2025 and to the reporting requirements in Paragraph 11 as of 31 May 2027.

In the case of pharmaceutical ingredients claimed not to be SPM on grounds of degradability or solubility, it is recommended that manufacturers provide their DUs with information proving that those ingredients are degradable or soluble in accordance with Appendix 15 or Appendix 16 to Annex XVII of REACH, respectively. Manufacturers, importers and industrial downstream users must have that information available and provide it to national competent authorities upon their request.

See Part I, Sections 9 and 10, for additional information on reporting requirements, and information for national competent authorities, respectively.

For further information on demonstrating degradability and solubility compliance, see Part I, Sections 3 and 4, and Part II, Q&A 13.11.

7. Paragraph 5 – Derogations for synthetic polymer microparticles in certain intended end uses

This Section aims to clarify how the derogation from the prohibition of placing SPM on the market applies to the SPM referred to in Paragraph 5.

7.1. What is an intended end use as referred to in Paragraph 5? Who are end-users? Who are industrial “downstream users”?

In general, an intended end use can be understood as a specific type of use intended as the final use of a substance, product or article, 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.

Industrial downstream users are downstream users that use substances or mixtures at industrial sites. The definition of the term "**downstream user**" in Article 3(13) of the REACH Regulation refers to individuals or companies established within the EU/EEA who utilise chemicals in their industrial or professional activities. A distributor or a consumer is not a downstream user according to that definition. Industrial downstream users include, for example: formulators who produce mixtures like paints and adhesives for further distribution, end users (except professionals or consumers) utilising substances or mixtures without further distribution, producers of articles integrating chemicals into finished products such as textiles and household appliances, re-fillers transferring substances between containers during repackaging, re-importers bringing substances that were originally produced within the EU/EEA back into the EU/EEA, and importers with an "only representative" designated by non-Community suppliers to act as registrants within the Community.

For additional information please refer to the ECHA website: https://echa.europa.eu/regulations/reach/downstream-users/about-downstream-users/who-is-a-downstream-user

7.2. Can derogations under Paragraph 5, e.g. 5(b), also apply to the placing on the market for the formulation stage at industrial sites? Or does any placing on the market of SPM for use at industrial sites fall under the Paragraph 4(a) derogation, by default?

Multiple derogations can apply to the placing on the market of the same SPM. The placing on the market of SPM for use at industrial sites is always derogated under Paragraph 4(a). However, the placing on the market of the same SPM can also be derogated, at the same time, under Paragraph 5(b) if the use at the industrial site is the end use of the SPM (or the product containing them), and the SPM stops being SPM during that end use. See discussion and further examples in Part I, Section 6 of this Explanatory Guide.

To verify which are the applicable IFUD and reporting requirements when multiple derogations apply, see additional information and examples provided under Part I, Section 6 of this Explanatory Guide.

7.3. Synthetic polymers may be used or regulated as food/novel foods (e.g., as a chewing gum base). This includes copolymers of methyl vinyl ether and maleic anhydride. Can the placing on the market of these polymers be derogated under Paragraph 5(b) or (c)?

SPM in food (within the meaning of Article 2 of Regulation (EC) No 178/2002), including novel foods but excluding food additives, are derogated from the ban on placing on the market under Paragraph 4(f). Food, including novel food, is also not subject to IFUD or reporting requirements.

7.4. Nail polish hardens into a film when used. Do the derogations under Paragraph 5(b) or 5(c) apply to the placing on the market of SPM in nail polish?

The placing on the market of film-forming polymers in nail polish is derogated under Paragraph 5(b) because these polymers permanently stop being SPM at end use (the SPM

coalesce to form a film). The derogation under Paragraph 5(c) does not apply to the placing on the market of SPM in nail polish (e.g., SPM-containing glitter) because the derogation does not intend to cover uses where the solid matrix is intended to be frequently removed and replaced, such as cosmetic products. See Part I, Section 6 for more information.

Note that SPM and products containing SPM for which the placing on the market is derogated under Paragraph 5 are subject to IFUD and reporting requirements under Paragraphs 8/10 and 12, respectively.

7.5. Are 'swellable' polymers included in the scope of the restriction?

Swellable solid polymers that fulfil the SPM conditions (i.e. are synthetic, organic/chemically modified, non-degradable, insoluble, are either contained in or coating particles, etc.) are within the scope of the restriction. However, the derogations under Paragraph 5 may apply to swellable SPM.

For example, swellable SPM contained in diapers may fall under Paragraph 5(a).

Paragraph 5(b) applies to swellable SPM that, during intended end use, become larger than 5 mm in at least one dimension and remain larger during the intended end use of the product. For example, in the case of diapers, Paragraph 5(b) would apply if the polymers are still swollen when the diaper is removed and disposed of. See also Text Box 9 in Section 6, Part I of this Explanatory Guide.

If the swelling of the polymer is temporary during intended end use, the original physical state of the polymer as placed on the market (i.e. prior to the swelling) determines whether the polymer is an SPM.

Paragraph 5(b) also applies to swellable SPM that lose their solid state, or stop being in particles, during intended end use.

Swellable polymers derogated under Paragraph 5 are subject to IFUD (Paragraph 8) and reporting requirements (Paragraph 12).

Swellable polymers that form gels in the presence of water (or other solvents) that do not contain particles do not fulfil the SPM definition.

7.6. Is granular rubber infill for road building in scope and, if yes, is there any applicable derogation?

Synthetic polymers in granular rubber infill for road building are in the scope of the restriction if they meet the definition of SPM.

Placing on the market of SPM in granular rubber infill for road building may be derogated from the prohibition of placing on the market. For example, when the SPM are permanently incorporated into the road surface, they can be regarded as permanently incorporated in a solid matrix (the road surface) and the derogation under Paragraph 5(c) applies. As per Paragraph 8, suppliers of SPM derogated under Paragraph 5 must provide IFUD by 17

October 2025, with compliance details outlined in Paragraph 10. Additionally, from 31 May 2027, suppliers are subject to annual reporting requirements to ECHA, as per Paragraph 12.

The placing on the market of SPM for the formulation and production of rubber infill at industrial sites is derogated under Paragraph 4(a). Uses of SPM for which the placing on the market is derogated under Paragraph 4(a) are subject to IFUD and reporting obligations under Paragraphs 7 and 11, respectively.

7.7. Is granular rubber for playgrounds where the granules are embedded in a solid matrix, such as a solid rubber layer/pad, exempted from the restriction?

SPM in granular rubber permanently embedded in a solid rubber surface in playgrounds or other applications, such as sport surfaces, can be considered as "permanently incorporated in a solid matrix" during intended end use and their placing on the market is therefore derogated under Paragraph 5(c).

SPM and products containing SPM derogated under Paragraph 5 are subject to IFUD and reporting requirements under Paragraphs 8, 10 and 12, respectively.

7.8. What are the obligations concerning the placing on the market of SPM contained in products like ion-exchange resins, water filtering cartridges, and other products? When do the derogations under Paragraph 5(a) and 5(c) of the REACH restriction apply and to what obligations do suppliers need to adhere to benefit from those derogations?

For products with SPM **contained by technical means**, such as filter cartridges, the derogation under Paragraph 5(a) applies. For the derogation in Paragraphs 5(a) to apply, there should be no release of SPM to the environment during intended end use when the product where the SPM are contained in by technical means is used as intended, in accordance with the instructions for use.

The placing on the market of products containing SPM that are permanently incorporated in a solid matrix during intended end use (e.g., reinforcing polymer particles in concrete/adhesives or polymer-encapsulated pigments in paint films) is derogated under Paragraph 5(c). For the SPM to be regarded as "permanently incorporated" in a solid matrix, the solid matrix needs to stay in place indefinitely, without any predetermined end date. The derogation in Paragraph 5(c) does not intend to cover uses where the solid matrix is intended to be frequently removed and replaced, such as cosmetic products. See Part I, Section 5 of this Explanatory Guide for additional information.

As per Paragraph 8, suppliers of products containing SPM for which the placing on the market is derogated under Paragraph 5 must provide IFUD by 17 October 2025. Additionally, from 31 May 2027, suppliers are subject to annual reporting requirements, as per Paragraph 12. The reporting should consider how the products are used and the likely releases to the environment of SPM during the end use e.g. from the product application or

removal, the disposal of residues in product packaging or during clean-up (e.g. washing of tools and equipment).

7.9. What are the obligations for suppliers placing SPM on the market that form films during their intended end use and are permanently modified in such a way that the polymer stops being an SPM and no longer falls within the scope of entry 78 (i.e., placing on the market of SPM derogated under Paragraph 5(b))?

The placing on the market of (a product containing) SPM is derogated for all intended end uses where the SPM meet the conditions indicated in Paragraph 5(a), (b) or (c), regardless of whether those intended end uses are industrial, professional or consumer uses.

Suppliers of products containing SPM for which the placing on the market is derogated under Paragraph 5 are subject to IFUD obligations laid down in Paragraphs 8 and10, while manufacturers and industrial DUs of those products are subject to reporting obligations under Paragraph 12. These obligations lie with the entity placing the product on the market. A definition of placing on the market is provided in Article 3(12) of the REACH Regulation as well as in Part II, Section 12. See in particular Q&A 12.2.

The responsibility for placing a product on the market is described in the flow charts presented in Part III, Annex 2 of this Explanatory Guide.

7.10. Is there a method to determine whether the placing on the market of an SPM is derogated under Paragraph 5(a), (b) or (c)?

There are no standard tests to demonstrate compliance with Paragraph 5(a), (b) or (c).

For the derogation in Paragraphs 5(a) to apply, there should be no release of SPM to the environment during intended end use, when the product where the SPM are contained in by technical means is used as intended, in accordance with the instructions for use.

Suppliers placing SPM derogated under Paragraph 5 on the market should ensure that they have sufficient scientific rationale/evidence available that the conditions of the derogation are met during the intended end use. It is for national enforcement authorities to decide whether the information provided by the supplier is sufficient to prove compliance. See Part I, Section 10, of this Explanatory Guide for additional information on information to be provided to competent authorities.

7.11. What specific information is required for a definitive assessment of whether the placing on the market of a product is derogated under Paragraph 5? For example, if a home decoration product is composed of natural materials, along with a binder and, potentially, polyester glitter, and applied to walls or ceilings, forming a solid layer removable with water, how would this be assessed?

Manufacturers should first determine if their product contains SPM when placed on the market. To this end, please see Part I, Sections 2 and 5 of this Explanatory Guide, and the workflows in Part III, Annex 1.

In case of home decorating products containing SPM, if the intended end use of the product is to form a permanent solid matrix (e.g. dried paint) on walls or ceilings, the derogation under Paragraph 5(c) applies, including for any polyester glitter that would be embedded within the solid matrix. The derogation does not intend to cover uses where the solid matrix is intended to be frequently removed and replaced.

Suppliers placing SPM on the market under Paragraph 5 should ensure that they have sufficient scientific rationale/evidence available to prove that the conditions of the derogation are met during the intended end use. It is for national enforcement authorities to decide whether the information provided is sufficient to prove compliance (note that Member States' enforcement authorities do not pre-approve products or product information). See Part I, Section 10, of this Explanatory Guide for additional information on information to be provided to competent authorities.

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 (i.e. natural polymers), are not within the scope of the restriction, unless the polymers have been 'chemically modified'. For more information on chemically modified polymers and, more generally, on chemically modified substances, see section 3.2.1.3 of the ECHA guidance for monomers and polymers, and the ECHA guidance for Annex V - Exemptions from the obligation to register.

There are IFUD and reporting obligations associated with derogations. For derogations under Paragraph 5, requirements under Paragraph 8, 10 and 12 apply.

7.12. How is it possible to demonstrate that the physical properties of SPM are permanently modified during end use (i.e., that they meet the conditions to be derogated under Paragraph 5(b))? What methods will be considered acceptable, and will these be harmonised at EU level?

Compliance is the responsibility of the operator placing products containing SPM on the market. The most suitable method depends on the type of SPM and its conditions of use; hence, specific methods cannot be recommended. Justification may not necessarily need to rely on analytical testing results but can be based on other credible scientific rationale and appropriate documentation. It is advised to thoroughly document and retain justifications for at least for a period of 10 years in accordance with Article 36 of the REACH Regulation.

8. Paragraph 6 – Transitional periods

These questions concern the (lack of) transitional periods, defined in Paragraph 6, for the application of the prohibition on the placing on the market SPM in microbeads, cosmetic products, synthetic sport surfaces, and other SPM-containing products.

Microbeads

8.1. Microbeads, as understood in common language, may have uses other than "to exfoliate, polish or clean", e.g. they can be used as anti-caking agents (to improve the flow characteristics of mixtures). Does that mean some uses of microbeads have a transitional period?

Entry 78 defines 'microbeads' as SPM for use as an abrasive, i.e. namely to exfoliate, polish or clean. SPM-containing particles that are referred to as microbeads in common language but are not used to exfoliate, polish or clean (e.g. anti-caking agents used to improve flow of mixtures) are not to be regarded as 'microbeads' for the purpose of entry 78.

Microbeads (as defined in entry 78) do not have a transitional period and their placing on the market is banned as of 17 October 2023 unless the placing on the market is derogated e.g. placing on the market for use at industrial sites, e.g for abrasive blasting (derogated under Paragraph 4(a)).

Cosmetic Products

8.2. Is perfume also subject to the restriction, and what is the permissible content of SPM in perfume?

Perfume is in the scope of the restriction if it contains polymers fulfilling the SPM definition. In that case, the prohibition on the placing on the market applies if the perfume contains at least 0.01% of SPM w/w.

If perfume contains fragrance encapsulated with SPM, it benefits from a 6-year transitional period and can be sold until 16 October 2029. If a product/perfume is liquid and it contains solid polymers that are dissolved in it (i.e. the polymers are not contained in particles or coating particles), the restriction does not apply.

8.3. Does nail polish that includes SPM-containing glitter benefit from a transitional period?

Nail polish that contains SPM - such as acrylic powder or SPM-containing glitter - benefits from a 12-year transitional period, so it can be placed on the market until 16 October 2035, in line with Paragraph 6(c) of the restriction. Note however that, from 17 October 2031 (or 17 December 2031 for products placed on the market before 17 October 2031) until 16 October 2035, in order to continue to be placed on the market, this product needs to bear a statement indicating that it contains microplastics (i.e. "This product contains microplastics").

Note that if SPM, or the mixture containing them, are 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 abovementioned statement (as well as any information required by Paragraphs 7 or 8) on the label, that statement (as well as any information required by Paragraphs 7 or 8) needs

to be placed in the section for supplemental information of the CLP label, in accordance with Article 25(9) of the CLP Regulation.

See also Part I, Section 8 of this Guide.

Infill material for synthetic sport surfaces

8.4. What is a "synthetic sport surface"?

For the purpose of applying Paragraph 6(j) of entry 78, a synthetic sport surface is a sport surface including at least one layer made of solid synthetic material (e.g. a synthetic rubber pad, synthetic turf, etc.), to which the granular infill material is added.

Examples of synthetic sport surfaces include artificial turf pitches for football, rugby, tennis, padel, etc.

Examples of sport surfaces that are not considered "synthetic sport surfaces" include: clay tennis courts; equestrian riding grounds made of sand or other natural material, including where sand is mixed with shredded synthetic fabric; etc.

8.5. Are indoor uses of granular infill for synthetic turf pitches in scope of entry 78? Does the 8-year transitional period apply to them?

Yes, indoor uses of granular infill for synthetic sport surfaces are in the scope of entry 78 and benefit from an 8-year transitional period before the prohibition of placing on the market starts applying on 17 October 2031.

Granular infill material used on indoor synthetic sport surfaces is not considered to be contained by technical means (e.g. by the building where the sport surface is located) and does not benefit from the derogation in Paragraph 5(a).

8.6. Are mixtures sand/polymers for use in equestrian grounds to be considered as "infill material for artificial sport surfaces"? Does the 8-year transitional period under Paragraph 6(j) apply?

An equestrian/horse riding ground can be considered a "synthetic sport surface" for the purpose of the restriction if it includes at least one layer made of solid synthetic material (e.g. a synthetic pad, a rubber pad, etc.), to which the granular infill is added. Should this be the case, and should the polymer in the sand/polymer mixture used as infill material for the equestrian ground fulfil the SPM definition, the placing on the market of the infill would be prohibited after 8-year (i.e. from 17 October 2031), in agreement with Paragraph 6(j).

If the outdoor equestrian ground cannot be considered a synthetic sport surface, and the polymer in the sand/polymer mixture used as infill material for the equestrian ground fulfils the SPM definition, then the placing on the market of that infill material is prohibited from 17 October 2023 (date of entry into force of entry 78) if the mixture contains more than 0.01% of SPM. Note that, if at least 1% of the particles that contain or are coated by solid

polymer in the sand/polymer mixture have all dimensions below 5 mm, the polymer in/coating all particles in the mixture is to be considered SPM and should be taken into account for the calculation of the 0.01% w/w. See also Part I, Section 2 of this Explanatory Guide for more information.

8.7. Is an infill material based on sand (99.2% w/w) with a polymer coating (0.8% of the sand weight) to be regarded as SPM?

Yes. While the SPM definition provides for a 1% concentration limit for polymers that are contained in particles, there is no such concentration limit when polymers coat particles. Consequently, polymer-coated particles are to be regarded as SPM even if the polymer represent less than 1% of the weight of the coated particle (provided all the other conditions in the SPM definition are fulfilled).

Other

8.8. Paragraph 16 states that the Paragraph 1 shall not apply to SPM placed on the market prior to 17 October 2023. Does this also apply to uses listed in Paragraph 6?

Products containing SPM that were placed on the market before 17 October 2023, do not need to be recalled or withdrawn from the market but can continue being sold. This would be the case, for example, for SPM and products that have already been placed on the market and are in stocks at suppliers (such as distributors, importers or retailers). However, this does not apply to SPM or products granted a transitional period under Paragraph 6, which cannot continue to be placed on the market beyond the date in Paragraph 6 even if they had been already on the market before 17 October 2023.

Suppliers should make plans to ensure that products containing SPM are sold or disposed of prior to the expiry of the applicable transitional period to avoid product recalls.

8.9. What is the transition period for toys?

As there is no transitional period granted to toys under Paragraph 6, the restriction applies to toys as of 17 October 2023.

Toys affected by the restriction are those that contain SPM on their own, or SPM that confer a sought-after-characteristic to mixtures (as defined under REACH) in concentration ≥ 0.01% w/w. Toys that are articles according to Art 3(3) of the REACH Regulation (including articles with mixtures that are an integral part of them) are excluded from the scope of the restriction. See also Part I, Section 1, to establish whether a product is within the scope of the restriction, and the ECHA Guidance on requirements for substances in articles to establish whether a product is (i) a substance/mixture, (ii) an article (including an article with a mixture that is an integral part of it), or (iii) a combination of an article and a mixture.

Products containing SPM, including toys, that have been placed on the market before 17 October 2023 do not need to be recalled or withdrawn from the market but can continue

being placed on the market. For imported products, this applies to products arrived on the customs territory of the Union before 17 October 2023.

9. Paragraph 7, 8, 9 and 10 – Information requirements, including Instructions for Use and Disposal (IFUD)

The questions in this Section concern how to apply the information (including IFUD) requirements, the information to be provided, means of providing information and the specific IFUD obligations for various product types.

9.1. Does the obligation to provide instruction for use and disposal (IFUD) apply under all circumstances?

IFUD are required for all products containing SPM that may be placed on the market under the derogations in Paragraph 4(a), 4(d), 4(e), 5(a), 5(b) and 5(c). IFUD should explain to industrial DU, professional users and the general public how to use and dispose of the product in such a way as to prevent releases of SPM to the environment. If SPM, or the mixture containing them, are subject to classification and labelling requirements under the CLP Regulation, IFUD and other information required by Paragraphs 7, 8 or 9 that are placed on the label need to be placed in the section for supplemental information of the CLP label, in accordance with Article 25(9) of the CLP Regulation – see Q&A 8.3.

See also explanations in Part I, Section 8 of this Explanatory Guide.

9.2. Are IFUD required for products for which the placing on the market is derogated from the restriction because the SPM they contain cease to be SPM during the product intended end use?

IFUD are required for all products that contain SPM that may be placed on the market under the derogations in Paragraph 4(a), 4(d), 4(e), 5(a), 5(b) and 5(c). While it is true that SPM derogated under Paragraph 5(b) stop being SPM when the product is used according to its intended end use, they remain SPM while the product is in the container/packaging, e.g. prior to the end use, or when residual product remains in the container prior to disposal or on tools/equipment. The IFUD should indicate how e.g. the product should be used and disposed of, including any residual product (that may still contain SPM) in the container/packaging or on work areas, tools and equipment, to prevent SPM emissions to the environment. Note that such instructions can be in the form of pictograms (e.g. in case space is an issue). See also explanations in Part I, Section 8 of this Explanatory Guide, and considerations for use of QR codes in Q&A 9.4 below.

9.3. In the case of SPM for which the placing on the market is derogated under Paragraph 5(b), should IFUD concern the product with SPM in the container/packaging or the SPM-free product as applied/used at end use?

In case of products containing SPM for which the placing on the market is derogated under Paragraph 5(b), IFUD should indicate to the professional user and/or the consumer how to prevent SPM emissions to the environment associated with (i) the use of the product,

including product removal and clean-up of tools, as well as (ii) how to dispose of the product after use, including any residual product in the container/packaging.

Nail products, for example, may contain film-forming SPM derogated under Paragraph 5(b). IFUD should address, for example, how to use the product to minimise SPM releases (for example, how to apply acrylic powder for permanent gel manicure in a way that minimises spills); how to properly dispose of materials that would typically be contaminated with SPM during the intended end use of the product, including when removing the product, e.g., tissues/wipes; or how to handle the product container (which may contain some residual product and SPM), e.g. by recommending not to rinse the container. The instructions can be in the form of text or pictogram(s) and can be placed on the product, the packaging or the product leaflet. They can be complemented by digital information accessible by scanning a QR code.

If SPM, or the mixture containing them, are subject to classification and labelling requirements under the CLP Regulation, the information required by Paragraphs 7-9, including IFUD, that is placed on the label needs to be placed in the section for supplemental information of the CLP label, in accordance with Article 25(9) of the CLP Regulation – see Q&A 8.3.

For additional information on IFUD, see Part I, Section 8.

9.4. Would 'Do Not Pour Product Down the Drain' or 'Do Not Rinse Packaging Before Disposal' be adequate IFUD for a cosmetic product containing SPM derogated under Paragraph 5(b)?

In principle, these statements may be regarded as adequate IFUD for a cosmetic product containing SPM derogated under Paragraph 5(b) when still in its container/packaging, as well as for the "empty" container which still has some product residues (with SPM) in it. A pictogram expressing the same concept may also be regarded as adequate. However, IFUD should also consider the clean-up of work areas and of any tools or equipment used with the product containing SPM.

Only national enforcement authorities can assess on a case-by-case whether the indicative sentences above would be sufficient or 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. It is encouraged, where space allows, to add a QR code in the labelling and/or package leaflet of the product with a link to complementary, more extensive instructions for professional users and the general public on how to apply the product and properly dispose of it in order to minimise releases of SPM into the environment. The presence of a QR code does not substitute for any of the packaging elements required by this or other Regulations, but rather it complements it. The European Medicines Agency (EMA) has published guidance on QR codes to be used in veterinary medicines; some principles from that guidance may be applicable to QR codes that can be used under the restriction for products that require IFUD.

If SPM, or the mixture containing them, are subject to classification and labelling requirements under the CLP Regulation, the information required by Paragraphs 7-9, including IFUD, that is placed on the label needs to be placed in the section for supplemental information of the CLP label, in accordance with Article 25(9) of the CLP Regulation – see Q&A 8.3.

For additional information on IFUD, see Part I, Section 8.

9.5. Are IFUD required for products in sealed containers/packaging, even if the consumer has no access to the residual product (and the SPM) in the container once the product is exhausted?

The obligation under Paragraph 8 applies to all products derogated under Paragraph 5, including those in containers that cannot be opened to access the product, such as aerosols, pumping systems and airless packaging systems. That said, it can be considered that once the product is "finished", i.e. cannot be further sprayed/pumped out of the container, the consumer has no access to the residual product (and the SPM) in the container, and the likelihood that the container is rinsed or the product poured down the drain is negligible. It can therefore be considered that the obligation under Paragraph 8 can be fulfilled by instructions/pictograms already present on the packaging indicating that the packaging should not be opened and how to safely dispose of the packaging, e.g. (non-exhaustive) a statement or a pictogram indicating to dispose of the packaging according to applicable waste legislation.

Alongside residues in packaging, IFUD should also consider possible SPM releases into the environment associated with the use of the product, including the clean-up of work areas, tools or equipment.

9.6. Some cosmetic formulations are not susceptible to rinsing in the normal course of disposal. This is where the product is, for example, solid or water resistant (such as sticks, compact powders, high viscosity formulations such as mascaras and nail polishes). Can these products be excluded from the IFUD obligation, since rinsing of the "empty" container rarely occurs because it is in fact difficult to do?

As explained in Q&A 9.2, IFUD are required for all products that contain SPM that may be placed on the market under the derogations in Paragraph 4(a), 4(d), 4(e), 5(a), 5(b) and 5(c). Furthermore, as the products mentioned in the question are not in sealed containers, it cannot be excluded that a professional user or consumer disposes of unused product down the drain or rinses the container before disposing of it, hence releasing SPM to the environment. It is therefore considered that those products should include appropriate instructions for how to dispose of the packaging, such as a statement or a pictogram indicating to consumers not to rinse the container. Alongside residues in packaging, IFUD should also consider possible SPM releases into the environment associated with the use of the product, including the clean-up of work areas, tools or equipment.

9.7. Recital 25 states "Where pollution in the environment from synthetic polymer microparticles can be minimised by the requirement to provide IFUD, the Annex XV dossier proposed a derogation from the prohibition of placing on the market". Therefore, in case such instructions are given, are SPM exempted from the restriction?

No, the only derogations are those laid down in Paragraph 4 and 5 of entry 78, the specific transitional periods specified in Paragraph 6 and the derogation for products already placed on the markets in Paragraph 16. The recitals describe the considerations that were taken by the Commission to prepare the legal text. In particular, that recital explains a proposal in the Annex XV dossier submitted by ECHA, not the binding restriction adopted by the Commission. IFUD are required for all products that contain SPM placed on the market under the derogations in Paragraph 4(a), 4(d), 4(e), 5(a), 5(b) and 5(c).

9.8. Should suppliers of products containing SPM derogated under Paragraph 4 or 5 provide IFUD for professional users and the general public?

Suppliers of products containing SPM for which the placing on the market is derogated under Paragraphs 4(d), 4(e) and 5 have obligations to provide IFUD (or ensure such IFUD are present) explaining to professional users or the general public how to use and appropriately dispose of the product containing SPM to prevent releases of SPM to the environment, in accordance with Paragraphs 7, 8 and 10.

For additional information, see Part I, Section 7 and Q&A in Part II, Section 8.

9.9. Are IFUD necessary for products designed for 'business to business' industrial use or do they only apply to products intended for professional and consumer use?

IFUD apply to both (i) SPM (and products containing them) for which the placing on the market is derogated under Paragraph 4(a) for use at industrial sites (Paragraph 7(a)) as well as (ii) products containing SPM which may be placed on the market for the general public and professional users under the derogations in Paragraphs 4(e), 4(d) and 5 (Paragraph 8). To increase their effectiveness, it is important to draft the IFUD with the right user in mind:

- The IFUD provided by suppliers of SPM (and products containing them) for use at industrial sites should be targeted to industrial DU (Paragraph 7) and should explain how the SPM (and the product containing them) should be handled, stored and disposed of in an industrial setting to prevent releases of SPM to the environment. In this case, suppliers also have to provide the additional information laid down in Paragraph 7(b), (c) and (d) to enable manufacturers, industrial DU and other suppliers to comply with their reporting obligations laid down in Paragraphs 11 and 12.

- The IFUD provided by suppliers of products containing SPM that are intended for professional use and the general public should explain to professionals and consumers how they should store and use the product, and dispose of it after its intended end use to prevent releases of SPM to the environment.

9.10. Is the sole use of electronic product pamphlets sufficient to comply with the requirement to provide IFUD for a product that is exclusively sold to professional users? Is the statement laid down in Paragraphs 7(b) and the information in Paragraph 7(c) and (7(d) mandatory, or is it enough to present the statement/information via a pictogram or QR code?

The statement laid down in Paragraphs 7(b) and the information in Paragraph 7(c) and (7(d) are mandatory for SPM (and products containing them) for which the placing on the market is derogated because they are used at industrial sites (Paragraph 4(a)). The derogation in Paragraph 4(a) and the information requirements in Paragraph 7 do not apply when SPM are placed on the market for consumer or professional use.

If the placing on the market of SPM is derogated under Paragraph 4(a) because they are used at industrial sites then, in addition to appropriate IFUD addressed to industrial DU (Paragraph 7(a)), suppliers need to include the statement laid down in Paragraph 7(b) and the information in Paragraph 7(c) and (d) on the label, leaflet, packaging or SDS of the product.

The information required in Paragraph 7(b), (c) and (d) needs to be provided in the form of clearly visible, legible and indelible text. The sole use of digital information, such as electronic product pamphlets or QR codes, is not sufficient, even if the product is exclusively sold to professional users. In addition, the use of pictograms is not appropriate for the information in Paragraphs 7(b), (c) and (d).

In conclusion, the information in Paragraphs 7(b), (c) and (d) should be provided as text and cannot be replaced by a pictogram or a QR code.

If SPM, or the mixture containing them, are subject to classification and labelling requirements under the CLP Regulation, the information in Paragraphs 7-9, including IFUD, that is placed on the label need to be placed in the section for supplemental information of the CLP label, in accordance with Article 25(9) of the CLP Regulation – see Q&A 8.3.

9.11. From when does the obligation to provide IFUD apply to a product containing SPM for which the placing on the market is derogated under Paragraph 4 or 5, when there is a transitional period under Paragraph 6 concerning that type of product? Does the obligation start from the dates indicated in Paragraphs 7 and 8 or after the end of the transitional periods granted to the product under Paragraph 6?

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. Consequently, 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 temporary derogation (transitional period) from the prohibition of placing on the market under Paragraph 6 refers 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 2035.

9.12. Do standard pictograms exist for IFUD purposes, or would they be released and by whom?

IFUD elements of the restriction are deliberately flexible so that suppliers can choose the most appropriate way to communicate with downstream or end users. Pictograms are not obligatory; the responsibility lies with the supplier if they opt to use them as an effective means of communication. The information could also be provided in the form of clearly visible, legible and indelible text.

The European Commission and ECHA do not intend to create pictograms that must be used. 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. Suppliers are encouraged to discuss with their relevant national or European trade association to determine if there are initiatives for sector-wide approaches to IFUD/pictogram development. A notable example of a sector-led approach to pictogram development is the AISE (the International Association for Soaps, Detergents and Maintenance Products) 'safe use' pictograms, although it is important to clarify that these were not specifically tailored for compliance with Entry 78 and may not necessarily be appropriate IFUD. Please also see Part I, Section 8, for more explanations and pictograms. Paragraph 10 of the restriction specifies the format of the information and where it needs to be placed. Furthermore, the final background document (page 101) to the RAC/SEAC Opinion on the Annex XV restriction dossier provides some additional supporting information. This document is accessible at https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73.

Note that it is for national enforcement authorities to assess, on a case-by-case basis, whether the IFUD sentences or pictogram provided with the product are sufficient/appropriate. Further note that Member States' enforcement authorities do not pre-approve provided IFUD or pictograms.

9.13. What are appropriate IFUD for products sold in different EU Member States?

IFUD are laid down in Paragraph 7(a) and 8 of entry 78. Paragraph 10 requires IFUD text to be in the official EU language(s) of the Member State(s) where the product is placed on the market, unless the competent Member State authority concerned indicates otherwise. Text and pictograms can be complemented by digital information, e.g. a QR code.

9.14. Products derogated under Paragraph 5(b) need to be supplied with IFUD from 17 October 2025. If they were already on the market before that date, can they remain on the market without such instructions?

Products derogated under Paragraph 5(b) need to be supplied with instructions for use and disposal from 17 October 2025, in accordance with Paragraph 8. Such information may be

placed on the label, the packaging, or the package leaflet of the product, in accordance with Paragraph 10.

Suppliers (manufacturers, importers, downstream users or distributors, see Art. 3(32) of REACH) placing products on the market containing SPM derogated under Paragraph 5(b) must comply with IFUD obligations as of 17 October 2025.

9.15. Is it possible to link the instructions for disposal to another regulation? Do suppliers need to provide the information referred to in Paragraphs 7(a), (b) and (c) in only one piece of documentation, for example SDS?

It is possible to use instructions for disposal stemming from other EU legislation (e.g. waste or sectoral legislation), provided that, if followed, they are effective in preventing or minimising SPM releases to the environment. IFUD need to be targeted to and suitable for the intended end users of the product.

The supplier can choose whether to place the information on the label, the packaging, the package leaflet or the SDS (when required). The information does not have to be all in one place, e.g. the information referred to in Paragraph 7(a) could be provided on the label as pictogram and that in Paragraphs 7(b), (c) and (d) could be in the SDS. That said, it is recommended to provide the information in one place where possible, so that it can be found more easily.

9.16. Who would judge if IFUD are correct or not and on which basis?

Enforcement is the responsibility of the Member States. It is for national enforcement authorities to assess, on a case-by-case basis, whether the IFUD sentences or pictogram provided with the product are sufficient/appropriate to 'prevent releases of SPM to the environment'. Note that Member States' enforcement authorities do not pre-approve IFUD or pictograms.

In order to demonstrate that IFUD are effective (e.g. to an enforcement authority), it is recommended that suppliers undertake sufficient research, which may include testing, to verify that IFUD are appropriate and effective to prevent SPM releases. This may be more effectively done at sector level in conjunction with a relevant national or European trade association.

9.17. For uses releasing very small amounts of microplastics, can the product still be sold/used if information is added to the CLP label e.g. as: "Contains microplastics, dispose of in the appropriate waste streams"?

No, only products containing SPM derogated under Paragraphs 4, 5 or 16, or granted a transitional period under Paragraph 6, can continue being placed on the market. Products containing SPM granted a transitional period under Paragraph 6 can continue being placed on the market until the end of that transitional period.

When products containing derogated SPM are required to bear IFUD in accordance with Paragraph 8, those IFUD should effectively 'prevent the release of SPM to the environment' (see Part I, Section 8 for more information) during both the use phase and the disposal phase. IFUD that just mention 'contains microplastic, dispose of in the appropriate waste streams' does not seem to explain in sufficient detail how to use and dispose of the product to prevent SPM releases. See Q&A 9.16.

9.18. Are instructions for use and disposal always required for products for which the placing on the market is derogated under any Paragraph, and particularly under Paragraph 5(b)? Could this be subject to MS interpretation?

If a product containing SPM is placed on the market on the basis of a derogation that comes with IFUD obligations, then IFUD must always be applied to the product.

The requirement is not subject to Member State interpretation.

9.19. Will there be any guidance regarding appropriate IFUD?

Part I, Section 8 and Part II, Section 9 of this Explanatory Guide explain IFUD requirements. No additional guidance is envisaged at this stage. The requirements of the restriction on IFUD were intentionally designed to be flexible to allow affected companies and sectors to develop the most appropriate solutions for their specific products and intended uses, harmonising IFUD where appropriate. The European Commission and ECHA do not intend to create pictograms that must be used.

Nevertheless, it is advisable that DU take steps to ensure that the IFUD provided are effective to prevent releases to the environment.

See Q&A 9.12.

10. Paragraph 11, 12 and 13 – Reporting of estimated SPM emissions

These questions are specifically related to the reporting of estimated SPM emissions as described in Paragraphs 11-13. They aim to clarify the reporting requirements, such as obligations within the supply chain (complemented by flow charts in Annex 2), what needs to be reported and how.

10.1. Will a specific portal be created on the ECHA website for reporting the SPM emissions? Where can instructions be found on the process to follow, the forms to fill in and how to fill them in?

The reporting is envisaged to take place through an online submission system in IUCLID, hosted by ECHA. Instructions on how to submit the required information will be made available on the ECHA website in due course and by December 2025 at the latest.

10.2. Do unintentional SPM, i.e. SPM that are not created as SPM or not added to the product or otherwise not intentionally used but are formed unintentionally at a later stage (e.g. from breakdown of larger particles, wear and tear, metabolic activity, etc.), need to be reported?

Only primary SPM, i.e. SPM created and/or added to the product as such or otherwise intentionally used, should be reported, including when generated from removal of the product. Secondary SPM, or unintentional SPM, for example from breakdown of large plastic products or washing of textiles, should not be reported. See Part I, Section 5 and Part III, Annex 1, Tier 3.

10.3. Most solid dosage forms of medicinal products containing SPM are not excreted in the same form as they were ingested. Would such digestion-modified SPM be regarded as unintentional or secondary SPM when excreted? Would excreted SPM need to be included in the reporting?

Excreting the medicinal product is considered part of its intended end use. After the medicinal product and its metabolites are excreted from the body, and reporting has taken place, there are no further obligations under the restriction. See also Q&A 10.2 above.

If the change in form during digestion was simply to a fragmented or 'broken' version of the initially ingested SPM with comparable composition, and the broken polymers remain SPM at all times, then the excreted SPM should be considered to be within the scope of the restriction and subject to the reporting obligation. If the polymers stopped being SPM at any point during digestion, they should not be reported. Reporting of emissions at end use should be done by the first supplier placing the medicinal product on the market for professional/consumer use, not by the end-user, in accordance with Paragraph 12 of the restriction.

10.4. Regarding reporting requirements for manufacturers and downstream users of SPM, Paragraph 11 mandates reporting starting from 2026 for certain manufacturers and industrial DU, and from 2027 for other manufacturers and industrial users. What are the reporting obligations for manufacturers and transporters, particularly regarding what they should report, such as waste from manufacturing? If the reporting obligation is split among different suppliers, will this 'split' be based on who has custody of the material at the time of loss?

As mentioned in Paragraph 11, manufacturers and industrial DU of SPM are required to estimate and report their own emissions during use and transport. In accordance with Article 3 of REACH (Regulation (EC) 1907/2006), the term "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.

Manufacturers of SPM are required to estimate and report SPM emissions taking place during the abovementioned activities, which includes SPM emitted during waste management activities, cleaning and spills.

Concerning how to report the estimated emissions during transport in case of SPM, or products containing them, being moved between supplier A and recipient B within the EU, the emissions should be reported by the actor (A or B) who is liable for the product at the time the emissions take place, unless the two parties agree differently. For example, supplier A and recipient B agree that supplier A delivers the product (including by means of one or more third-party transporter(s)) to recipient B, and remains liable for that product until recipient B receives it. In that case, supplier A reports to ECHA estimated emissions during pre-transport and transport, including (but not limited to) handling and storage, loading and transport itself; recipient B reports to ECHA post-transport emissions, including emission during unloading and subsequent handling and storage.

See also Part I, Section 9 for more information on reporting responsibilities, including reporting estimated emissions during transport.

How the reporting works is further explained in Part I, Section 9 of this Explanatory Guide, and recitals 56 and 58 of Commission Regulation (EU) 2023/2055.

10.5. Does Paragraph 12, regarding the obligation to submit information to the Agency starting from 2027, apply to all items that are on the market, including the ones that were placed on the market before the date of entry into force of the Regulation?

The reporting obligation under Paragraph 12 of the restriction does not apply to products placed on the market before 17 October 2023.

Reporting obligations under Paragraph 12 concern estimated SPM emissions that were incurred in the previous calendar year, i.e. between January and December 2026 for reporting by 31 May 2027.

10.6. Regarding reporting requirements in Paragraphs 11 and 12, will there be a calculation model for the quantities released into the environment to be declared in the reporting of microplastics exempted under Paragraph 4? Will a method be provided for calculating the quantities released into the environment, including during transport?

Reporting companies are free to use the method they consider is most appropriate. A calculation method will not be provided in this Explanatory Guide.

10.7. What is the reporting requirement for products produced outside of the EU?

Any product imported into the EU must comply with the applicable EU legislation, including entry 78 of Annex XVII to REACH. Reporting is obligatory for SPM derogated under Paragraphs 4(a), 4(b), 4(d), 4(e), 5(a), 5(b) or 5(c).

Importers that have to estimate and report SPM emissions in accordance with Paragraph 12 should estimate emissions generated as of the moment the SPM or product containing them enters the custom territory of the Union.

10.8. When reporting to ECHA, does the name of each SPM need to be included when microparticles contain or are coated by more than one polymer? How are we able to

maintain confidentiality if companies have the obligation to disclose specific polymer names? Can we use polymer abbreviations, such as PVC, PET, as generic polymer names? Can we use tariff codes as generic polymer identifiers?

The generic identity of each polymer fulfilling the SPM conditions will need to be reported. Paragraphs 7, 11 and 12 do not require the specific polymer identity to be provided.

The exact format to be used to report the polymer generic identity will depend on the reporting system being developed by ECHA. Instructions on how to submit the required information will be made available on the ECHA website once the reporting system is operational, which is expected by the end of 2025 at the latest.

10.9. Do reporting obligations in Paragraphs 11 and 12 apply to products placed on the market after 17 October 2023 and before 2027? Should the reporting cover only the SPM placed on the market the previous calendar year as it is in case of points a, b and c of Paragraph 12?

Reporting obligations in Paragraph 11 and 12 apply to SPM and products containing SPM derogated under Paragraph 4 or 5 as of 31 May 2026 (derogations under 4(a) - pellets) and 31 May 2027 (derogations under 4(a) – SPM other than pellets, 4(b), (d) and (e), and 5). Reporting obligations concern estimated SPM emissions of products that were incurred in the previous calendar year, i.e. between January and December 2025 for reporting by 31 May 2026, and between January and December 2026 for reporting by 31 May 2027, respectively. Paragraphs 11(d) and 12(d) require SPM manufacturers and industrial downstream users, and suppliers of products containing SPM, respectively, to specify which of the different derogation(s) under Paragraphs 4 or 5 apply to its product.

10.10. What is the definition of a supplier and what are their responsibilities for undertaking reporting?

A supplier of a substance or a mixture is defined under REACH as any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture (Article 3(32)). Therefore, the supply chain actors mentioned need to comply with Paragraph 12 if they place a product containing SPM on the market for the first time for use by the general public or professionals (i.e. in previous steps in the supply chain the product, or the derogated SPM present in it, would have been placed on the market for use at industrial sites, if previously placed on the market at all). 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.

Suppliers of products containing derogated SPM that place those products on the market for the first time to professional users and the general public have to estimate their own SPM emissions, including during transport, plus the downstream SPM emissions from the

moment the product is placed on the market to the moment it is disposed of after end use. These can be sector-specific release estimates, such as those described by spERCs.

Please refer to the flow charts in Annex 2 as well as Part I, Section 9 for further information on responsibilities.

10.11. What is the meaning of the term 'plastic feedstock' in Paragraph 11?

Plastic feedstock are plastic pellets, flakes or powders as raw materials used as an input to an industrial process i.e., plastic 'compounding' or producing articles using via, for example, moulding or extrusion processes etc.

10.12. Under Paragraph 11, the requirement for a "description of the uses of SPM in the previous calendar year" is challenging for users because manufacturers do not always know the end uses of the materials supplied to their customers, which may be confidential.

- Will "use at industrial site" suffice as a description of use by the suppliers?
- Does the manufacturer have to provide only the description of its customers' use, or do they have to indicate any further uses known to him during the life cycle of the product?
- Are there any obligations for the customers to communicate to producers their use and/or their downstream customers' use?

Users covered by Paragraph 11 only need to report releases from their own uses (which should be known to the operator) and associated transport. There is no requirement for an upstream user to report on downstream uses. The only actor that reports releases from an actor other than themselves are those (including importers) that place products as substances/mixtures on the market for the first time for consumers or professionals (in accordance with Paragraph 12).

In this instance, "use at industrial site" is a generic term and is an insufficient description of a use. The operator would need to describe the use more specifically, for example, as per the ECHA guidance R.12 use descriptor system. The precise form of use description required will be determined by the ECHA reporting IT system that will support this reporting obligation. Instructions on how to submit the required information will be made available on the ECHA website once the reporting system is operational, which is expected by the end of 2025 at the latest.

There are no obligations for customers to communicate to manufacturers their use and/or their downstream customers' use.

Please refer to the flow charts in Annex 2 as well as Part I, Section 9 for further information on responsibilities.

10.13. Resellers may hold custody of the pellets while they are being transported. What are the reporting responsibilities of resellers, who are neither manufacturers nor industrial DUs?

If a reseller meets the definition of a distributor according to Article 3(14) of REACH – meaning they solely store and place products on the market for third parties – they would not have any reporting obligations (Paragraph 11 only applies to manufacturers and industrial downstream users; Paragraph 12 only applies to the first (industrial) suppliers placing a product on the market for consumers/professional users (those suppliers are never distributors). Manufacturers and industrial DUs are responsible for reporting emissions of SPM during transport, including those occurring while the product is held, stored, or transported by a distributor, in their estimates.

Transport service providers that further process or re-package products are regarded as DUs and have their own reporting obligations. However, if they only transport the product for a third party without further processing it, they are not obligated to report estimated SPM emissions during transport themselves but may provide relevant information to their clients responsible for reporting those estimated emissions.

See Section 9, Part I of this Explanatory Guide for more information.

10.14. Plastic pellets are manipulated several (a dozen or more times) when moving from a manufacturer to an industrial DU. Who has an obligation to report throughout the supply chain while the pellet is being transformed?

Each industrial DU that handles pellets containing SPM is obliged to report under Paragraph 11. Note that distributors are not DUs, so they do not have an obligation to report under Paragraph 11. They can provide information to their DU customers (who have a reporting obligation for estimated releases associated with their SPM use, including transport) that help those customers estimate the releases to be reported, including from transport.

10.15. Are harbours considered part of the transportation chain and would they have reporting obligations?

Harbours could be considered distributors if they meet the definition outlined in Article 3(14) of REACH, meaning they exclusively store and place SPM or products on the market for third parties. Distributors are not DUs, so they do not have an obligation to report under Paragraph 11.

10.16. Assuming there are losses from a large vehicle with multiple loads from different sources during transportation, how are these to be estimated and reported knowing that the transporter can be carrying different types of products from different companies?

Transport service providers may inform each of their clients about the estimated respective SPM losses. Their clients would use this information to report to ECHA. See also Q&A 10.4 and Part I, Section 9.

10.17. Assuming there are losses during import from a non-EU manufacturer, which part of the release needs to be reported?

Reporting obligations begin from the entry of the product containing SPM in the EU customs territory. See also Q&A 10.4.

Importers of derogated 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.

By contrast, importers 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 downstream SPM emissions from the moment the product is placed on the market to the moment it is disposed of after end use.

See also Part I, Section 9.

10.18. Recital 58 reads: "To avoid double reporting, when there is more than one actor in the supply chain placing on the market the same product containing SPM, only the first actor within that supply chain should provide the required information to the Agency". What is the meaning of the "same product"? Does it refer to the same SPM or is each formulation a different product?

The expression "same product" refers to an individual unit of a given product. Each unit in a batch is a different product. Please refer to Part I, Section 9 of this Explanatory Guide for information on the reporting requirements for suppliers placing products containing SPM on the market for the first time for use by consumers and professionals.

10.19. If a company has multiple sites and different legal entities in Europe, who is responsible for reporting obligations? Would the reporting be done at a site, legal entity or corporate level?

As regards the reporting in Paragraph 11, the reporting has to be done by the legal entity(ies) that are the manufacturers or downstream users for the uses in question. As regards the reporting under Paragraph 12, the reporting has to be done by the legal entity that supplies the product for the first time to professionals or consumers, for the use in question. Further details on the reporting process are explained in Part I, Section 9 of this Explanatory Guide, and in Recitals 56 and 58 of Commission Regulation (EU) 2023/2055.

10.20. Does Paragraph 12 indicate that information must be submitted to ECHA for products containing SPM mentioned in Paragraphs 4(b), (d), and (e), and Paragraph 5, only when a new product is introduced to the market after the regulation's entry into force? If not, does it mean that starting from 2027, reporting needs to be completed annually (by 31 May) for

all products containing SPM mentioned in Paragraphs 4(b), (d), and (e), as well as Paragraph 5?

For all products containing SPM placed on the market after 17 October 2023 on the basis of a derogation under Paragraphs 4(b), (d), and (e), and Paragraph 5, reporting needs to be completed annually by 31 May of each year, as of 2027.

SPM, and products containing SPM, placed on the market before 17 October 2023 are not subject to reporting obligations.

10.21. Paragraph 11 requires reporting to the Agency by 31 May of each year of the following information outlined in point (c): "for each end use for which the SPM were placed on the market, an estimate of the quantity of SPM released to the environment in the previous calendar year, which shall include also the quantity of SPM released to the environment during transportation."

- Can you provide a definition of "released to the environment" and outline what is to be included in the estimation? If spillages are swept up and disposed of as hazardous waste, do they need to be reported?
- Could you clarify what is meant by the "microparticles released to the environment during transportation"?

Please refer to ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.16 " Environmental exposure assessment" for guidance on what is meant by "released to the environment". All losses to the environment have to be reported. If (part of) the spillage is collected and disposed of, only the amount that is not collected should be estimated and reported.

SPM released to the environment during transportation encompass any material losses occurring during transportation, including loading and unloading, as explained in Part I, Section 9, and Q&A 10.4 in this Explanatory Guide.

10.22. There are instances in which the SPM content cannot be determined. In these cases, is it sufficient to report the released polymer content instead?

As the SPM is the polymeric content/coating of a particle, the polymer content is the relevant data to estimate SPM releases.

10.23. How should the environmental emission be calculated for a polymer with a water solubility close to 2 g/L? This polymer may be above the solubility threshold when it is released and therefore may not be an SPM when released. The same question applies to polymers which will no longer be classed as SPM due to e.g. their size when released to the environment (such as swellable polymers).

If the polymer falls within the scope of the restriction and is subject to Paragraphs 11 and 12, then emissions of the SPM based on its state at the point of end use must be reported.

The fate and behaviour of SPM after release are not relevant for the reporting since any change in state/particular form could be temporary e.g. associated with concentration, temperature, salinity, etc.

Please refer to Q&A 7.5 for further information on derogations for swellable polymers.

10.24. Paragraph 11 refers to "other manufacturers of SPM and other industrial DUs using SPM at industrial sites." It is uncertain how toll manufacturing fits into reporting obligations and whether they are seen as uses at industrial sites. To avoid double counting, should tollers report emissions, even if they make a derogated product? Or is it the contracting company's duty to report?

Toll manufacturing is understood as the arrangement where one company processes materials for another. A toll manufacturer manufacturing SPM for a third party is responsible for reporting its own estimated SPM emissions to ECHA but can ask the third party (or another party) to report the toll manufacturer's estimated emissions to ECHA, on the toll manufacturer's behalf, by means of contractual arrangements. This is in line with the ECHA's factsheet on "Information for parties involved in contractual arrangements for toll manufacturing".

A toll manufacturer who is undertaking formulation using SPM ingredients for a third party is a DU, and therefore required to report its own estimated emissions to ECHA (or its own emissions and all downstream emission from the moment the formulation is placed on the market to the moment it is disposed of after end use, if the formulation is placed on the market for the first time for consumers/professionals).

10.25. With regards to medicinal products and food (for which placing on the market is derogated in Paragraph 4 of entry 78), what information must be documented and submitted to regulators and in what format?

Please refer to Q&A 6.4, 6.8, 6.9, 7.3, and 10.5 for detail on specific reporting and IFUD requirements for these product categories.

11. Paragraph 14 and 15 – Information to national competent authorities

These questions are about the information to be provided to national competent authorities for the purpose of enforcement.

11.1 What will happen if controls are undertaken on SPM-containing products that were placed on the market before 17 October 2023? What will happen if they are found to be non-compliant?

SPM-containing products that were placed on the market before 17 October 2023 are not covered by the restriction on placing on the market in Paragraph 1. They can continue being sold or otherwise placed on the market until stocks run out. See also Q&A 12.1 and Part I, Section 11 of this Explanatory Guide for further details.

Concerning controls and what to do with non-compliant products in general, this is to be decided by the relevant Member States enforcement authority, as enforcement is a national competence.
Note that Member States' enforcement authorities do not pre-approve products or product information.

12. Paragraph 16 – Derogation for products on the market at entry into force

These questions concern the derogations for SPM, and products containing SPM, already on the market at entry into force, as laid down in Paragraph 16. They cover issues such as the implications for products manufactured outside of the EU that were in transit at entry into force, implications along the supply chain and repackaging of products, etc.

12.1. What are the implications for products ordered, manufactured, and purchased before 17 October 2023 but not delivered, and how can Paragraph 16 of the restriction be applied to such products? Furthermore, what should shops that have affected products do with stock already on the market and with newly imported stock after 17 October 2023? Are there specific guidelines for products currently in transit to the EU market?

The definition of "placing on the market" is laid down in Article 3 of REACH as "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". A product is to be considered imported (and therefore placed on the market) only when physically introduced into the customs territory of the Union.

Finished products placed on the market before 17 October 2023, such as those in wholesalers' or importers' stocks, can continue being sold or otherwise placed on the market until stocks run out. Therefore, finished products already on the retail market, such as in shops or supermarkets, can still be sold until stocks are depleted without the need for recalls. However, newly imported stock after 17 October 2023 cannot be sold or otherwise placed on the market unless it benefits from a derogation under Paragraphs 4 or 5 or a specific transitional period under Paragraph 6. Products in transit must have arrived in the EU and cleared customs before 17 October 2023 to benefit from the derogation in Paragraph 16.

See Part I, Section 11 of this Explanatory Guide for further details.

12.2. Can manufacturers who have products in large bags (e.g., loose SPM-containing glitter) purchased before 17 October 2023, and later repackage it into small bags (e.g., for use in creative sets or other ready products), continue to sell these products after 17 October 2023 until their stocks are depleted?

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.

12.3. What are the implications of Paragraph 16 on the onward sale of products containing synthetic polymers microparticles (SPM) within the EU supply chain after their initial placement on the market? How is Paragraph 16 applicable to importers, distributors, retailers or other entities further down the supply chain?

SPM and products containing SPM (for uses other than those laid down in Paragraph 6) that have been placed on the market before 17 October 2023 do not need to be recalled or withdrawn from the market. They can continue being sold or otherwise placed on the market along the supply chain until stocks run out, in accordance with Paragraph 16. This would be the case, for example, of SPM and finished products containing them in distributors/importers/retailers' stocks. A product in a distributor's stocks can continue being sold until it reaches its end user. There is no limit date by when the sale of stocks needs to be completed.

12.4. How can one determine whether a product containing SPM was placed on the market before or after 17 October 2023 if there is no date provided? Specifically, if the product consist of glitter in bulk, would providing an invoice for glitter purchased in bulk before this date suffice as proof?

Products containing SPM placed on the market before 17 October 2023 are exempted from the restriction for placing on the market by Paragraph 16. Compliance should be proved to Member State enforcement authorities, as enforcement of REACH, including entry 78, is the responsibility of Member States.
Note that Member States' enforcement authorities do not pre-approve products or product information.

See Part I, Section 10 of this Explanatory Guide for additional information on information to competent authorities.

13. Appendix 15 – Degradability

These questions concern the application of Appendix 15 to determine polymer degradability. They include clarification of the testing methods that should be used and the applicable pass/fail criteria to demonstrate compliance.

13.1. How can the degradation of polymers be proven, for the purpose of entry 78?

The rules for proving degradability of polymers for the purposes of entry 78, namely the permitted test methods and the pass criteria for those methods, are laid down in Appendix 15 of Annex XVII of REACH.

See Part I, Section 3 for this Explanatory Guide for additional information on proving polymer degradability.

13.2. What is the pass criterion for proving degradation with test methods in groups 1 to 4 and group 5?

The pass criterion for groups 1 to 4 is expressed as % mineralisation, thus the tests measure ultimate degradation. In group 5 simulation tests, the pass criterion is expressed as degradation half-life ($DegT_{50}$) values, thus the test measures ultimate and primary degradation (the latter meaning breakdown into degradation products). Tests in Groups 1 to 4 provide indirect measurements of polymer degradation, while tests in Group 5 directly measure polymer degradation by measuring the disappearance of the polymer.

The pass criteria to be achieved, i.e. the % mineralisation (for groups 1-4) and the degradation half-life (for group 5), are indicated in Appendix 15 for each permitted testing method.

13.3. At which point in the polymer (product) life cycle should the degradability criteria be assessed?

The criteria for degradability apply throughout the life-cycle of a polymer (product), as degradability is considered an intrinsic property of the polymer.

The degradability should be tested in accordance with Appendix 15 of the restriction, using as test material the polymer particle as placed on the market or, if not technically feasible, as released. When testing the released polymer particle, operators should keep adequate proof that testing the degradability of the polymer particle as placed on the market was not technically feasible.

As indicated in Appendix 15, a polymer particle is a particle which contains or is coated by the polymer(s). If, when testing degradation, the polymer particle meets the pass criteria for the chosen test method in Appendix 15, the polymer(s) in the particle are considered degradable and are not in the scope of the restriction. If, on the other hand, the polymer particle does not meet the pass criteria, the polymer(s) in the particle are not degradable and may be SPM (if the other SPM conditions are met). See Part I, Sections 2 and 3, and Part III, Annex 1 for more information.

13.4. Can degradability testing be performed in GLP-certified laboratories, instead of ISO 17025 accredited laboratories?

Yes, laboratories with ISO 17025 accreditation or GLP compliance proven by a national enforcement authority GLP monitoring programme or complying with other international standards recognised as equivalent by the European Commission or ECHA (currently there are none), would be acceptable.

In accordance with Directive 2004/10/EC and Directive 2004/9/EC on GLP, acceptable GLP data can also come from a laboratory in countries participating to the OECD mutual acceptance of data (MAD) system. Under certain circumstances, data from a laboratory in a country which has not joined the OECD MAD system can be accepted if the laboratory

is found to be operating in compliance with GLP principles. For more details on GLP requirements, see Part I, Section 3 of this Guide.

Degradation studies which follow the conditions set out in Appendix 15 of the regulation, but that have been performed in laboratories with no GLP compliance confirmed by a national enforcement authority GLP monitoring programme or an authority participating in the OECD MAD system or no ISO 17025 accreditation, or not complying with other international standards recognised as equivalent by the European Commission or ECHA (currently there are none), will not be in compliance with the entry 78, i.e. it is not sufficient for a laboratory to work "in line" with the requirements of ISO 17025. Note that in the case of ISO 17025, the laboratory needs to be accredited for each of the specific test method performed.

13.5. Does a degradation test have to be listed in Appendix 15 in order to be accepted as a valid degradation test for the purpose of entry 78? Can other methodologies be used?

The test methods (and their respective pass criteria) listed in Appendix 15 are the only acceptable test methods for proving degradability for the purpose of entry 78. Other methods cannot be used.

13.6. Can the test methods in Appendix 15 be used to assess the degradability of inorganic polymers?

Polymers that do not contain any carbon in their structure are outside the scope of entry 78, regardless of whether they are degradable or not, so testing their degradation is not necessary.

Polymers that contain carbon in their side-chains are organic. The degradability of all organic polymers can be assessed using the tests listed in Appendix 15.

13.7. Can SPM-containing glitter which has a degradability percentage of >85% remain on the market? And can it be excluded from scope of entry 78?

It depends on whether the >85% degradation is measured using one of the permitted test methods in Appendix 15 of Annex XVII REACH and whether the achieved >85% degradation is higher than the pass criteria for the chosen test method. In order to be considered degradable for the purpose of the restriction, and therefore be outside its scope, the degradation of the SPM-containing glitter must be tested using one of the test methods laid down in Appendix 15 and must reach the pass criteria for the chosen test method. No other test methods and pass criteria are allowed.

Appendix 15 includes a list of the accepted test methods and their respective pass criteria. Moreover, Appendix 15 provides that the tests must be conducted by laboratories complying with the principles of GLP of Directive 2004/10/EC or other international standards recognised as equivalent by the European Commission or ECHA (currently there are none), or accredited to ISO 17025. Please refer also to Part I, Section 3 of this Guide.

13.8. What is the pass degradation level for agricultural and horticultural products? Is it 90% absolute or 90% relative degradation?

The answer depends on the test method used. The test methods in group 1-3 and 5 measure absolute degradation (i.e. the actual break-down, measured from released CO_2 or consumed O_2). The tests methods in group 4 measure relative degradation (i.e. amount of degradation relative to the degradation of a reference material).

Note that, for polymers that are coating agents or which increase the water retention capacity or the wettability in non-CE marked fertilising products (referred to in Paragraph 2.1 of Appendix 15), the degradability should be demonstrated in accordance with Commission Delegated Regulation (EU) 2024/2770.

For testing the degradation of polymers in other agricultural and horticultural products (referred to in Paragraph 2.2 of Appendix 15), specific pass criteria for group 4 and 5 test methods that are consistent with Article 42(6) of Regulation (EU) 2019/1009 have been set. These specific pass criteria are laid down in Tables A and B of Appendix 15. For functionality periods not covered in Tables A or B, the pass criteria must be calculated using the exponential decay formulas provided in Appendix 15.

The pass criteria for test methods in group 1-3 do not change for agricultural and horticultural products and are listed in Paragraph 1.1.2, 1.2.3 and 1.3.3 of Appendix 15.

For more information on the application of degradability criteria, please see Part I, Section 3 of this Explanatory Guide.

13.9. Is the functionality period of agricultural or horticultural products considered in the test method? For example, for an agricultural product with a functionality period of 6 months, will there be 48 months to pass the test or 48+6 months?

The functionality period of the product does not affect the standard duration of the degradability test but determines the specific pass criteria for group 4 and 5 test methods for products for agricultural or horticultural applications referred to in point 2.2 of Appendix 15. The longer the functionality period, the lower the degradation % or half-life to be achieved in the standard test duration to pass the test. The specific pass criteria are listed in Tables A and B of Appendix 15.

13.10. How can ISO 14851 be used for marine water testing when it is a method of freshwater testing?

The ISO 14851 test provides information on ultimate degradability in an artificial aqueous medium and it is not conducted under conditions that are directly comparable to fresh water or marine water.

13.11. Would a certification showing that a product, e.g. glitter, is 74% biodegradable suffice to demonstrate degradation and be considered out of the scope of the restriction? Is

degradability information provided in section 12.2 of the SDS sufficient to prove degradability (or solubility) of an SPM?

The certificate validity depends on whether the 74% degradation is measured using one of the permitted test methods in Appendix 15 of Annex XVII REACH and whether that degradation meets the pass criteria for the chosen test method. In order to be considered degradable for the purpose of the restriction, and therefore be outside of its scope, the degradation of the SPM-containing glitter must be tested using one of the test methods laid down in Appendix 15 and must reach the pass criteria for the chosen test method. No other test methods and pass criteria are allowed.

The certificate needs to confirm that the tests performed on the polymer particles as placed on the market or, if this is not technically feasible, released were in accordance with the requirements of Appendix 15 and the pass criteria are met. A laboratory test report should contain sufficient information to prove that the degradability of the test material was tested in accordance with the methods specified in Appendix 15 and the appropriate pass criteria met. An SDS may not provide sufficient information.

Tests must be conducted by laboratories complying with the principles of GLP of Directive 2004/10/EC or other international standards recognised as equivalent by the European Commission or ECHA (currently there are none), or be accredited to ISO 17025. For more details on GLP requirements, see Part I, Section 3 of this Guide.

In accordance with Paragraph 15, manufacturers, importers, and industrial DU claiming that the polymers in their products are derogated because they are degradable shall provide proof that those polymers are degradable in accordance with Appendix 15 to competent (e.g. enforcement) authorities upon their request. It is the responsibility of the manufacturer, importer or industrial DU to ensure that the proof of degradability provided is sufficient.

13.12. Is read-across permitted within products containing polymers with similar physical properties?

Read-across methodologies are not included in Appendix 15. Consequently, such methodologies are not permitted to prove degradability for the purpose of entry 78.

The possible use of ’non-standard’ test methods, such as read-across methodologies, to fulfil Appendix 15 testing requirements, was considered by ECHA’s Committee for Risk Assessment but eventually not recommended because it was considered not protective for the environment.

13.13. For non-European laboratories, are national certifications valid (e.g. EPA for the USA) which in many cases are accepted as an international reference?

Only the specific degradation test methods and pass criteria specified in Appendix 15 may be used to demonstrate that polymers are degradable for the purposes of the restriction.

Studies conducted by non-European laboratories using these methods/pass criteria may be used, provided those laboratories comply with the principles of GLP or other international standards recognised as being equivalent by the European Commission or ECHA (currently there are none), or are accredited to ISO 17025. For more details on GLP requirements, see Part I, Section 3 of this Guide.

13.14. If a product (e.g. compounded polymer pellets) contains both polymeric and non-polymeric substances, can the degradability study be conducted on the product itself, or do the components need to be tested separately? If the latter, in which form should the individual polymer be tested?

Section 3 of Appendix 15 of Annex XVII of REACH sets out the specific requirements for the test material to be used in degradation studies.

The test should be carried out with a 'polymer particle' comparable in terms of composition, form, size and surface area to the polymer particles present in the product. If this is not technically feasible the test can be carried out with polymer particles that are disposed of or released to the environment.

Section 3 also has considerations for SPM used for encapsulation, which may be tested in any of the following forms:

- in the form placed on the market;
- in the form of isolated coating;
- in the form placed on the market where the organic core of the material is replaced by an inert material such as glass.

It also contains considerations for instances where test methods from groups 1-3 are used to prove degradation and:

a) the test material contains more than one polymer; and

b) when the test material contains a single polymer and other non-polymeric organic substances (>10% concentration) and.

In both cases a) and b) above, either the degradability of the test material and of the polymer are tested separately, or the test material is assessed and it must be demonstrated how the SPM contributes to the degradation observed.

While the form in which the individual polymer should be tested is not specified in the Appendix and, as far as it is comparable, it is left to the discretion of the person performing the test, the test material tested should be, as far as possible, in the same form as found in the product.

See Part I, Section 3 for more information on testing polymer degradability and choosing an appropriate test material.

13.15. Can publicly available data be used to demonstrate degradability, thereby obviating the need for testing?

In reference to Paragraph 15 of the restriction, how information on degradability or solubility is obtained is the responsibility of manufacturers, importers and industrial DUs of these products. In this respect, information from available studies can also be used, provided that the information is obtained from tests performed in accordance with Appendix 15 and that it can be demonstrated to enforcement authorities, upon request, that the material related to test data is the same as the products for which exclusion from designation of SPM is claimed.

Note that Member States' enforcement authorities do not pre-approve products or product information.

13.16. Does every particle size within a material need to be tested, or can results with larger particles be read across to smaller particles?

Results from tests performed in more restrictive conditions or variables (such as is the case with larger particles) can be applied to less restrictive conditions or variables (such as smaller particles of the same composition and comparable shape). Therefore, with everything else remaining constant, if larger particles are degradable in accordance with Appendix 15, it can be assumed that smaller particles of the same composition and comparable shape are also degradable (smaller particles are expected to degrade faster than bigger ones).

13.17. Recital (47) of Commission Regulation (EU) 2023/2055, indicates that it may be necessary to review the standard degradability (and solubility) test methods to take into account scientific developments. Is there a time frame and/or procedure already existing on when and how this review will be performed?

Recital 47 reflects that there "may" be a need to review the test methods to take into account scientific developments. This is the case, for instance, in case specific methods to test SPM solubility and degradability are developed. This means the review is just a possibility, not a certainty, and there is no time frame set for it, nor a specific procedure.

13.18. Appendix 15, Section 2 discusses the degradability of polymers serving as coating agents or enhancing water retention or wettability in fertilising products. It mandates that degradability assessment follows delegated acts mentioned in Article 42(6) of Regulation (EU) 2019/1009 on fertilising products. Where can the criteria and acts to confirm if the restriction applies be found?

The (bio)degradability conditions to be complied to by polymers used in CE-marked fertilisers are set in Regulation (EU) 2019/1009 on fertilising products and in three delegated acts complementing that Regulation:

- 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).

Please see Figure 7 in Section 3, Part I of this Guide for an overview of (bio)degradability requirements for polymers used in CE-marked and non-CE marked fertilisers.

13.19. A functionality period for polymers in products for agricultural and horticultural applications should be considered when performing Group 4 and 5 tests. How can this be achieved when the functionality period of a polymer is close to or exceeds the standard test duration (e.g., 120 days in an OECD 307 soil simulation test)?

The functionality period does not affect the duration of the standard test - which does not change. As reflected in Paragraph 2.2 of Appendix 15, the functionality period is taken into account to calculate the percentage of degradation (for group 4 tests) or the half-life (for group 5 tests) that needs to be observed at the end of the standard test duration in order to pass the test. The longer the functionality period, the lower the degradation % or half-life to be achieved in the standard test duration to pass the test.

The specific pass criteria are listed in Tables A and B of Appendix 15. The Tables provide the target degradation and half-life, respectively, for functionality periods comprised between 0 and 9 months. For functionality periods not covered in Tables A or B, the target degradation or half-life needs to be calculated using the exponential decay formulas indicated in Paragraph 2.2.

See also Q&A 13.9 and Part I, Section 3 for more information.

13.20. With regards to proof of compliance with degradability of a substance or mixture throughout the supply chain there are some questions based on the following scenario:

Company A is a manufacturer of degradable SPM (particle size <5 mm), as proved in accordance with Appendix 15;

Company B then purchases the degradable polymer from Company A and reworks the polymer without changing compositional properties of the degradable polymer from Company A (who provided the polymer degradation certificate);

Company C purchases the degradable polymer reworked by Company B, formulates the final product (such as in a make-up application) and places it on the market (Company B provides them with Company A polymer biodegradation certificate).

- If Company B and Company C use the degradability certificate from Company A, is this a valid proof in the restriction? Or is it only valid in case the polymer remains both physically and chemically unchanged?
- Which company should provide a degradability certificate? Only Company A or all three companies?

- If all companies are expected to provide a biodegradability certificate on their product, is it acceptable to provide a rationale on the unchanged compositional properties of the biodegradable polymer, without re-testing the product?

Based on Appendix 15, degradation tests should be conducted on the synthetic polymer in the form placed on the market. Because Company B reworked the synthetic polymer, some properties of the polymer (other than its composition), or the composition, size and/or shape of the particle containing or coated by the polymer, may have changed. Therefore, additional testing is required to demonstrate that it still meets the degradability criteria (because changing some properties of the polymer, or for the particle containing/coating the polymer may affect the degradability of the polymer particle). Company C can use company B's certificate and provide it to competent authorities upon their request.

14. Appendix 16 – Solubility

These questions concern the application of Appendix 16 to determine polymer solubility. They include clarification of the definition of solubility and solubility testing methods.

14.1. Are water-soluble synthetic polymers such as polyvinyl alcohol (PVA) in the scope of the restriction?

Synthetic polymers fulfilling the solubility criteria listed in Appendix 16 of Annex XVII of REACH are outside the scope of the restriction.

14.2. Regarding solubility testing of either raw materials or formulations, is it necessary that the laboratory is accredited according to ISO 17025? Or will tests performed by laboratories without any certification, which follow conditions prescribed in Appendix 16, be accepted by enforcement authorities?

Only tests performed by laboratories with ISO 17025 accreditation or GLP compliance proven by a national competent authority GLP monitoring programme (or an authority participating in the OECD mutual acceptance of data (MAD) system) or complying with other international standards recognised as being equivalent by the Commission or ECHA (currently there are none) would be acceptable.

For more details on GLP requirements, see Part I, Section 3 of this Guide.

14.3. If an end product does not contain any SPM, does it have to be checked for its water-solubility, or are checks necessary for the water-solubility of any polymers inside products that could be considered as SPM?

Entry 78 prohibits the placing on the market of SPM on their own or in mixtures, unless derogations (under Paragraph 4, 5 and 16) or transitional periods (under Paragraph 6) apply. Therefore, it is necessary to ascertain that a product does not contain SPM subject to the ban before placing it on the market.

For that purpose, it is necessary to verify the presence in the product of polymers that fulfil the definition of SPM given in the regulation. This implies checking for polymers meeting

the criteria of composition, size, physical state, degradability and solubility. Some help in identifying SPM may be provided by Part I, Section 2, Q&A 1.10 in Part II, and the decision trees in Part III, Annex 1.

A product that does not contain SPM when placed on the market is not in the scope of the restriction.

14.4. Is it possible to test the solubility of a product containing glitter as a whole item? For example, is it possible to test slime that contains glitter, or does the glitter have to be isolated first? Similarly, can a solubility test be conducted on a polymer within a solvent?

Details on the test material to use in solubility studies are provided in Appendix 16 of Annex XVII of REACH. The test needs to be performed on the "polymer particles" comparable in terms of composition, form, size and surface area to what is present in the product. If this is not technically feasible, then the test can be conducted on the polymer particles that are disposed of or released in the environment.

Therefore, the solubility test cannot be performed on the whole item, but on a test material that fulfils the conditions in Appendix 16. For example, the solubility of the polymer in the glitter should be tested on the isolated glitter.

14.5. What is the definition of solubility? For instance, some polymers may be water dispersible. How can these products be assessed?

Water solubility measures the maximum amount of a material that can be dissolved in water, while dispersibility (commonly used in medications) is the ability of a product to become suspended in water. Water solubility, for the purposes of the restriction, must be measured in accordance with the test methods reported in Appendix 16 of the restriction. The pass criterion presented for solubility in Appendix 16 is 2g/L.

15. Cosmetics – Specific questions

These questions concern the application entry 78 to cosmetic products. The Section includes questions regarding the use of nail dipping powders and similar products, nail decorations, and the transitional period of cosmetics, etc.

15.1. Are both nail cosmetic products listed as "dipping powder" and "nail gel" within the scope of the restriction? During use, the powder (and gel) become a solid which is applied to the nail. It is removed with acetone only and disposed of in the residual waste. Are there any exceptions?

A precise answer would require knowing the exact composition of the dipping powder or the nail gel and how it is used. The reply below is based on the most common case, i.e. a "dipping powder" or "nail gel" containing methacrylate polymer particles smaller than 5 mm that create a polymeric layer on the nail (the answer may not apply in other cases). In the case mentioned above, methacrylate is an SPM, as it is a solid, synthetic polymer that is insoluble and not degradable, and it is contained in particles measuring less than 5 mm.

The dipping powder and the nail gel mentioned above are in the scope of the restriction as they consist of a mixture containing SPM (the methacrylate) as defined in entry 78.

The following provisions apply:

- Nail products, as defined in point (1)(g) of the Preamble to Annexes II to VI to Regulation No 1223/2009, benefit from a 12-year transitional period in accordance with Paragraph 6(c) of the restriction. Since "dipping powder" and "nail gel" are nail products, the prohibition of placing these products on the market applies as of 17 October 2035.

- Cross-linking polymers in the dipping powder/nail gel, i.e. those that bind together to create the solid layer on the nail, are permanently derogated from the sale ban under Paragraph 5(b) as they are modified in such a way that the polymer stops meeting the conditions of SPM in the left column of entry 78 during intended end use, so they can continue being sold (on their own or in products) after the end of the above mentioned transitional period.

- However, the restriction will apply to SPM in the product that do not have cross-linking function and are not modified during end use in the way described above, such as (but not limited to) SPM-containing glitter. Those SPM will need to be removed or replaced with degradable, soluble or inorganic alternatives from 17 October 2035.

15.2. Can 'loose' SPM-containing glitter be included in artificial nails to be used by nail professionals?

Concerning the manufacturing of artificial nails that include SPM-containing glitter as an integral part, the placing on the market of loose SPM-containing glitter can only be derogated under Paragraph 4(a) if the use of the glitter in the manufacturing process takes place at an industrial site.

Concerning the placing on the market of artificial nails which include SPM-containing glitter for use by nail professionals, it should be noted that artificial nails are articles under REACH. Consequently, since entry 78 does not apply to SPM in articles (as defined under REACH), artificial nails that include SPM-containing glitter are not in the scope of the restriction, and their placing on the market is not restricted by entry 78.

15.3. Does the restriction apply to loose SPM-containing glitter used as a cosmetic product?

The restriction bans, among other things, the placing on the market of SPM intentionally present in mixtures in concentration equal or greater than 0.01% w/w. SPM-containing glitter is regarded as a mixture and is in the scope of the restriction, regardless of whether it is on its own ('loose') or added to a mixture.

SPM-containing glitter can be used on its own as make-up product, e.g. applied as an eye shadow or as blush.

The placing on the market of SPM-containing glitter for use as a make-up product benefits from the transitional period laid down in Paragraph 6(c) and is therefore allowed until 16 October 2035. From 17 October 2031 until 16 October 2035, the placing on the market of such glitter requires a statement that the product contains microplastics.

See also Q&A 15.2.

15.4. Does a transitional period apply to uses of SPM-containing glitter in cosmetic products, such as lip products, nail products and make-up?

The placing on the market of SPM-containing glitter for use in lip products, nail products and make-up products has a transitional period of 12 years (i.e. it is allowed until 17 October 2035), according to Paragraph 6(c). From 17 October 2031 until 16 October 2035, the placing on the market of such glitter requires a statement that the product contains microplastics.

See also Q&A 15.2 and 15.3.

15.5. Do nail decorations and SPM-containing glitter fall under the derogations in Paragraphs 5(b) or 5(c) when used in "permanent" or "semi-permanent" manicure where fixation, such as nail top and hardening with a LED lamp, is required?

Derogation 5(c) does not apply to SPM-containing glitter in nail products, including those for "permanent" or "semi-permanent" manicure (e.g. lacquers and enamels that are fixed using UV lights, including "permanent" nail gels, "permanent" lacquers, etc.). The derogation does not intend to cover uses where the solid matrix is intended to be frequently removed and replaced, such as cosmetic products. See Part I, Section 6, and Part II, Q&A 7.4 and 7.8.

Derogation 5(b) does not apply to SPM-containing glitter in nail products for "permanent" or "semi-permanent" manicure because the SPM in the glitter are not modified but remain SPM during end use (i.e. when the manicure product is on the nail).

Nail products with SPM-containing glitter, can be sold until 16 October 2035, in line with Paragraph 6(c) of the restriction. From 17 October 2031 until 16 October 2035, to continue to be sold, these products need to bear a label indicating they contain microplastics in accordance with Paragraph 9 of the restriction. See Q&A 15.4.

The same reasoning applies in principle for nail decorations. However, nail decorations that are regarded as articles, such as jewels or decals, are not within the scope of the restriction. See Q&A 15.2.

See also Q&A 15.1.

15.6. Do the transition periods that apply to cosmetic products in Paragraph 6(b), 6(c) and 6(d) also apply to cosmetics used as toys? Is there a difference between an SPM-containing

cosmetic mixture intended to be used only for dolls, and one intended to be used on dolls and humans?

The transitional period only applies to cosmetic products in the scope of the Cosmetic Product Regulation (CPR), as stated in Paragraph 6. Cosmetics for dolls are not in the scope of the CPR (which is limited to cosmetic product for human use) and do not benefit from a transitional period. However, if a cosmetic product is intended for use on both dolls and humans, and fulfils the definition of leave-on product, rinse-off product, make-up product, nail product or lip product, it would benefit from the respective transitional period when placed on the market for human use.

16. Infill material for synthetic sport surfaces – Specific questions

This Section includes questions regarding the definition of a synthetic sport surface, the transitional period for the infill material, etc.

16.1. Does the microplastic restriction apply to outdoor rubber-based surfaces, such as athletic tracks, or rubber-based surfaces in playgrounds?

The restriction applies to the placing on the market of SPM-containing rubber granulate for use in the production of outdoor rubber-based surfaces, unless the derogations in Paragraphs 4, 5 or 16 apply. For example, in the case of rubber-based surfaces casted in situ from rubber granulate and a binder, the placing on the market of the granulate is in the scope of the restriction but is derogated under Paragraph 5(c) (IFUD obligations under Paragraph 8 and reporting obligations under Paragraph 12 apply).

The restriction also applies to SPM-containing rubber granulate if placed on the market on its own (i.e. loose) and not intended to be incorporated in a solid matrix (e.g. in the rubber-based surface) at end use.

Note that the transitional period of 8 years in Paragraph 6(j) for the placing on the market of granular infill for use on synthetic sports surfaces does not apply to the placing on the market of granular infill, including SPM-containing rubber granulate, for use on playgrounds or any other surface that is not a synthetic sport surface. Consequently, the placing on the market of SPM-containing rubber granulate for use on playgrounds is prohibited since 17 October 2023, unless the derogations in Paragraphs 4, 5 or 16 apply. The derogations in Paragraphs 4 and 5 do not apply to the placing on the market of SPM-containing rubber granulate for use in playgrounds as a layer of loose rubber granulate.

In case of rubber-based surfaces built from pre-made tiles or rolls that are then seamed together in place, the restriction does not apply to the placing on the market of the tiles or rolls (even if they contain rubber granulate), as they are articles.

The SPM (e.g. the polyurethane) placed on the market to be used by the industrial DUs as feedstock for producing the rubber granulate or the rubber-based surface rolls or tiles is in

the scope of the restriction. The placing on the market of that feedstock SPM is derogated under Paragraph 4(a) but information requirements (including IFUD) under Paragraph 7 and reporting obligations under Paragraph 11 apply.The ECHA Guidance on requirements for substances in articles contains detailed information and guidance to help determine whether a product is considered an article or a mixture.

16.2. How does the restriction apply to placing on the market and use of granular infill for use in synthetic sport surfaces? Is the intention of the transitional period to allow synthetic sport pitches to reach the end of their life span within that period?

The restriction prohibits the placing on the market (e.g. the sale, donation, loan, rent, etc.) of SPM-containing granular infill for use on synthetic sports surfaces, as of 17 October 2031, but not the use of such infill. Consequently, SPM-containing granular infill can continue being used after 17 October 2031 by the person that has it in their possession (for example, if the sport surface owner has some stocks of it available).

The intention of the 8-year transitional period in Paragraph 6(j) is to ensure that many of the synthetic sport surfaces using granular infill do not need to be replaced prematurely due to lack of maintenance/repair. The restriction does not require the replacement of synthetic sport surfaces using granular infill as of 17 October 2031. However, after that date, it is not permitted to place SPM-containing granular infill on the market, which may reduce the capacity to maintain and repair the synthetic sport surface. For a better understanding of what is a “synthetic sport surface”, see Part I, Section 7 and Part II, Q&A 8.4.

16.3. Is infill material mainly made of a ceramic sand based on aluminium oxide used in tennis courts out of scope? Also, is ceramic infill coated with a resin, which mainly consists of an alkaline phenolic coating, in the scope of the restriction?

Aluminium oxide particles on their own are not in the scope of the restriction as they are inorganic substances and are not polymers. However, aluminium oxide particles coated with a synthetic polymeric resin are in the scope of the restriction, provided they fulfil the size criterion (at least 1% w/w of the particles need to be smaller than 5 mm in all dimensions) and the resin is not a natural, water soluble or degradable polymer (according to the criteria set in the restriction).

For a definitive answer additional consideration needs to be given to, for example: the composition of the ceramic particles (is it always aluminium oxide?), dimensions, the composition of the coating (is it always a alkaline phenolic polymeric coating?) and how much the weight of the coating contributes to the weight of the particle, expressed as % (i.e. is it more than 0.01%?).

16.4. Is a tennis court surface that, in addition to brick dust, uses a loose synthetic granulate as the top layer considered a "synthetic sports surface"? If it is not considered a synthetic

sport surface, could those courts continue to use the unbound synthetic granulate or are they subject to the restriction?

The definition of a synthetic sport surface is provided in Q&A 8.4. Based on this, the sport surface needs to be (mostly) synthetic on its own, i.e. before the synthetic granulate used as infill is added.

This would imply that a tennis court surface having a base layer made of clay from brick dust would not be considered a synthetic sport surface. Consequently, the sale of granulate for this use would not benefit from the 8-year transitional period and is banned as of 17 October 2023.

17. Glitter – Specific questions

The Section includes questions specific to glitter, how to determine if a glittered article is within the scope of the restriction, the transitional period for glitters, and derogations for substances containing glitter.

17.1. What is the definition of glitter? Should it be considered to be a substance/mixture or an article under REACH?

The term "glitter" is not defined in the restriction. It is generally understood that the term "glitter" refers to tiny pieces of sparkling material used for decoration. The primary function of glitter is decorative, namely, to provide a sparkle to whatever object (or person) it is applied to. Loose glitter refers to glitter on its own, i.e. not incorporated in another product

Concerning whether glitter should be considered to be a substance/mixture or an article under REACH, the term mixture is defined in Article 3(2) of REACH as "a mixture or solution composed of two or more substances". Article 3(3) defines an 'article' as an "object that during production is given a special shape, surface or design that determines its function to a greater degree than does its chemical composition".

SPM-containing glitter is commonly made of polyethylene terephthalate (PET), which is coated with aluminium to create a reflective surface. The sparkle of the materials (i.e. the polymer covered by aluminium) used for glitter primarily depends on the chemistry of these materials, in particular the reflective properties of aluminium. In short, it is the presence of aluminium (or another reflective material) that makes glitter sparkle. Other factors, such as its flat surface, play a less important role (metal-containing glitter can still shine when not made of flat flakes e.g. when in form of powder). Consequently, the decorative function of glitter is primarily dependent on its chemistry/composition and to a lesser extent on its shape, surface or design (these may play a role, but not as important as the chemistry/composition). Given the above, glitter is to be regarded as a substance or a mixture, not an article.

For more information on articles, and to verify whether products are articles or substances/mixtures, please refer to the Guidance on requirements for substances in articles. Please refer to Part III, Annex 3 of this document for examples of glitter on its own or in products.

17.2. What are the provisions applicable to the placing on the market of glitter purchased before and after 17 October 2023?

SPM-containing glitter and products containing such glitter (for uses other than those laid down in Paragraph 6) that have been placed on the market before 17 October 2023 do not need to be recalled or withdrawn from the market and can continue being sold, in accordance with Paragraph 16, regardless of their use. This would be the case, for example, of SPM and products containing SPM placed on the market before that date that are in the stocks of distributors/importers/retailers.

The prohibition of placing on the market (Paragraph 1) applies as of 17 October 2023 to SPM in glitter on its own or in products, for uses for which no transitional period is set under Paragraph 6 (e.g. art and crafts kits, toys).

Glitter that was not placed on the market by 17 October 2023 can continue being placed on the market in the following scenarios:

- Glitter made of material that is inorganic (e.g. glass, metal), natural, degradable or soluble in water (out of scope of Entry 78).
- Glitter placed on the market for use at industrial sites (derogated under Paragraph 4(a))
- Glitter affixed to articles, or other cases where glitter can be defined as an integral part of the article (since articles are out of the scope of the restriction). See ECHA guidance on requirements for substances in articles for more information and Part III, Annex 3 for examples;
- Glitter with SPM contained by technical means so that SPM releases to the environment are prevented when used in accordance with the instructions for use during intended end use (derogated under Paragraph 5(a)); or glitter with SPM that is permanently incorporated into a solid matrix during intended end use (e.g. in glue, in solid films such as paints) (derogated under Paragraph 5(c)).

Manufacturers, DU and suppliers of products derogated under Paragraphs 4 and 5 may be required to comply with IFUD and other information requirements (Paragraphs 7, 8, and 10). They may also be required to report estimated releases and other information to ECHA on a yearly basis (Paragraphs 11 and 12). See Sections 8 and 9 of Part I of this Guide for more information.

In addition, loose SPM-containing glitter used as a cosmetic product, as well as cosmetic products containing glitter are granted specific transitional periods under Paragraph 6, except for products containing microbeads, for which no transitional period is granted and the prohibition of placing on the market applies since 17 October 2023. Loose SPM-containing glitter used as a cosmetic product, as well as cosmetic products containing glitter can be placed on the market until:

- 16 October 2027, for rinse-off cosmetics (Paragraph 6(b)), unless they contain encapsulated fragrances, in which case they can be placed on the market until 16 October 2029 (Paragraph 6(a)), or contain microbeads, in which case their placing on the market is prohibited since 17 October 2023;
- 16 October 2029, for leave-on cosmetics (Paragraph 6(d)), including when they contain encapsulated fragrances (Paragraph 6(a)), unless they are make-up, lip and nail cosmetic products, (Paragraph 6(c)), in which case they can be placed on the market until 16 October 2035;
- 16 October 2035, for make-up, lip and nail products (Paragraph 6(c)), unless they contain encapsulated fragrances (Paragraph 6(a)), in which case they can be placed on the market until 16 October 2029; or are rinse-off cosmetic products (Paragraph 6(b)), in which case they can be placed on the market until 16 October 2027; or contain microbeads, in which case their placing on the market is prohibited since 17 October 2023.

When used in a cosmetic product, glitter needs to satisfy the conditions of the Cosmetic Products Regulation, including the product safety assessment, for example.

Note that, from 17 October 2031 (or 17 December 2031 for products placed on the market before 17 October 2031) until 16 October 2035, in order to continue to be placed on the market, make-up, lip and nail products need to bear a label indicating that they contain microplastics (Paragraph 9).

17.3. Is the lid of a spray-can with SPM-containing glitter incorporated included in the scope of the restriction?

The cap of the spray can, regardless of whether it incorporates synthetic glitter, is an article under REACH and therefore is excluded from the scope of the restriction.

17.4. Are glitter glues, which consist of glue mixed with synthetic glitter measuring less than 5 mm, for painting on paper and carton, in the scope of the restriction?

Glitter glues are considered mixtures containing SPM and fall within the scope of the restriction. If the glue completely solidifies during intended end use, the SPM-containing glitter in it can be considered to be permanently incorporated into a solid matrix during intended end sue. In this case, the placing on the market of glitter glues can be derogated under Paragraph 5(c) of the restriction. It is the supplier responsibility to assess whether their product can benefit from the derogation in Paragraph 5(c) (or any other derogations), based on their knowledge of the product.

For glitter glue derogated under Paragraph 5(c), the IFUD obligations under Paragraph 8 and 10 apply as of 17 October 2025, and the reporting obligations under Paragraph 12 apply as of 31 May 2027.

17.5. Can glitter be considered a "make-up product" under entry 78?

Loose glitter that contains SPM and is intended for application to the skin, eyebrows, and eyelashes to alter the appearance falls under the definition of "make-up product" and is subject to the restriction. Concerning requirements when using glitter as a cosmetic product, as well as applicable transitional periods for the placing on the market of SPM-containing glitter for use as a make-up product, or in make-up, lip or nail products, see Q&A 17.2.

17.6. Can you clarify whether SPM-containing glitter affixed to articles constitutes an integral part of the article in products such as: costume/festival items, gift sets, general bags, gift boxes, general packaging material and dual-function fashion accessories? If yes, would that glitter be considered out of scope of the restriction? Are articles with glitter affixed on them exempt, even if glitter detachment occurs during normal use and if they are incorporated for decorative purposes to attract consumers?

The restriction targets SPM on their own or in mixtures, including SPM in glitter, but exempts articles from its scope. SPM in glitter affixed to articles are considered an integral part of those articles following ECHA guidance on requirements for substances in articles. Therefore, articles with glitter affixed on their surface fall outside the scope of the restriction, irrespective of whether glitter detaches during normal use due to wear and tear.

See also Part III, Annex 3, and Q&A 17.2 and 17.7.

17.7. Is SPM-containing glitter that is added to an article via a layer of glue or affixed to an article via heat sealing an integral part of the article and therefore exempt from the restriction?

SPM-containing glitter that is affixed on to articles, via any means, is considered as an integral part of the article and is therefore outside of the scope of the restriction (see also Part III, Annex 3 of this Explanatory Guide for examples of articles with glitter as an integral part of them).

17.8. Is there a standard testing method to prove whether SPM-containing glitter detaches from articles during normal end use?

If glitter is affixed to an article, it is considered part of the article and is out of scope of the restriction, even if some glitter detaches from the article during use due to wear and tear. Therefore, there is no legal requirement for such a standard testing method. See ECHA guidance on requirements for substances in articles and Part III, Annex 3 for examples of articles with glitter.

17.9. Can you clarify the transitional period for SPM-containing glitter, particularly glitter derogated under Paragraph 5(c)?

The placing on the market of SPM-containing glitter for an intended end use where such glitter is incorporated in a solid matrix during that end use (e.g. glitter in paint) is permanently derogated under Paragraph 5(c). No transitional period is therefore necessary.

For SPM derogated under Paragraph 5(c), the IFUD obligations under Paragraph 8 and 10 apply as of 17 October 2025, while the reporting obligations under Paragraph 12 apply as of 31 May 2027.

The restriction does not have a specific transitional period for products containing glitter with SPM. SPM on their own or in products, for uses for which a transitional period is laid down in Paragraph 6 of the restriction (e.g. cosmetics, detergents, etc), can continue to be placed on the market until the end of that transitional period.

The placing on the market of SPM on their own or in products, for uses for which **no** transitional period is laid down under Paragraph 6 of the restriction, is banned as of 17 October 2023. Products that have been placed on the market before 17 October 2023 do not need to be recalled or withdrawn from the market but can continue being, e.g. sold. This would be the case, for example, of SPM and products containing SPM that were already placed on the market before that date and are in the stocks of distributors/ importers/ retailers.

Please refer to Section 7 in Part I of this document for more information on transitional periods.

17.10. Is a balloon filled with SPM-containing glitter or confetti in the scope of the restriction?

Article 3(3) of REACH defines an article as "an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition". In order to determine whether an object fulfils the definition of an article under REACH, the object's function and its shape, surface or design need to be assessed.

Following the logic in the Guidance on requirements for substances in articles, a balloon filled with SPM-containing glitter/confetti should be regarded as a combination of an article (functioning as a container or a carrier material) and a substance/mixture. Therefore, SPM-containing glitter in such balloons are within the scope of the restriction and, given that they are not granted a transitional period under Paragraph 6, their placing on the market is prohibited since 17 October 2023.

17.11. A kit includes SPM, e.g. SPM-containing glitter, for the consumer to apply. Should the SPM-containing glitter be treated as a mixture? Does it fall into the scope of the restriction?

SPM-containing glitter is a mixture and its placing on the market on its own, including in products such as a kit, or in mixtures is regulated by the restriction. SPM-containing glitter

can only be placed on the market in a kit if one of the derogations in Paragraphs 4, 5 or 16 apply to it, or if the placing on the market of the SPM in the kit is granted a transitional period in Paragraph 6. See also Q&A 17.1.

17.12. Can SPM-containing glitter/beads be supplied to consumers or professionals in kits for an intended end use where the SPM are trapped into a solid matrix, such as that resulting from hardened embossing powder, acrylic paint, pastes, glue applied to paper, brick or wood?

SPM-containing glitter that is permanently incorporated into a solid matrix as its intended end use may be derogated under Paragraph 5(c). For example, SPM-containing glitter incorporated in a paint during its intended end use, e.g. when a professional or consumer paints a wall or an object, would fall under this definition.

Note that products derogated under Paragraph 5(c) can continue to be supplied but obligations concerning IFUD obligations described in Paragraphs 7, 8 and 10, and the reporting obligations under Paragraph 12 are required. The provided IFUD need to be feasible and sufficiently clear to ensure that releases of SPM-containing glitter to the environment are prevented or minimised.

See Part I, Section 8 and 9 for additional information.

17.13. Are paints and inks containing SPM (including SPM-containing glitter) derogated from the restriction by Paragraph 5(c)?

Paints and inks that contain SPM (including those incorporating SPM-containing glitter) are within the scope of the restriction but they may continue to be placed on the market if their intended use is consistent with the derogations described in Paragraphs 4(a), 5(b) or 5(c) of the restriction.

Paragraph 4(a) derogates the placing on the market of SPM for use at industrial sites (e.g., paint formulation, paint application to objects, or re-packaging activities).

Placing on the market of SPM in paints may also be derogated from the restriction on the basis of Paragraphs 5(b) or 5(c). Paragraph 5(b) applies where the physical properties of SPM are permanently modified during the intended end use of the paint e.g., when ‘binder’ or ‘film-forming’ SPM coalesce when the paint dries and, eventually, cures. Other SPM, that do not coalesce, but are permanently incorporated into the resulting solid paint film (such as a pigment or SPM-containing glitter) are derogated on the basis 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. See Part I, Section 6 for more details on the application of Paragraph 5(c) to inks. Given that some case-by-case assessments may be needed, if claiming a derogation under Paragraph 5(c), operators are encouraged to keep proof that their products indeed fulfil the conditions for the derogation.

Note that products derogated under Paragraph 5(b) and 5(c) can continue to be supplied but obligations concerning IFUD described in Paragraphs 7, 8 and 10, and the reporting obligations under Paragraph 12 are required. See Part I, Section 8 and 9 for additional information on information and reporting requirements.

17.14. If a toy manufacturer has imported SPM-containing glitter before the date of entry into force (17 October 2023), with the intention to repackage the glitter in the EU and add it as a toy component (e.g., in kits), is this glitter considered to be on the market before the entry into force and therefore derogated under Paragraph 16?

Yes. Please see Q&A 12.2, 12.3 on the application of Paragraph 16, and 17.11 and 17.12 for SPM in kits

18. Toys – Specific questions

This Section includes questions regarding the definition of a toy, how to determine if a toy is within the scope of the restriction, and further clarification on derogations that relate to substances and articles that may be considered toys.

18.1. Are moulded plastic toys within the scope of the restriction?

Toys that are articles according to the REACH definition in Article 3(3) are not covered by the restriction. Moulded plastic toys usually are articles and therefore are not within the scope of the restriction.

Toys that consist of SPM on their own, or toys that are mixtures containing SPM are in the scope of the restriction.

The placing on the market of SPM (e.g. uncompounded polymer powder or pellets) or mixtures containing SPM (e.g. compounded polymer pellets) to produce moulded toys at industrial sites is in the scope of the restriction but is derogated according to Paragraph 4(a). In that case, suppliers of such SPM must provide information (Paragraphs 7 and 10) to DU of those SPM at industrial sites. In addition, manufacturers and industrial downstream of those SPM are subject to reporting obligations according to Paragraph 11. For specific examples of toys in the scope of the restriction, please refer to Part III, Annex 3 of this Explanatory Guide.

18.2. Regarding sets that are sold with small gem-like beads that are to be placed on pictures as stickers, a wax is used for the purpose of transporting the gems to the sticker. Some parts of the wax become detached during use. The wax is made of soft solid resin and has a dimension of 0.5x2x3 cm. Are the gems and wax in the scope of the restriction?

The dimensions of the wax are too large to be covered under the definition of an SPM, therefore it is out of the scope. In addition, the unintentional generation of smaller SPM during use is out of scope.

The gem-shaped beads are articles and therefore out of scope of the restriction. Please refer to Part III, Annex 3 of this Explanatory Guide for relevant examples.

18.3. If beads and sequins are intended to be adhered by using glue instead of being threaded or sewn, will their placing on the market be banned?

Beads and sequins are articles, regardless of whether they have (or not) a hole for threading/sewing. Please see Part II, Annex 3 for examples.

18.4. Will Paragraph 1 of the entry apply to toys placed on the market before the date of entry into force of the restriction?

In accordance with Paragraph 16 of the restriction, Paragraph 1 does not apply to toys placed on the market before 17 October 2023.

18.5. Is slime with polystyrene balls or plastic balls (or other elements of similar size <5 mm) in the scope of the restriction?

Polystyrene balls (or similar balls made of synthetic polymers) of size < 5 mm are to be regarded as substances or mixtures, not articles, and are therefore in the scope of the restriction. They cannot be sold on their own, as of 17 October 2023, unless derogated under Paragraphs 4, 5 or 16 or used in products granted a transitional period under Paragraph 6.

Slime containing polystyrene balls (or other SPM – such as the SPM in glitter) cannot be placed on the market as of 17 October 2023 (products already on the market can continue being placed on the market (e.g. sold)). The derogation under Paragraph 5(c) would not apply to slime, because slime cannot be considered "a solid matrix". Please refer to Part III, Annex 3 of this Guide for examples.

18.6. Scratch Artcards have a layer of synthetic resin to be scratched to reveal the picture hidden under the resin. This resin detaches from the Artcards in the process of scratching. If the synthetic resin contains SPM, are Artcards within the scope of the restriction?

The Scratch Artcard is considered an article and is therefore out of the scope of the restriction. ECHA guidance on requirements for substances in articles provides guidance on how to establish whether a product can be considered an article or a combination of an article and a substance/mixture.

18.7. Are 'middles' (the cut out of the hole in the middle of a sequin) that may be found in packaging of sequins in the scope of the restriction?

If 'middles' of sequins are placed on the market with sequins for the purpose of being used by the customer, e.g. as additional decorations, and the polymers in the "middles" fulfil the criteria to be considered as SPM, then the restriction would apply, as they would constitute mixtures. If "middles" are unwanted leftovers, they are outside the scope of the restriction.

18.8. Would a container of SPM-containing glitter sold as part of a toy moulding kit be permitted to be placed on the market under derogation 5(c)if the SPM-containing glitter is intended to be used in a moulding process to form an article (e.g. an animal figurine)?

The SPM-containing glitter in this specific example would benefit from the derogation described in Paragraph 5(c) for SPM permanently incorporated into a solid matrix during intended end use – provided that the mouldable material is solid once moulded into shape (e.g. after cooling down). Whether the solid matrix within which the SPM are permanently incorporated is an article or a substance/mixture is not a relevant consideration for the application of the derogation in Paragraph 5(c).

19. Textiles – Specific questions

This Section includes questions regarding whether textiles are within the scope of the restriction and how the restriction impacts textile and fabric manufacturers.

19.1. What does the restriction mean for fabric manufacturers and wedding dress designers who are currently producing dresses and fabrics with SPM-containing glitter, such as wedding dresses, costumes, festive clothes and footwear?

Glitter affixed to fabric is considered as an integral part of the fabric, which is an article (based on ECHA guidance on requirements for substances in articles). Glittered fabric is therefore outside the scope of the restriction and can continue being placed on the market for any use, including professional use by wedding dress designers.

The placing on the market of SPM-containing glitter for use at industrial sites to produce glittered fabric is allowed (permanent derogation under Paragraph 4(a)), but comes with related IFUD (Paragraphs 7 and 10) and reporting obligations (Paragraph 11).

The placing on the market of SPM-containing glitter for use to produce glittered fabric outside of industrial sites (e.g. artisanal production of glittered fabric) is not derogated under Paragraph 4(a) and is only possible in the case that the SPM in the glitter are derogated under Paragraph 5 because, for example, they are permanently incorporated into a solid matrix (such as a resin layer or film) during intended end use, i.e. when placed on the fabric.

To note that sequins are considered as articles and are therefore out of the scope of the restriction. See also Q&A 18.3.

19.2. Does the unintentional breakdown of synthetic fibres (e.g. polyester, nylon etc.) from garments/textiles during mechanical processes like washing, fall within the scope of the restriction?

The restriction bans the placing on the market of SPM on its own, or intentionally present in mixtures in concentration ≥ 0.01% w/w to confer a wanted property (‘sought-after characteristic’) to the mixture. Synthetic fibres released from garments during washing are

not in the scope of the restriction because the released fibres are not placed on the market, nor are they conferring a sought-after characteristic to a mixture.

The restriction does not ban the placing on the market or the use of articles containing SPM. Therefore, the fact that SPM may be released from articles during the normal use of the article does not prevent that article from being placed on the market.

19.3. Does the restriction apply to SPM in coatings affixed to textiles?

SPM affixed to textiles, such as in coatings, are considered as an integral part of those articles and therefore outside the scope of the restriction.

19.4. Will bridal fashion shops still be allowed to sell their stocks of garments with SPM-containing glitter after the restriction comes into force?

Retailers can continue to sell their stocks of garments with SPM-containing glitter (regardless of whether they have been bought before the entry into force of the restriction on 17 October 2023) because garments with SPM-containing glitter are articles and therefore outside the scope of the restriction. Bridal fashion shops placing on the market glittered fabrics will not be affected because glittered garments or footwear are outside the scope of the restriction. See also Q&A 19.1.

19.5. What are the measurements used to estimate the release of SPM from non-woven textiles into the environment?

Any SPM that may be released from non-woven textiles are outside of the scope of the restriction and their releases do not have to be reported.