**GUIDANCE on the REACH RESTRICTION of SYNTHETIC POLYMER MICROPARTICLES**

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

*Disclaimer: The information contained in this Q&A is intended for general guidance only, to help the industry understand the REACH Restriction on Synthetic Polymer Microparticles published in the OJ on 25 September 2023. The Q&A was compiled with the support of the Cefic network of experts on microplastics. Whilst the information is provided in good faith and has been based on the best information currently available, it is to be relied upon at the user’s own risk. No representations or warranties are made with regards to its completeness or accuracy and no liability will be accepted by Cefic nor any company participating in Cefic for damages of any nature whatsoever resulting from the use of or reliance on the information. This document does not necessarily represent the views of any company participating in Cefic.*

***Cefic strongly recommends that companies continue to assess their legal responsibility with regards to*** ***REACH Synthetic Polymer Microparticles Restriction.***

Table of Contents

[**Introduction** 3](#_Toc170394053)

[1.SCOPE and DEFINITIONS 4](#_Toc170394054)

[2.DEROGATIONS 8](#_Toc170394055)

[3.TRANSITION PERIODS 11](#_Toc170394056)

[4.INSTRUCTIONS for USE and DISPOSAL 14](#_Toc170394057)

[5.REPORTING 16](#_Toc170394058)

PART II

[6.SCOPE and Definitions 18](#_Toc170394059)

[7.DEROGATIONS 19](#_Toc170394060)

[8.TRANSITION PERIODS 21](#_Toc170394071)

[9.INSTRUCTIONS FOR USE AND DISPOSAL 21](#_Toc170394074)

[10.REPORTING 26](#_Toc170394075)

 [REPORTING DURING TRANSPORTATION 28](#_Toc170394076)

[11.LABELLING 36](#_Toc170394077)

[12.BIODEGRADATION TESTING PROPOSAL 37](#_Toc170394078)

[13.SOLUBILITY TESTING PROPOSAL 39](#_Toc170394079)

# **Introduction**

This document aims at compiling a list of the key questions that Cefic member companies and partner associations have regarding the application of the REACH Annex XVII Restriction on Synthetic Polymer Microparticles (hereby referred to as SPM in the entire guidance).

**The present document does NOT represent any legal advice but only some considerations which follow Cefic’s reading of the restriction.**

This document is intended to be a living document which can periodically be updated.

The final text of the REACH Restriction on SPM (Commission Regulation (EU) 2023/2055) of 25 September 2023 can be found via the following link:

[Commission Regulation (EU) 2023/… of 25 September 2023 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) as regards SPM (europa.eu)](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R2055)

# SCOPE and DEFINITIONS

## What is an ‘SPM’ Synthetic Polymer Microparticle in the SPM restriction?

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| **Synthetic solid polymer** meeting following conditions **are in the scope** of the restriction: * where **≥ 1% w/w** of particles have
* all dimensions **0.1μm1 ≤ x ≤ 5mm**, or
* a length of **0.3μm1 ≤ x ≤ 15mm** and length to diameter ratio of >3
 |

**Decision flowchart to understand whether the material is included or excluded from the restriction**



## What is meant by ‘exclusion’ in the SPM restriction?

A polymer **excluded** from the restriction means that the polymer is out of the scope of the SPM restriction and can be placed on the market without any limitations.

## What is meant by ‘derogation’ in the SPM restriction?

A polymer or a specific use **derogated** refers to a polymer or use that is within the scope of the restriction but, because of specific provisions laid down in the legal text, is allowed to be placed on the market. However, additional requirements exist for these materials/uses, including Instructions for Use and Disposal and Reporting.

1It is stated in Recital 32 that the restriction includes a temporary 100 nm size limit for enforcement when analytical methods and accompanying documentation cannot confirm the concentration of synthetic polymer microparticles below that size.

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| Is a polymer in solution in scope of the restriction?If the polymer is placed on the market as **a solution with no solid particles** (≥ 1% w/w), it is **not in the scope of the restriction**. If a polymer is solid, but dissolved in the end use, what is the consequence?If the polymer is a **solid**, it might benefit from a derogation with the condition that it **dissolves in the solvent when used** **by the end user (**properties of polymer are permanently modified).  Evidence: If it can be verified that no SPM, covered by the restriction, are present after intended end use, the product falls under the derogation described in paragraph 5b. In this context, demonstrating that the physical properties of the SPM are permanently modified is more important than the solubility itself.  |

## The definition of SPM excludes “polymers that have a solubility greater than 2 g/L“ (proven in accordance with Appendix [16]). Is this correct ?

Yes, with regards to solubility, the SPM restriction only **excludes** polymers that are **soluble in water (see Recital 13 below)** , according to the methods specified in Appendix 16.

Solubility in other solvents cannot benefit from this entry.

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| *(13)* ***Water-soluble solid polymers*** *lose their solid state after their release into the environment, and therefore do not contribute to the identified concern. The Annex XV dossier therefore proposed internationally accepted methods to test solubility and to exclude those* ***water-soluble polymers*** *from the scope of the restriction.**§5 exemptions refer to non-industrial uses in which a synthetic polymer containing substance/ mixture is placed on the market but during end use either the microparticle is technically contained (§5 a), cease to exist (§5b) or incorporated into a solid matrix (§ 5 c). include easy examples (polymer soluble in ethanol).* |

## Is solubility in solvents, other than water, also derogated by paragraph 5b?

Not necessarily, solubility in other solvents does not necessarily allow a derogation according to paragraph 5b of the restriction. Physical properties of SPM need to be permanently modified in a such a way that it no longer falls withing the scope of the restriction.

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| *(5) Paragraph 1 shall not apply to the placing on the market of the following synthetic polymer microparticles, as substances on their own or in mixtures:**(b) synthetic polymer microparticles* ***the physical properties of which are permanently modified*** *during intended end use in such a way that the* ***polymer no longer falls within the scope*** *of this entry;* |

## Which methods can be applied for the determination of the solubility in solvents other than water?

Method selection is a case-by-case decision for the respective product/material.

##  What is the definition of Industrial Site?

There is no definition of industrial and professional use in REACH i.e. in Title 1 chapter II, but there are references to the two types of use in its definitions 13, 25 and 35, as well as in section 6 of Annex VI. In Annex XVII, the terms “industrial installation” and activity of “professional outside industrial installations” are mentioned.

ECHA’s Guidance on Information Requirements and Chemical Safety Assessment and, specifically its Chapter R.12 on use description, recommends understanding the concept “professional” as a characteristic to distinguish between use (i) at industrial sites and (ii) uses outside industrial sites (but not consumers or general public).

Typical examples of “uses at industrial site”, the ECHA guidance mentions are the following:

* Production of cars and other vehicles;
* Production of paper;
* Textile dyeing and finishing and
* Production of semiconductors

## What is the definition of End users?

Similar to the definition of industrial site, REACH does not contain a definition of end user as such, but there are some mentions of the concept in its Annex V: ‘’substances which result from a chemical reaction occurring upon end use of other substances, mixtures or articles and which are not themselves manufactured, imported or placed on the market’’.

ECHA website also gives some explanation on end users, in the context of explanation of downstream users: end users are those that use substances or mixtures but do not supply them further downstream. Examples include users of adhesives, coatings and inks, lubricants, cleaning agents, solvents and chemical reagents like bleaching products.

# DEROGATIONS

## How to demonstrate that the polymer has been permanently modified during the intended end use in such a way that it is no longer in scope of the restriction?

 The decision is made on a case-by-case basis depending on the product and the application/end-use. Companies should obtain documentation based on the specific use and, if necessary, supported by individual analyses, which confirms whether derogations apply., e.g. the loss of the SPM properties. This applies to professional and consumer uses, as industrial uses fall under derogation 4a).

## In case of gel formation, can we consider other conditions beyond condition 5b)?

 Gels are dispersion (solid particles dispersed in a liquid phase). One of the basic properties of gels is that they are polymers able to swell in certain solvents. If physical properties of a gel are permanently modified during intended end use in such a way that the polymer no longer falls within the scope of restriction, it is derogated subject to instructions for use and disposal and reporting.

 Gels are specifically mentioned under Recital 18

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|  *(18) [...] Moreover , derogations from the ban on placing on the market are proposed where the risk from releases is expected to be minimized because synthetic polymer microparticles are contained by technical means, such as those in chromatography columns, water filtering cartridges or printer toners, or* ***permanently lose their particle form because, for example, they swell*** *or form a film, like in diapers, nail polish or paint, or are permanently enclosed in a solid matrix during end use, such as fibers added to concrete or pellets used as feedstock for molded articles.* |

## In case of gel formation, does the general exclusion for polymer in liquid form “under conditions (d)(i),(ii), (iii)” apply ?

Yes, if one can demonstrate that a substance or mixture meets any conditions stipulated in paragraph 2(d) and that less than 1 % by weight of the particles (gels) fulfil either of the following conditions.

* all dimensions of the particles are equal to or less than 5 mm;
* the length of the particles is equal to or less than 15 mm and their length to diameter ratio is greater than 3.

## Is a raw material based on inorganic particles coated with a liquid polymer in scope of the restriction?

 A liquid polymer is per definition out of the scope of the restriction. However, if during its end-use, the formulation based on it is solidifying by film formation (evaporation of solvents, cross-linking, physical entanglement), a solid polymer microparticle is formed (derogation 5(b)), Synthetic Polymer Microparticle is formed.

## Does the application of points 5a) 5b) and 5c) exclude the obligation for record keeping at point 11 and 12 of the restriction?

 No. The last industrial supplier is responsible for the reporting if derogated under paragraph 5. The derogations listed in paragraph 5 apply to selected synthetic polymer microparticles (as defined in the restriction) that are allowed to be placed on the market. The requirements set out in paragraphs 8, 10, 11 and 12 apply to synthetic polymer microparticles placed on the market in accordance with paragraph 5.

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|  *(5) Paragraph 1 shall not apply to the placing on the market of the following synthetic polymer microparticles, as substances on their own or in mixtures:* *(a)synthetic polymer microparticles* ***which are contained by technical means*** *so that releases to the* *environment are prevented when used in accordance with the instructions for use during the intended end use;* *(b)synthetic polymer microparticles* ***the physical properties of which are permanently modified*** *during intended end use in such a way that the polymer no longer falls within the scope of this entry;* *(c) synthetic polymer microparticles which are* ***permanently incorporated*** *into a solid matrix during intended end use.* *(8) From 17 October 2026 suppliers of products containing synthetic polymer microparticles referred to in paragraph 4, point (e), and from 17 October 2025 suppliers of products containing synthetic polymer microparticles referred to in paragraph 4, point (d), and paragraph 5, shall provide instructions for use and disposal explaining to professional users and the general public how to prevent releases of synthetic polymer microparticles to the environment.* *(10) The information referred to in paragraphs 7,8 and 9 shall be provided in the form of clearly visible, legible and indelible text or, where appropriate regarding the information in paragraphs 7 and 8, in the form of pictograms…* *(11) Starting from 2026 manufacturers and industrial downstream users of Synthetic Polymer Microparticles in the form of pellets, flakes, and powders used as feedstock in plastic manufacturing at industrial sites, and starting from 2027, other manufacturers of Synthetic Polymer Microparticles at industrial downstream users using synthetic polymer microparticles at industrial sites shall submit the following information to the Agency by 31 May of each year:* *(a) a description of the uses of Synthetic Polymer Microparticles in the previous calendar;* *(b) for each use of Synthetic Polymer Microparticles, generic information on the identity of the polymers used;* *(c)for each use of Synthetic Polymer Microparticles, an estimate of the quantity of Synthetic Polymer Microparticles released to the environment in the previous calendar year, which shall include also the quantity of Synthetic Polymer Microparticles released to the environment during transportation.* *(d)for each use of Synthetic Polymer Microparticles, a reference to the derogation laid down in paragraph 4, point (b), (d) or (e), or 5 point (a), (b) or (c).* *(12) From 2027, suppliers of products containing Synthetic Polymer Microparticles referred to in paragraphs 4, points (b), (d) and (e ), and paragraph 5, placed on the market for the first time to professional users and the general public….* |

## What is meant by the term “permanently incorporated”?

 The exact applicability of the term "permanently incorporated into a solid matrix" will depend on the respective end use and is a case-by-case decision by each company considering whether the intentionally added synthetic polymer microparticles are released during normal conditions of use.

 Synthetic polymer microparticles that are contained by technical means in a solid are specifically mentioned under Recital 18

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| *(18) Moreover,* ***derogations*** *from the ban on placing on the market are proposed where the risk from* ***releases is expected to be minimized*** *because synthetic polymer microparticles* ***are contained by technical means****, such as those in chromatography columns, water filtering cartridges or printer toners, or permanently lose their particle form because, for example, they swell or form a film, like in diapers, nail polish or paint, or are permanently enclosed in a solid matrix during end use, such as fibers added to concrete …* |

## Can you confirm, that the use of synthetic polymer microparticles listed in paragraph 6 are excluded from the restriction of placing on the market if they are covered by paragraph 5?

 No, they are derogated from the restriction and not excluded. The list in Paragraph 6 is a collection of temporary derogations. After the end of the transitional periods mentioned in §6, the substance groups listed can no longer be placed on the market. However, if the criteria listed in paragraph 5 applies, individual products can still be placed on the market, but subjects to specific requirements; i.e. instructions use and disposals and reporting emissions to ECHA.

# TRANSITION PERIODS

## 3.1 From….[Publications Office, 17 October 2028 = 5 years after the date of entry into force of this amending Regulation] for products for agricultural and horticultural uses not covered by points (g) or (h); Is it possible to provide some examples of which types of products would fall within this category (for example, do we mean adjuvants according to art. 2(3)(d) of Reg. 1107/2009 or instead does it refer to other products)?

Examples are given in the Recital 23. To obtain further clarification and examples, the relevant trade associations should be contacted. Below is the transcription of Recital 23.

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|  *(23) [...] As regards other agricultural and horticultural uses, such as seeds coated with colorants or lubricants or other products which are not or do not contain plant protection products, a transitional period of 5 years was considered appropriate.”* |

## 3.2 Are there reporting obligations for transition periods?

For the chemical sector, there are no reporting and information duties within transition periods.

## 3.3 Are there reporting obligations after the transition period?

After the transition period, there is a reporting obligation as well as a duty to provide information for use and disposal, under the condition that the derogation, according to Paragraph 5, can be applied. Otherwise, the synthetic polymer microparticle is banned from placing on the market at the end of transition period.

**Figure 1.** Transition Periods

**Figure 2.** Dates for the Bans

# INSTRUCTIONS for USE and DISPOSAL

## Could instructions for use and disposal be linked to a specific website communicated to the customers or can a company use a leaflet (not necessarily linked to QR code)?

Yes. The Synthetic Polymer Microparticles restriction text recognizes the possibility of having different formats to communicate instructions for use and disposal, including digital solutions (to complement text).

According to paragraph 10 of the restriction, the information requirements under paragraph 7 can be communicated in the form of clearly visible, legible and indelible text by different means including:

* Label
* Leaflet
* Safety data sheet
* Packaging

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| *(10) The information referred to in paragraphs 7, 8 and 9 shall be provided in the form of clearly visible, legible and indelible text or, where appropriate regarding the information in paragraphs 7 and 8, in the form of pictograms. The text or pictograms shall be placed on the* ***label****, the* ***packaging****, or the package* ***leaflet*** *of the products containing synthetic polymer microparticles or, regarding the information in paragraph 7, on the* ***safety data sheet****. In addition to the text or pictograms, suppliers may provide a* ***digital tool that gives access to an electronic version of that information****.* |

## Will a statement like ‘disposal in accordance with local regulations’ be acceptable?

The text used for the instructions for use and disposal should have a clear reference to the product and should give the industrial downstream user/professional user/consumer / end-user the opportunity to use and dispose of the product properly to minimize any releases to the environment. This information will be product specific.

Recital 25 mentions that instructions should explain the proper use and disposal of the SPM.

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| *(25) Where pollution in the environment from synthetic polymer microparticles can be minimized by the requirement to provide instructions for use and disposal, the Annex XV dossier proposed a derogation from the prohibition of placing on the market. Those instructions should explain how to properly use and dispose of products in order to minimize releases to the environment.* |

It is an individual company decision/responsibility to assess how to communicate with their consumers and end-users to fulfill the SPM restriction obligations. For example, one may choose to opt for a pictogram, see example below.

*Example of a pictogram:*



## Will a generic instruction for disposal of a mixture, that contain SPM, be acceptable?

Please see the answer provided for next question below.

##  Will instructions for the disposal of a mixture, that contain synthetic polymer microparticles, need to have a specific statement that mentions how to dispose of the SPM contained in it?

Due to the large number of different mixtures, it should be decided on a case-by-case basis whether a downstream user/ consumer/ end-user can dispose of synthetic polymer microparticles separately. **Therefore, the answer to this question is a case-by-case decision made by the company that places product for a first time on the EU market:**

* If it is not possible to separate the SPM from the mixture at the disposal stage, the instructions for use and disposal should focus on how to dispose of the product/mixture and not the SPM.
* If it is possible, to separate SPM from the mixture at the disposal stage, the disposal instructions should include a statement on how to dispose of the SPM.

## 4.5 Can an industrial downstream user assume that a raw material is not in the scope of the restriction if the EU-based supplier of the raw material has not informed him, by the end of the two-year transitional period (paragraph 7), that the raw material supplied is subject to the REACH Synthetic Polymer Microparticles restriction and he leaves the polymer in his product physically and chemically unchanged?

Each individual company should continue to assess their legal responsibility with regards to REACH SPM restriction. If in doubt, one should check with supplier if a product is in the scope of the restriction. If the supplier obeys the law, any product in scope of the restriction should be out according to the timelines. One should be vigilant as transition timelines differ between different product groups. Even if a product is derogated/excluded from the restriction it may still be affected by obligations stipulated in the legal text, for example reporting &labelling.

# REPORTING

## 5.1 Paragraph 12 requires suppliers to report products containing SPM referred to in paragraph 4- (b), (d) & e and paragraph 5. Clarification is required for the following Polymers derogated in paragraph 5 b) that are completely transformed and lose their particle properties under certain conditions. If a polymer is permanently transformed during the formulation stage prior to end use or during end use, no release of microparticles will occur during the use of the product. Does reporting of derogated products under paragraph 5 apply ?

A SPM can be permanently transformed during different life cycle stages of the product. This is reflected in the text of the restriction. Therefore, reporting will be a case-by-case requirement. See the different cases below:

Scenario mentioned in the question:

* **Manufacturer** obligations in paragraph 11
* **Industrial downstream User** (SPM is permanently transformed during formulation stage, prior to end use) The case reported in this question does not apply to the derogation set in paragraph 5b). Formulation during industrial use follows paragraph 4a). As such, reporting should be done according to the requirements for paragraph 4 a), set out under paragraph 11 of the restriction.

Paragraph 5 (a), (b), (c) lists SPM that are derogated from restriction due to the limit of their emissions to the environment. However, these polymers still have instructions of use and disposal and reporting obligations during use phase. Paragraph 12 indicates which uses need to be reported.

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| *(5)* ***Paragraph 1 shall not apply*** *to the placing on the market of the following synthetic polymer microparticles, as substances on their own or in mixtures:**(a) synthetic polymer microparticles which are contained by technical means so that releases to the environment are prevented when used in accordance with the instructions for use during the intended end use;**(b)* ***synthetic polymer microparticles the physical properties of which are permanently modified during intended end use in such a way that the polymer no longer falls within the scope of this entry;****(c) synthetic polymer microparticles which are permanently incorporated into a solid matrix during intended end use.**(11) Starting from 2026* ***manufacturers and industrial downstream users of synthetic polymer microparticles in the form of pellets, flakes, and powders used as feedstock in plastic manufacturing at industrial sites****, and, starting from 2027,* ***other manufacturers of synthetic polymer microparticles*** *and other industrial downstream users using synthetic polymer microparticles at industrial sites shall submit the following information to the Agency by 31 May of each year**(12) From 2027, suppliers of* ***products containing synthetic polymer microparticles*** *referred to in paragraphs 4, points (b), (d) and (e), and paragraph 5,* ***placed on the market for the first time*** *to professional users and the general public, shall submit the following information to the Agency by 31 May of each year:**(a) a description of the end uses for which the synthetic polymer microparticles were placed on the market in the previous calendar year**(b) for each end use for which the synthetic polymer microparticles were placed on the market, generic information on the identity of the polymers placed on the market in the previous calendar year;**(c) for each end use for which the synthetic polymer microparticles were placed on the market, an estimate of the quantity of synthetic polymer microparticles released to the environment in the previous calendar year, which shall include also the quantity of synthetic polymer microparticles released to the environment during transportation.**(d) for each use of synthetic polymer microparticles, a reference to the applicable derogation or derogations laid down in paragraph 4, point (b), (d) or (e), or 5 point (a), (b) or (c).* |

## 5.2 Section 11 also covers transport, therefore, if a package is damaged in transit and material is spilled, swept up and disposed of as hazardous waste by either the transport company or a 3rd party (e.g. warehouse or distributor), does this not need to be reported?

Yes, REACH Restriction addresses the release of SPM into the environment. If proper mitigation measures are put in place and prevention of release into the environment can be demonstrated this would not require reporting as no “release to environment occurred”

## 5.3 Which information is included in the reporting obligations?

The annual reporting obligations, according to paragraphs 11 and 12, consist of different elements that can be presented in different ways, e.g. as free text or in the form of standard phrases. Furthermore, there may be different relationships between the different elements, e.g. one or more polymers per use.

## 5.4 Will ECHA impose specific requirements on the format, structure and content of the notifications?If so, how will these requirements and standard formats be developed and by when will they be available?

It is not possible to give an answer to this question at this stage. ECHA may develop specific tools for reporting or use existing tools that are available.

# PART II

***All of the questions below were submitted to the Commission***

# SCOPE and DEFINITIONS

The present section includes questions received from companies and associations concerning paragraphs 1, 2 and 3 and entry 78 of the restriction on SPM..

## 6.1 What is to be understood behind the term “plastic feedstock”?

There is currently no definition in the restriction document of what plastic feedstock is.

However, legal text refers to **synthetic polymer microparticles** in the form of:

* Pellets
* Flakes
* Powders

and their **use in plastic manufacturing** at industrial sites. In addition, Cefic suggests to look at the Regulation currently being discussed on preventing plastic pellet loss and recital (57) transcribed below. The shorter transition time for reporting refers to feedstock used in the production of plastic articles.

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| “(57) *The loss of plastic pellets represents an important industrial source of microplastics in the environment. The plastic pellet supply chain is already putting in place voluntarily initiatives, which will include reporting, to minimize pellet loss. Against this background, the Commission considers a 24-month transitional period for reporting requirements for this sector justified.*” |

## 6.2 For mixtures containing microparticles from two or more synthetic polymers, do companies need to add the percentages of synthetic polymer microparticles from each polymer and the cumulative concentration of microparticles needs to be compared to 1% limit established in the definition? For example: if the individual concentrations of the different polymers are < 1% is the whole particle out of scope or is the 1% referring to total polymer content irrespective of the different polymers present? e.g. A Particle containing 0.5% of Polymer X and 0.5% polymer Y.

The total of SPM in the microparticle has to be below the threshold established in the restriction (1%).

## 6.3 In the final version of the text there is no mention for Research and Development uses, is this covered by the “for use at industrial sites” in case the R&D laboratory is inside the industrial site? If so a reference to Article 67(1) of REACH should be made (“Annex XVII shall specify if the restriction shall not apply to product and process orientated and development, as well as the maximum quantity exempted”)

Scientific development R&D is exempted from the REACH Restriction (Article 67.1 of the REACH Regulation). However, process development is not exempted. If process development is done in industrial settings, companies can still do it but need to report the emissions (as established under paragraph 11).

# DEROGATIONS

## The present section includes questions received from companies and associations concerning paragraphs 4, 5 and 16 of the restriction on SPM.

## 7.1 Could Cefic provide additional practical examples on SPM which are contained by technical means?

Examples of SPM contained by technical means can be found in the recitals: chromatography columns, water filtering cartridges or printer toners. The logic followed for the REACH Restriction on SPM is that “SPM are permanently enclosed in a solid matrix during end use” and are not intended to be released under normal or reasonably foreseeable conditions of use.

*(18) Derogations from the ban on placing on the market are proposed where the risk from releases is expected to be minimized because synthetic polymer microparticles are contained by technical means, such as those in chromatography columns, water filtering cartridges or printer toners, or permanently lose their particle form because, for example, they swell or form a film, like in diapers, nail polish or paint, or are permanently enclosed in a solid matrix during end use, such as fibers added to concrete or pellets used as feedstock for molded articles.*

## Liquid polymers are excluded from the restriction. In case of liquid polymers used as coating, and if the end product is solid, what is the way to prove the derogation ? Would it be enough to argue that “The importance is what form exists on the market?

## Yes, if it is a solution on the market (SPM are polymers that are solid and are contained in particles and constitute at least 1 % by weight of those particles; or build a continuous surface coating on particles ) does not meet the legal definition of the liquid according , it should not be in the scope of the restriction. Each case has to be evaluated individually. If polymer stays liquid in the coating, than it won’t be in the scope of the restriction.

## Paragraph 16 states that the paragraph 1 of the restriction shall not apply to synthetic polymer microparticles placed on the market prior to a certain date. There is an additional sentence that this would not apply to uses listed in paragraph 6. ?

There is a grace period for those uses without transitional period. Those with transitional period are subject to the paragraph 6 conditions. Different transition periods for ‘placing on the market’ apply for different sectors. However, according to the Commission Regulation all transition periods refer to ‘placing on the market’. Placing on market is equivalent to leaving the distribution facilities or “on shelf”. The definition in REACH. (Article 3.12): means 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;

## Is read-across permitted within a product family?

## This is a technical question for ECHA and Commission to address.

## How to assess whether a seed coating formulation falls under SPM restriction? Can we have examples considering the weight of the seed and each polymer in a formulation in relation to the threshold value of 0.01% by weight (and size of the seed considering the 1%)

## This is a question that Cefic cannot answer. Cefic recommends that CropLife Europe or Euroseeds should be contacted to provide the answer to this question, not Cefic.

## In connection with what could be the definition of "end use" and "products on the market", along the supply chain, with all B2B actors and the final company placing the final product in the market. Who of each company must declare the "synthetic polymer microparticle" or "non-synthetic polymer microparticle" status of their product or only give an assessment against exemptions (liquid, soluble, biodegradable, natural, <0.01%) each user needs to report.In order to determine the SPM downstream risk, can a company be satisfied with a "non-synthetic polymer microparticle" upstream statements or must it receive an assessment against exemptions (liquid, soluble, biodegradable, natural, <0.01%?

It depends on what company does. If there is no change of polymer then it should not need to be declared but referred to the status from the previous player on the supply chain. If the formulation changes then companies might need to generate additional information to understand if the product contains or not SPMs. Please note that even if a company does not have a SPM, additional information might be needed to show on what grounds it is not a nonsynthetic polymer microparticle (soluble, degradable, natural or non-carbon polymer).

# TRANSITION PERIODS

## The present section includes questions received from companies and associations concerning paragraph 6 of the restriction on SPM.

## 8.1 "From [Publications Office, 17 October 2028 = 5 years after the date of entry into force of this amending Regulation] for products for agricultural and horticultural uses not covered by points (g) or (h); Is it possible to provide some examples of which types of products would fall within this category (for example, do we mean adjuvants according to art. 2(3)(d) of Reg. 1107/2009 or instead does it refer to other products)?

For the moment Cefic is not able to provide the answer to this question. The corresponding trade association should be contacted by the company in order to get the examples requested.

# INSTRUCTIONS FOR USE AND DISPOSAL

The present section includes questions received from companies and associations concerning paragraph 7, 8, 9 and 10 of the restriction on SPM.

## 9.1 Are urban water discharges in scope, even if a water treatment plant collecting any plastics residues is operating?

This answer depends, weather the filters are sufficient in preventing SPM release into environment.

## 9.2 Does the name for each SPM need to be included when microparticles are made of more than one polymer? (Referring to the text written under Paragraphs 5(b), 7(d), 11(b) )

Yes, manufacturers, suppliers, and industrial users of SPM should maintain **generic information** on the identity of the **polymers** contained in the substance of mixture.

Manufacturers, importers and industrial downstream users of **products containing synthetic polymer** microparticles shall provide **specific information** on the identity of polymers covered by this entry contained in those products and the function of those polymers in the products to competent authorities upon their request. The specific information on the polymer identity shall be sufficient to unequivocally identify polymers and shall at least include the information laid down in points 2.1 to 2.2.3 and points 2.3.5, 2.3.6 and 2.3.7 of Annex VI, where applicable.

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| *(4)* ***Paragraph 1 shall not apply*** *to the placing on the market of:**(a) synthetic polymer microparticles, as substances on their own or in mixtures, for use at industrial sites;* |

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| *(5)* ***Paragraph 1 shall not apply*** *to the placing on the market of the following synthetic polymer microparticles, as substances on their own or in mixtures:**(a) synthetic polymer microparticles which are contained by technical means so that releases to the environment are prevented when used in accordance with the instructions for use during the intended end use;**(b)* ***synthetic polymer microparticles the physical properties of which are permanently modified during intended end use in such a way that the polymer no longer falls within the scope of this entry;****(c) synthetic polymer microparticles which are permanently incorporated into a solid matrix during intended end use.* |

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| *(7) From 17 October 2025 suppliers of synthetic polymer microparticles referred to in paragraph 4, point (a), shall provide the following information:**d)* ***generic information*** *on the* ***identity of the polymers*** *contained in the substance or mixture that enables manufacturers, industrial downstream users and other suppliers to comply with their obligations laid down in paragraphs 11 and 12.* |

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| *(11) Starting from 2026* ***manufacturers and industrial downstream users*** *of synthetic polymer microparticles in the form of pellets, flakes, and powders used as feedstock in plastic manufacturing at industrial sites, and, starting from 2027, other manufacturers of synthetic polymer microparticles and other industrial downstream users using synthetic polymer microparticles at industrial sites shall submit the following information to the Agency by 31 May of each year:**(a) a description of the uses of synthetic polymer microparticles in the previous calendar year;**(b) For each use of synthetic polymer microparticles,* ***generic information on the identity of the polymers used;*** |

## 9.3 Referring to the text written under Paragraphs 5(b), 7(d), 11(b) How are we able to maintain confidentiality if companies have the obligation to disclose specific polymer names?

Cefic is not in a position to answer this question. The question should be addressed by the Commission and ECHA. However, based on previous experience, CBI issues are kept confidential by ECHA and not shared with other companies.

## 9.4 Referring to the text written under Paragraphs 5(b), 7(d), 11(b). Can we use polymer abbreviations, such as PVC, PET, as generic polymer names?

Cefic is not in a position to answer this question. The question should be addressed by the Commission and ECHA.

## 9.5 Referring to the text written under Paragraphs 5(b), 7(d), 11(b) – Can we use tariff codes as generic polymer identifiers?

Cefic is not in a position to answer this question. The question should be addressed by the Commission and ECHA.

## 9.6 Referring to the text written under Paragraph 7(a) i) What level of detail is expected that a supplier should provide to industrial downstream users on the instructions for use and disposal (IFUD) of synthetic polymer microparticles? Do instructions for use and disposal (IFUD) need to be specific or generic?

## This information will be product specific and use dependent. Recital 25 mentions that instructions should properly explain the use and disposal in order to minimize pollution in the environment from SPM. It is an individual company decision/responsibility to assess how to communicate with their consumers & end-users to fulfill the REACH SPM Restriction obligations.

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| *(7) From 17 October 2025 suppliers of synthetic polymer microparticles referred to in paragraph 4, point (a), shall provide the following information:**(a) instructions for use and disposal explaining to industrial downstream users how to prevent releases of synthetic polymer microparticles to the environment;* |

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| *(25) Where pollution in the environment from synthetic polymer microparticles can be minimized by the requirement to provide instructions for use and disposal, the Annex XV dossier proposed a derogation from the prohibition of placing on the market. Those instructions should explain how to properly use and dispose of products in order to minimize releases to the environment.* |

## Referring to the text written under Paragraph 7(a) iii) – In a mixture with two or more types of synthetic polymer microparticles, do suppliers need to indicate the overall quantity/concentration of synthetic polymer microparticles in the mixture rather than quantity/concentration of each type of polymer?

Paragraph 7c) does not contain provisions to report “per polymer” thus the overall quantity/concentration of SPM should be sufficient.

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| *(7).From 17 October 2025 suppliers of synthetic polymer microparticles referred to in paragraph 4, point (a), shall provide the following information:**(a)instructions for use and disposal explaining to industrial downstream users how to prevent releases of synthetic polymer microparticles to the environment;**(b)the following statement: “The synthetic polymer microparticles supplied is subject to conditions laid down by entry 78 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council”;**(c)the information on quantity or, as applicable,* ***concentration of synthetic polymer microparticles*** *in the substance or mixture;**(d)* ***generic information on the identity of the polymers contained*** *in the substance or mixture that enables manufacturers, industrial downstream users and other suppliers to comply with their obligations laid down in paragraphs 11 and 12.* |

## 9.7 Referring to the text written under Paragraph 7(a) iii) – Can suppliers use any range to describe the concentration of synthetic polymer microparticles in the substance or mixture?

Cefic is not in a position to answer this question. The question should be addressed by the Commission and ECHA.

## 9.8 Referring to the text written under Paragraph 7(a) iii) – What is the maximum concentration range width that a supplier can use to describe the concentration of synthetic polymer microparticles in the substance or mixture?

Cefic is not in a position to answer this question. The question should be addressed by the Commission and ECHA.

## 9.9 Paragraph 7(a) iii) – Considering that the exact concentration/quantity may be confidential, can suppliers describe the concentration of synthetic polymer microparticles in the substance or mixture > x% or <x%?

As there is no explicit mentioning of concentration ranges (in opposition to e.g. Annex II, Section 3.2) it has to be assumed that the exact concentration needs to be given.

## 9.10 From suppliers of SPM referred to in paragraph 4, point (a), shall provide the following information:

*7(c) the information on quantity or, as applicable, concentration of synthetic polymer microparticles in the substance or mixture.*

## For a pure polymer this would be 100% or the assay value from a COA if there is an assay but it could also be the quantitative formulation for a mixture. In the latter, this information is often highly confidential and shared only in documents submitted directly to regulators (e.g. a Drug Master File), but there is no provision in the EU for excipient Master Files so how can this information remain confidential?

This question should be answered by the Commission as Cefic is not in the position to provide any answer to this question.

## 9.11 Where a consumer product is derogated under paragraph 5b (e.g. forming a solid film -cosmetics on hair) and the residual polymer is considered to be removed by water ending up down the drain. How can instructions for use and disposal (IFUD) be applied?

The answer to this question will highly depend on the product and packaging. type and therefore is a case-by case assessment. Legal text refers to instructions that will facilitate prevention synthetic polymer microparticles being released to the environment.

One example for instructions for use and disposal could be: “ do not flush/clean with water before disposing with municipal waste”

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| *(8) From 17 October 2026suppliers of products containing synthetic polymer microparticles referred to in paragraph 4, point (e), and from 17 October 2025suppliers of products containing synthetic polymer microparticles referred to in paragraph 4, point (d), and paragraph 5, shall provide* ***instructions for use and disposal explaining to professional users and the general public how to prevent releases of synthetic polymer microparticles to the environment.*** |

# REPORTING

The present section includes questions received from companies and associations concerning paragraph 11, 12, 13, 14 and 15 of the restriction on SPM.

## 10.1 Paragraph 11 requires reporting for both manufacturers and downstream users of SPM (at industrial sites). Clarification is required for following: Description of the uses of synthetic polymer microparticles in the previous calendar year is required. Manufacturers do not always know the end uses of the materials they supply to customers as it may be confidential. Will “use at industrial site” suffice for suppliers?

**The manufacturer** of a product sold under paragraph 4a) needs to report on losses during his own use of the product (details are included in paragraph 11); the end use is irrelevant at this stage.

**The downstream user,** producing a product for professional users and/or the general public, needs to report both on losses during his own use (according to paragraph11) as well as on estimated losses during end use of the product (according to paragraph12). Further rationale on this matter can also be found in **recital** (56) transcribed below.

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| *“(56) As regards the reporting requirements proposed in the Annex XV dossier, as modified by RAC and SEAC, the Commission finds that they will contribute to monitoring the effectiveness of the instructions for use and disposal and will improve the evidence base for the risk management of the uses exempted from the prohibition of placing on the market. The Commission further considers that including a reference to the applicable derogations in the information to be reported to the Agency is needed in order to facilitate enforcement without imposing additional burden on industry. In addition, manufacturers and industrial downstream users should be required to estimate and report their own emissions. Furthermore, in order to ensure that all emissions along the supply chain are monitored and reported without adding undue burden on end users, suppliers of products containing synthetic polymer microparticles that place those products on the market for the first time to professional users and the general public are to also estimate, in addition to their own emissions, the downstream emissions from the moment the product is placed on the market to the moment it is disposed of after end use and report the total emissions to the Agency. To ensure the optimal use of the reported information and facilitate enforcement, such information should be made available to the Member States.*” |

## 10.2 Does the manufacturer have to provide only the description of its customers' use, or they have to indicate any further uses known to him during the life cycle of the product?

*From 2027, suppliers of products containing synthetic polymer microparticles referred to in paragraphs 4, points (b), (d) and (e), and paragraph 5, placed on the market for the first time to professional users and the general public, shall submit the following information to the Agency by 31 May of each year:*”

According to paragraph 12 c) producers of a product for professional users and/or the general public must report on estimated losses during intended end use(s) of the product (per intended end use).

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| *“Paragraph 12(c) for each end use for which the synthetic polymer microparticles were placed on the market, an estimate of the quantity of synthetic polymer microparticles released to the environment in the previous calendar year, which shall include also the quantity of synthetic polymer microparticles released to the environment during transportation.”* |

10.3 Are there any obligations for the customers to communicate to producers their use and/or their downstream customers’ use?
No such obligation can be found in the legal text.

## REPORTING DURING TRANSPORTATION

## 10.4 Which amount during transport should be included in estimate volumes? (ref. Paragraph 11 c)

According to legal text manufacturers and industrial users of SPM shall submit to Agency **estimate** of the **quantity** of SPM **released to the environment**. Restriction does not provide further information on methodology to be used.

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| *( 11) Starting from 2026* ***manufacturers and industrial downstream users of synthetic polymer microparticles*** *in the form of pellets, flakes, and powders used as feedstock in plastic manufacturing at industrial sites, and, starting from 2027, other manufacturers of synthetic polymer microparticles and other industrial downstream users using synthetic polymer microparticles at industrial sites shall submit the following information to the Agency by 31 May of each year:**(a)a description of the uses of synthetic polymer microparticles in the previous calendar year;**(b)for each use of synthetic polymer microparticles, generic information on the identity of the polymers used;**(c)for each use of synthetic polymer microparticles, an* ***estimate of the quantity of SPM released*** *to the* ***environment i****n the previous calendar year, which shall include also the quantity of synthetic polymer microparticles* ***released to the environment during transportation.****(d) for each use of synthetic polymer microparticles, a reference to the derogation laid down in paragraph 4, point (a).* |

## 10.5 Will “released to the environment during transportation.” be based on who has custody on the SPMs / product ?

Legal text refers to manufacturers and industrial users of SPMs. At this stage further clarity on the element of reporting transportation losses is required. Ultimately, Commission should provide an answer to this. Transportation is not subject to REACH, however, reporting on losses during transportation is explicitly required in the SPM restriction. Double counting (estimation) or under-counting (estimation) should be avoided.

## 10.6 How is the split being made between the different parties (manufacturers / industrial downstream users) that will have to report, in particular on the quantity of microparticles released to the environment during transportation ?

See above

## 10.7 What in case of distributers, which are not manufacturers nor industrial downstream users?

For this question, Cefic is of the opinion that distributers may hold custody while pellets are being transported.
According to paragraph 11 only manufacturers and industrial downstream users have to report and according to paragraph 12 suppliers of SPM containing products according to paragraph 4 points b, d and e and paragraph 5 which place the product for the first time on the market to professional users or the general public. If a distributer does not have either the role as industrial downstream user or is placing the product on the market, distributers have no obligation to report. According to Act 3.24 of REACH says that 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 utilization. Additionally, according to Art 3.13 of REACH a distributor or a consumer is not a downstream user.

## 10.8 What about the full supply chain ? For instance, plastic pellets are manipulated a dozen (or much more times) during transportation when moving from a manufacturer to an industrial downstream user.

Only industrial downstream users have a reporting obligation according to paragraph 11 and according to paragraph 12 suppliers of SPM containing products according to §4 points b, d and e and §5 which place the product for the first time on the market.

## 10.9 What about logistics service providers (KTN / Huver Geys / …) ? Are they considered part of the transportation chain ?

**No**, only in case they use the substance (s. above). They do not have to report, but the manufacturer/ industrial downstream user must estimate environmental emissions, including releases during transportation.

## 10.10 Is the ‘geographical scope’ that needs to be considered for reporting of losses (and description of the uses), restricted to the plastic pellets handled in the EU ?

REACH applies to EEA (European Economic Area). Therefore, reporting applies to manufacturing, use and placing of the market of products in EEA for the uses and products covered under paragraphs 11 and 12.

## 10.11 Will an (online)- tool for reporting be provided by ECHA? The Agency is named in paragraphs 11 and 12 of the restriction proposal as recipient of the data that must be reported each year)

Yes, ECHA is working on an IT tool and emission data will be reported to ECHA.

## 10.12 Which data format will be required for reporting?

This is unknown to industry yet.

## 10.13 How emissions are supposed to be estimated and reported during transportation, knowing that a transporter can transfer different types of products not all from same company at the same time?

Environmental emission data can be estimated.

## 10.14 Regarding paragraph 15 assuming the following situation: Company 1: producer of biodegradable polymer (particle size <5 mm), as proved in accordance with Appendix Company 2: purchases biodegradable polymer from Company 1 and reworks polymer without changing compositional properties of the biodegradable polymer from Company 1 (*Company 1 provides polymer biodegradation certificate*) Company 3: Purchases biodegradable polymer reworked by Company 2, formulates the final product (i.e. make-up application) and places it on the market (*Company 2 provides Company 1 polymer biodegradation certificate*)Is the new Restriction changing the current industry model where company 2 and company 3 can use the biodegradability certificate from company 1? Which company should provide a biodegradability certificate? Only Company 1? (cfr. current industry model) Or all 3 companies?

## In the case every company is 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. If company 2 does not chemically modify the polymer, the assessment of company 1 should still be valid. Information flow and roles in case of inspection are detailed in paragraphs 14 and 15.

## 10.15 When are applicable the information laid down in points from 2.2 to 2.2.3 and points 2.3.5, 2.3.6 and 2.3.7 of Annex VI?

In appendix 15.3 the requirements for test materials in degradation tests are described.

## 10.16 Recital. 58 states (reporting requirements): “To avoid double reporting, when there is more than one actor in the supply chain placing on the market the same product containing synthetic polymer microparticles, only the first actor within that supply chain should provide the required information to the Agency.” What is meant with „the same product“ as this is critical for the decision who has to report. Does the „same product“ mean it‘s the same microplastic or is each different formulation a new product? Please see the Power-Point slide for a comprehensive illustration:



Companies have to report the uses. If a company has the same SPM for different uses, companies have to report for each end use. If multiple polymers are used in the same end use, the report can be done as the sum of all (however it might depend on how the IT tool is prepared).

## 10.17 Which part of the release during transportation shall be considered in case of import from a non-EU manufacturer?

REACH applies to the European economic area. Therefore, also only releases to the EEA environment should be in scope.

## 10.18 Which of the deadlines and duties for labelling and/or reporting applies if a company uses for example synthetic polymer microparticles at an industrial site to manufacture/formulate a fertilizer or a medical device, which in itself falls under the definition of synthetic polymer microparticles?

Unless you are using or producing SPM in form of flakes or powders used as feedstock in plastic manufacturing, all dates are the same (31st May 2027 for the uses in the year 2026). The content of the reporting is different (for the material you use and for the material you place on the market).

## 10.19 Who has the duty to report in case a company has different sites and different legal entities in Europe? Is this at site, legal entity or Corporate level?

Any reporting is for emission of SPM per Legal entity.

## 10.20 Can an industrial downstream user rely and refer to the results of solubility and degradability tests carried out by its suppliers when competent authorities request this information from him by reference to paragraph 15, provided that he can ensure that the polymer in its product remains physically and chemically unchanged?

If the supplier of a polymer has proven that the polymer is excluded from the SPM restriction (soluble, biodegradable, etc.), there is no legal requirement to inform the downstream (industrial) user on the presence of that polymer. If no information has arrived until 25th October 2027, the industrial downstream user can rely on that conclusion and does not have to prove it again. However, if the industrial downstream user is making changes to the polymer (adding acid/base, salts, increasing concentration, etc) an assessment should be done inhouse if that change may impact the SPM status.

## 10.21 As stated in Paragraph 12. “From … [Publications Office, please insert the calendar year in which the date 36 months after the date of entry into force of this amending Regulation falls. However, if this calculated date is later in the year than 31 May, please insert the following calendar year], suppliers of products containing synthetic polymer microparticles referred to in paragraphs 4, points (b), (d) and (e), and paragraph 5, placed on the market for the first time to professional users and the general public, shall submit the following information to the Agency by 31 May of each year:…”Does it mean that the information above have to be submitted to ECHA, for products containing synthetic polymer microparticles referred to in paragraph 4, points (b), (d) and (e), and paragraph 5 only in case of new product placed on the market after EIF+36 months? If not, starting from EIF+ 36 months, do we to have send the information to ECHA (ref. paragraph 12) each year (within 31 May) for all the products containing synthetic polymer microparticles referred to in paragraph 4, points (b), (d) and (e) and paragraph 5?

The reporting obligation is for all emission of the year prior to the date of the reporting. This has to be done annually for all uses of the SPM and if derogation 5 is applicable also for all intended end uses outside industrial sites.

## 10.22 Paragraphs 11 and 12 and the following information to the Agency by 31 May of each year:(c) for each end use for which the synthetic polymer microparticles were placed on the market, an estimate of the quantity of synthetic polymer microparticles released to the environment in the previous calendar year, which shall include also the quantity of synthetic polymer microparticles released to the environment during transportation. “an estimate of the quantity of synthetic polymer microparticles released to the environment”: Does it means the quantity of synthetic polymer microparticles purchased in the previous year (i.e. quantity used for finished product manufacturing and quantity lost as production waste)?

According to paragraph 12, only estimated losses during the end use shall be reported for each end use. This reporting is for the emitted amount of all SPMs during such end use without separation into the different generic polymers contained in the SPMs. There is no need to report the quantity of purchased SPMs, but the release only. However, the release is typically the quantity used multiplied by use specific release factors. In addition to this and according to paragraph 11 the reporting on own use (during the production) needs to be done, including transportation (separately). It does not mean releases that were fully contained, proper disposal of production waste or purchased amounts.

## 10.23 Which shall include also the quantity of synthetic polymer microparticles released to the environment during transportation”: Could you specify what means microparticles released to the environment during transportation?

During transportation releases can happen by filling and emptying tanks and in exceptional cases also during the transport itself, when emission can´t be avoided. (releases due to accidents to be discussed)

## 10.24 Can the polymer content be reported in cases where the particle content cannot be determined?

If only the polymer content is known that is bound in SPMs, and the amount of SPMs can´t be determined, the polymer content can be reported. Possibly, companies can make an estimate of the particle content and report that. However, this might need to be done on a case by case and expert assessment.

## 10.25 Who is responsible for reporting losses during transportation and distribution?

Supplier of SPM have the obligation to inform every user how to avoid emission to the environment. This should also include transportation and distribution. However, the reporting of unavoidable emissions during transportations should be reported by the user demanding the transport. Distributers are seen as professional and therefore the emission during use of a distributer should be taken into account by the last industrial supplier of the value chain. who owns the material during transportation part should be the responsible for the reporting of the releases into the environment. It also depends on the terms of the agreement / contract between companies of the supply chain.

## 10.26 What about responsibilities in case of tolling?

Please see the question below

## 10.27 Section 11 Reporting – “other manufacturers of synthetic polymer microparticles and other industrial downstream users using synthetic polymer microparticles at industrial sites shall submit the following information to the Agency by 31 May of each year:…” It has been interpreted by some that tolling (contract manufacturing) is considered an industrial site (i.e. business to business) even if it is used to manufacture a derogated product. There is discussion in industry that the company contracting the tolling would be responsible for any reporting obligations, not the toller(s) to avoid duplication of reporting. Therefore, if material was released into the environment by the toller, the company responsible for that product must do the reporting. Please confirm if this is correct.

This will most likely depend on the contract with the toller. If the toller is also responsible for REACH registration, the toller will most likely also be considered as manufacturer or user of a SPM and should be responsible for the reporting for the own uses (including transportation). In case REACH obligations are taken over by the contractor of the tolling, the reporting will be laying with the contractor including any emissions at toller site.

## 10.28 We are only required to report quantity in terms of that material released to the environment. Is "released to the environment" defined anywhere? If spillages are swept up and disposed of as hazardous waste they do not need to be reported?

There is no defined method to estimate the release to environment. Therefore, there is also no legal requirement for testing of emission. Every user of a SPM should assess the various processes involved and make an expert judgment for releases after the measures to reduce emission as specified by the supplier are implemented.

## 10.29 What is legally binding for manufacturers of pharmaceutical or food ingredients (derogated uses) to communicate to the pharmaceutical or food company purchasing the material? Must they provide data for solubility and/or biodegradation to these users or just the instructions for use and disposal if classified as a synthetic polymer microparticle? If data must be provided, does it need to be actual values or is it sufficient for solubility, for example, to state >2 g/L? For example, a Safety Data Sheet has sections that include information on physical/chemical characteristics, e.g. solubility and biodegradability. Do values need to be provided in these sections or is it sufficient to add a statement that the material is classified as a synthetic polymer microparticles and include disposal information?

As the formulation of excipients and food additives to medicinal products and food is in scope of the synthetic polymer microparticles restriction (industrial use) and require reporting of environmental emissions, the supplier needs to provide the industrial downstream user all information according to paragraph 7 of the restriction. All general obligation towards SDS generation remain unchanged.

## 10.30 How should the environmental emission be calculated for a polymer with e.g. water solubility close to 2 g/L which will not reach the water solubility limit when released and therefore will not be released as microparticle. Same question will apply to polymer which will not have a microparticle shape when released to the environment (e.g. swellable polymers).

There is no need for reporting if a polymer is not emitted as SPM. If SPM status is lost after use and so is not released to the environment as a SPM,, there is no need to report. If it enters in the environment as a SPM you need to report. If not a SPM, then you don’t need to report.

# LABELLING

## 11.1 Is a label to be applied also to B2B industrial users or only to professionals and consumers?

Paragraph 7 refers to suppliers as mentioned in paragraph 4a: these are the labeling requirements for uses on industrial sites. Paragraph 8 mentions the duties for suppliers to professional users and the general public: They have to be informed about use and disposal and release prevention. Paragraph 9 describes the label, paragraph 10 indicated clearly that the information from paragraphs 7 to 9 has to be on a label: i.a.: labeling requirements apply to industrial, professional and consumer.

## 11.2 Is labelling mandatorily mentioning the phrase stipulated in section 7b? or is it enough with a pictogram or a QR code?

Paragraph 10 reads clearly: The information referred to in paragraphs 7, 8 and 9 shall be provided in the form of clearly visible, legible and indelible text or, where appropriate regarding the information in paragraphs 7 and 8, in the form of pictograms. In addition to the text or pictograms, suppliers may provide a digital tool that gives access to an electronic version of that information. a QR code might be an add-on, but the phrase itself must occur on the label.

## 11.3 Is the sole use of electronic product pamphlets sufficient for a product that is exclusively sold to professional users?

No. Paragraph 10 reads clearly:

*The information referred to in paragraphs 7, 8 and 9 shall be provided in the form of clearly visible, legible and indelible text or, where appropriate regarding the information in paragraphs 7 and 8, in the form of pictograms. In addition to the text or pictograms, suppliers may provide a digital tool that gives access to an electronic version of that information.”*

# BIODEGRADATION TESTING PROPOSAL

The present section includes questions received from companies and associations concerning Appendix 15 of the restriction on synthetic polymer microparticles.

## 12.1 Concerning Appendix 15. The tests are conducted by laboratories that comply with the principles of good laboratory practice, set out in directive 2004/10/EC, or other international standards recognized as equivalent by the Commission or by the Agency or accredited according to the ISO 17025 standard. For non-European laboratories, are national certifications valid (e.g. EPA for the USA) which in many cases are accepted as an international reference?

It can be assumed, that international references are accepted as long as the above mentioned standards and the GLP requirements are fulfilled.

## 12.2 Is a read across/analogy possible to prove the degradability or the solubility of a polymer?

There is no reference given to the acceptance of read across / analogy approaches. Usually, the SPM itself is to be tested, as set out in Appendix 15, Point 3 ‘*Specific requirements for the test material to be used in degradation tests’*. As the identity of the tested SPM is not and cannot be clearly defined by the legal text, it is up to the producer / importer of SPM to define it. The producer / importer of the SPM defines identity of the tested SPM and which SPMs lie within the boundaries.

## 12.3 What are the specific requirements to demonstrate the degradability of polymers in products intended for agricultural and horticultural applications?

Fertilizer products containing polymers which are glazing agents or increase the water holding capacity or wettability of the product The degradability of polymers which are coating agents or increase the water retention capacity or the wettability in fertilizing products, as defined in Article 2, point (1), of Regulation (EU) 2019/1009, which do not fall within the scope of that Regulation shall be demonstrated in accordance with the delegated acts referred to in Article 42(6) of that Regulation. In case of absence of such delegated acts, products containing such polymers shall not be placed on the market after 16 July 2026.

## 12.4 Article 42 states that the biodegradability criteria must be evaluated by 16 July, how can we verify the restriction proposal?

This is a question that for Cefic is related to the fertilizers act instead of the REACH Restriction on SPM.

## 12.5 Concerning section 1.5.1: While the specified test methods in Group 1 to 4 specify a threshold for proving degradation expressed as % mineralization, I.e. referring to ultimate degradation, Group 5 simulation tests specify degradation half-life (DT50/DegT50) values, I.e. referring to primary degradation, I.e. breakdown into degradation products. Since it is not specified differently, could you confirm that this is also true in context of the synthetic polymer microparticles restriction?

This refers to the primary degradation. Please consider mineralization.

## 12.6 Concerning section 2.2: A functionality period for polymers in products for agricultural and horticultural applications should be considered when performing Group 4 and 5 tests. How to deal with the situation that the functionality period of a polymer is close to or exceeds the standard test duration (e.g., 120 days in a OECD 307 soil simulation test)?

Extrapolating degradation in that situation is connected with a high degree of uncertainty or is even impossible. The degradation criteria should only start at the end of the functionality period.

## 12.7 Recital 47 of the legal text takes into account the need for reviewing the standard degradability and solubility test methods due to scientific developments. Is there a time frame and/or procedure already existing on when and how this review will be performed?

According to Recital 47 there may be a need to review the test methods in case specific test methods for SPM solubility and degradability are developed. There is no time frame nor a specific procedure for that.

# SOLUBILITY TESTING PROPOSAL

The present section includes questions received from companies and associations concerning Appendix 16 of the restriction on synthetic polymer microparticles.

## 13.1 According to Appendix 16 The conditions for the solubility test shall be as follows: - Temperature: 20°C - pH: 7 Loading: 10 g/1 000 ml Duration of the test: 24 hours Threshold: solubility > 2 g/l". In some cases, for example, solid polymers have pH other than 7 because their use, in application processes, requires different conditions, and the pH 7 is not applicable for a chemical designed to be used in different conditions. Is it possible to derogate in this case the solubility tests conditions, with a description of the reasons?

No. In this case, it might be considered that the polymer is solid and insoluble as the conditions to test solubility are legally stated.