CE/EFfCI Guidance on the EU Microplastics Restriction

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PLEASE NOTE:

This document IS NOT formal legal advice – it is for guidance only!

Please send all requests for the inclusion of additional information to: mpguidance@cosmeticseurope.eu

The key elements of the Restriction for the Cosmetic Industry

1. THE DEFINITION

Synthetic polymer microparticles (SPM):

Polymers that are solid and which either are contained in particles and constitute at least 1 % by weight of those particles, or build a continuous surface coating on particles, where at least 1 % by weight of those particles fulfil either of the following conditions:

a. all dimensions of the particles are equal to or less than 5 mm;

b. the length of the particles is equal to or less than 15 mm and their length to diameter ratio is greater than 3.

Lower Size limit:

Where the concentration of synthetic polymer microparticles covered by this entry **cannot be determined by existing analytical methods** or accompanying documentation in order to verify the compliance with the concentration limit [0.01% by weight] only the particles of at least the following size shall be taken into account:

a. 0,1 µm for any dimension, for particles where all dimensions are equal to or smaller than 5 mm;

b. 0,3 µm for any dimension, for particles that have a length that is equal to or smaller than 15 mm and a length to diameter ratio greater than 3.

Key points to note:

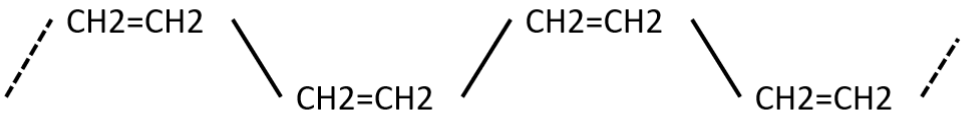
- The definition does not refer to microplastics. There are no named substances. Companies need to apply the definition, taking into account the characteristics of the substance in question - **see decision tree in Appendix 1**.

2. SUBSTANCES NOT IN SCOPE OF THE BAN

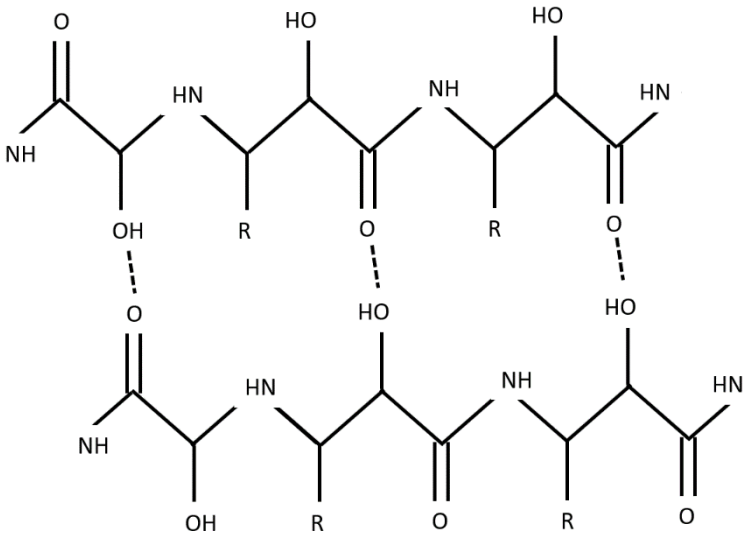
A. Natural Polymers

- Polymers that are the result of a polymerisation process **that has taken place in nature**, independently of the process through which they have been extracted, **which are not chemically modified.**

Examples:
Natural rubber:



Silk protein / generic structure:



Key points to note:

- Polymers obtained by fermentation (a biotechnology process) are not considered natural polymers
  - The polymerisation process takes place in an industrial setting and therefore does not meet the definition "…polymerisation process that has taken place in nature…"
    - when assessed according to the criteria set out in the definition from by REACH regulation, natural polymers are not necessarily 'substances which occur in nature'.

B. Biodegradable Polymers

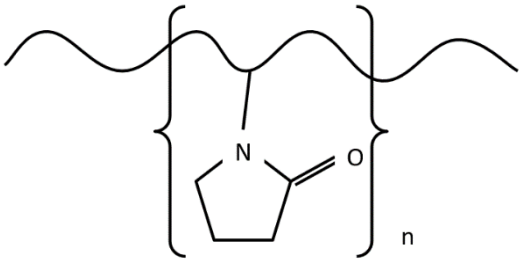
- Polymers that meet pass criteria using test guidelines and conditions specified within the text of the restriction – **see Appendix 15.**
- Each methodology has been placed in a group – groups 1 to 5.
  - For groups 1-3, a pass in one test is sufficient to place a polymer outside the scope of the ban.
  - For groups 4 and 5 biodegradability needs to be proven in three different compartments.

C. Water soluble Polymers

- Polymers that have a solubility of greater than 2g/L according to OECD 105 or OECD 120. Examples of such polymers are given in the Annex to Background Document (10 December 2020): hydroxypropyl methylcellulose (HPMC), polyethylene glycol, starch, povidone, hydroxypropyl cellulose (HPC), polyvinyl alcohol (PVA), polyvinyl pyrrolidone.

Example:

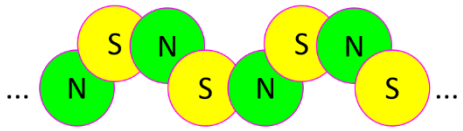
Polyvinyl pyrrolidone



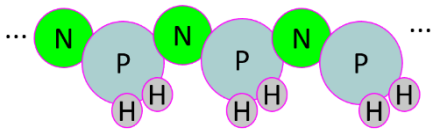
D. Polymers without carbon atoms in their structure

Examples:

Polythiazyl



Polyphosphazene



Key points to note:

These polymers – known also as inorganic polymers – are generally not used for personal care applications

3. POLYMERS IN SCOPE OF THE RESTRICTION BUT NOT BANNED (i.e. DEROGATED USE)

1. SPM, as substance or in mixture, for use at industrial sites.

- Paragraph 4 (a) of the restriction – **see section 4 below. See also flowchart under Rulebase 8.**
- If the SPM is permanently modified during use at an industrial site, then the obtained formulation no longer contains a SPM and is out of scope. - s**ee section 4 below.**
- Paragraph 5(a) focuses on SPM which are incorporated by technical means so that any release to environment is excluded when in use according to its intended use. Reference to this paragraph 5(a) is not applicable to cosmetic ingredient and products

2. SPM where physical properties are permanently modified during intended end use.

- Paragraph 5(b) of the Restriction - **see section 5 below.**

3. SPM that are permanently incorporated into a solid matrix at the time of use.

- Paragraph 5(c) of the Restriction – in the current view of the EU Commission cosmetic use is not regarded as permanently incorporated, therefore any reference to this paragraph 5(c) is not applicable. This is currently under discussion with focus on permanent make up and artificial nails.

Key points to note:

- Labelling and/or reporting obligations are in place for all substances where the above derogations are applied - **see section 9 below**.
- Film-forming polymers in nail polish are derogated under Paragraph 5(b) because they permanently stop being SPM at end use (the SPM coalesce to form a film). The derogation under Paragraph 5(c) does not apply to other SPM in nail polish (e.g., SPM-containing glitter) because any SPM incorporation in the hardened nail polish (solid matrix) is not permanent, as the hardened nail polish is intended to be removed after a relatively short time.
- Note that products derogated under Paragraph 5 are subject to IFUD and reporting requirements.

4. PARAGRAPH 4A – THE 'INDUSTRIAL SITES' DEROGATION

- The use of SPM at industrial sites is derogated
- Cosmetic product manufacturers may receive SPM from raw materials suppliers, who must provide with Instructions for Use and Disposal to avoid release of SPM into the environment, statement that the SPM is covered by the Restriction, and information of identity, quantity or concentration of the SPM – **see section 7 below**.
- When the SPM is permanently modified during use at an industrial site, the obtained cosmetic formulation no longer contains a SPM and is out of scope. However, there is an obligation for the cosmetic manufacturer to Report in respect of use at industrial sites and to have sufficient scientific rationale/evidence available to demonstrate that the SPM is permanently modified in the cosmetic formulation - **see section 9 below**.

Key points to note:

- Test methodologies to demonstrate physical properties of the SPM have been permanently modified are not listed in the Restriction.
    - Identified as a key area for further work – **see "Areas for further work / interpretation"**.

5. PARAGRAPH 5(B) – WHERE THE PHYSICAL PROPERTIES ARE PERMANENTLY MODIFIED DURING THE INTENDED PROFESSIONAL/CONSUMER END USE

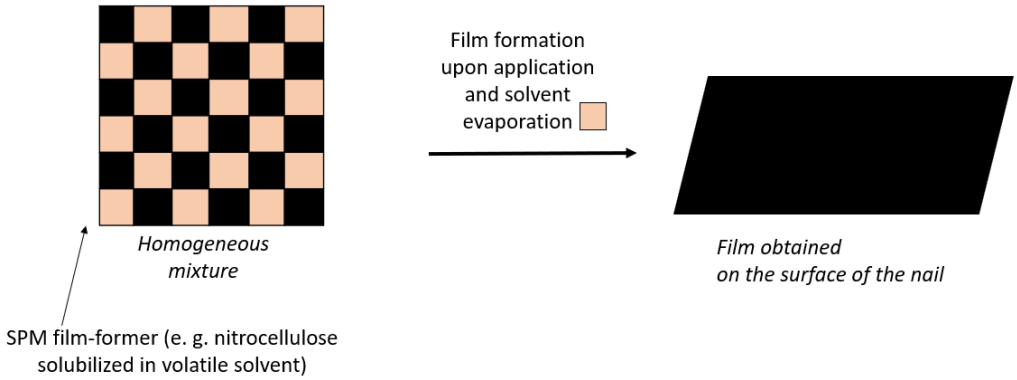
- The Restriction aims to cover SPM that may enter the environment. This derogation addresses scenarios when the finished product as placed on the market contains SPM, but they are permanently modified during professional/consumer end use e.g. by coalescing into a film during or following application.
- If during the use of the product by the consumer or professional end user the SPM cease to meet the definition i.e., they change their size and / or shape, their use is allowed under this derogation
- For example, this could apply because the SPM forms a film, changing size and/or shape in use.
- Film-forming polymers in nail polish are derogated under Paragraph 5(b) because they permanently stop being SPM at end use (the SPM coalesce to form a film). Note that products derogated under Paragraph 5 are subject to IFUD and reporting requirements.
- These products need to be labelled with Instructions for Use and Disposal - **see section 9 below**.
- They are also subject to Reporting obligations – **see section 8 below.**

Examples:

Nail polish

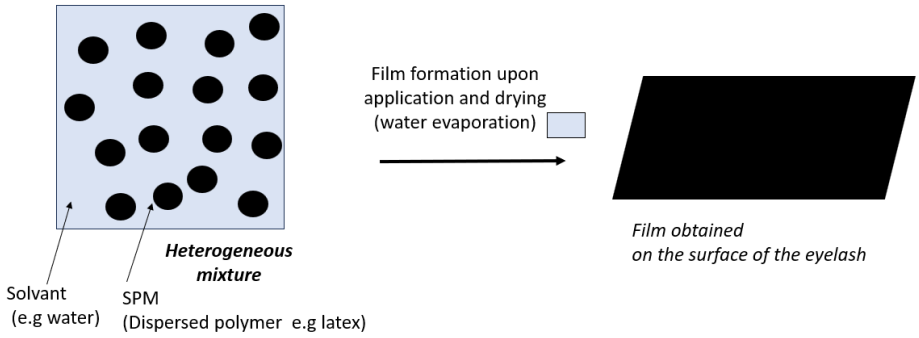
- Film-forming SPM that are dissolved in the nail polish product and are no longer in particle form when placed on the market are out of scope of the ban (but subject to reporting obligations). Derogation 5b would only apply to particles present in the finished formulation that are permanently modified during consumer use (i.e. the SPM coalesces during or after application to form a film).

- Other SPM present that remains solid particles in the dried matrix do not qualify for Derogation 5c because incorporation in the hardened nail polish (solid matrix) is not permanent, due to the intended removal after a relatively short time.



Mascara

- Film-forming SPM that are present in particle form in the mascara, coalesce and dry to form a film during/after application (Derogation 5b applies).
- Any polymer pigments that remain solid following application do not benefit from any derogation.



Key points to note:

- Test methodologies to demonstrate physical properties of the SPM have been permanently modified are not listed in the Restriction. Some ideas to explore further on a case-by-case basis are presented here:
  - Microscopy (incl. ASM)
  - DSC (Differencial Scanning Calorometry)
  - For any polymer dispersions a white point or MFFT below room temperature (around 20°C) would be an emulsion, indicating it does not contain synthetic polymer microparticles (cf. https://www.epdla.eu/policy/polymer-dispersions-and-synthetic-polymer-microparticles).
  - Identified as a key area for further work – **see "Areas for further work / interpretation".**
- In case the Cosmetic product manufacturers use SPM in the final products, the only possibility to use SPM is to apply Derogation 5
- For example, Derogation 5(b) could be applied subsequently when the physical properties of the SPM are permanently modified **during the intended (professional/consumer) end use**.

6. PARAGRAPH 6 – TRANSITION TIMES AND ARTICLE 16 EXEMPTIONS

- If an SPM is neither out of scope nor falls under a derogated use, then ultimately, use will be restricted to less than 0.01% by weight.
- Paragraph 6 of the Annex to the legal text details the number of years after which the use of SPM at (equal or greater ≥0.01% will be banned based on intended application. These are referred to as transition periods.
- Note that these transition times are in order to allow for reformulation. SPM can still be placed on the market during the transition times but must not be on the market at the end of the transition times.
- Microbeads and SPMs without transition periods placed on the market before 16th October 2023 do not have to be recalled (article 16).
- Transition periods are as follows:

APPLICATION	# YEARS IN TRANSITION PERIOD	TRANSITION PERIOD END DATE
• Microbeads (SPM for use as an abrasive, i.e.. to exfoliate,) used in any application	0	16 October 2023
• Rinse off cosmetic products	4	16 October 2027
• Detergents, waxes, polishes and air care products • Fertilisers • Agricultural and horticultural uses that are not plant protection products, seeds or biocides	5	16 October 2028
• Leave on cosmetic products (excluding lip, nail and make-up products) • Fragrance encapsulates used in any application • Medical devices	6	16 October 2029
• Granular infill on sports field	8	16 October 2031
• Make up, Lip and Nail leave on cosmetic products	12	16 October 2035

Note:
Make-up Lip and Nail products, from 17 October 2031 such products must be labelled 'Contains Microplastics' if they contain SPM.
Products already on the market at that date do not have the obligation until December 17th, 2031.

7. PLACING ON THE MARKET

- The ban applies to the placing of SPM as substances on their own or in mixture on the market.
- Please note, the definition of "placing on the market" is different in REACH compared to the European Cosmetic Product Regulation.

Key points to note:

- NB ban of 'Placing on the market' under REACH means that is it forbidden by this date to make available product on the market that do not comply with the requirements. It is forbidden to introduce new products to the market, and it is also forbidden to continue selling existing products that are already on the shelves.
- This is different from the Cosmetics Regulation where there is usually a sell through period.

8. PARAGRAPH 7 – INFORMATION REQUIREMENTS

- From 17 October 2025, suppliers of SPM derogated under §4(a) will provide to industrial downstream user - DU the following:
    - Instruction for use and disposal for downstream user explaining how to avoid releases into the environment
    - SPM statement (SPM supplied in accordance with the Restriction)
    - The quantity or concentration of SPM in the substance or mixture supplied
    - Generic identity details required to comply with reporting requirements
- Where requested manufacturers, importers and industrial downstream users of products containing synthetic polymer microparticles shall according to §14 t provide detailed information on solubility and/or biodegradation. If the information is not available to industrial downstream users, they shall request it from their supplier within 7 days from the receipt of the request from the competent authorities and shall inform the authorities of the request made without delay.

Key points to note:

- Information can be provided on the Safety Data Sheet - SDS
- How to identify the SPM is contained in the product for the purpose of reporting is not specified by the restriction.
- Ingredients suppliers will provide the generic data **(see section 10 and 11)**.

9. PARAGRAPHS 5 AND 8 - INSTRUCTIONS FOR USE AND DISPOSAL (IFUD)

- All products containing SPM using a derogation under paragraph 5(a-c) must provide Instructions for Use and Disposal (IFUD)
- The purpose of the IFUD is to prevent the release of unmodified particles into the environment. In the case of cosmetics, their normal intended use will lead to permanent modification, and therefore CE's interpretation is that Instructions for *Use* are not required. Instructions for Disposal would apply to prevent the release of unmodified SPM in unused product residues.
- Cosmetics Europe recommends that IFUD should consist of the message '*Do not rinse packaging before disposal ',* using the sentence or the following pictogram:

Key points to note:

- IFUD do not need to be added to sealed packaging such as aerosols where there is no possibility of the consumer accessing the residue
- The pictogram or the sentence can be on secondary or primary packaging, or the package leaflet
- The pictogram or the sentence should appear in the area where the other 'end of life' information is communicated. It can be supplemented (but not replaced) by digital means. At this stage this is a CE Recommendation only and has not been formally endorsed by the Commission

10. PARAGRAPH 11 AND 12 - REPORTING REQUIREMENTS

- The data that needs to be provided depends on the derogation you are using for your product:

Derogation Paragraph	Description	First reporting deadline	Data required for submission
4(a)	Use of SPM at industrial sites as a substance or in a mixture	31 May 2027	• Uses of SPM in previous calendar year • Generic information on identity • For each use estimate of releases to the environment (including transportation) • Reference to 4(a) derogation
5(a)	SPM contained by technical means	31 May 2027	• Description of end uses • Generic information on identity • Estimate of releases for each end use • Reference to applicable derogation
5(b)	SPM physical properties permanently modified in use		
5(c)	SPM is permanently incorporated into a solid matrix		

Key points to note:

- Reporting to ECHA is mandatory annually and must be submitted by 31 May each year
- NB if making plastics using pellets, powders or flakes, reporting starts from 2026. Data requirements are as per paragraph 4(a)

11. PARAGRAPHS 13 & 14 – PROVISION OF ADDITIONAL SPM IDENTIFIERS TO ENFORCING AUTHORITIES

- ECHA will provide all data submitted in line with Paragraphs 11 and 12 to national authorities.
- National authorities will be responsible for enforcement of the Restriction within its own country
- National regulatory authorities may request additional SPM identifiers, in addition to what has been provided in accordance with paragraphs 11 and 12, of any SPM placed on the market at any point in the supply chain during yearly reporting.

Key points to note:

- Available information must be provided to the regulatory authorities within 30 days of receiving the request.
- In case requested information is not available, request must be forwarded upstream to the supplier within 7 days, and in parallel, the competent authority must be informed of this.
- When the data request is received by a downstream user, the SPM manufacturer can provide data to the downstream user or directly to the regulatory authorities
- Data endpoints that may be required will be:
    - Name
    - IUPAC Name
    - Other name (usual name, trade name, abbreviation)
    - EC Number or number assigned by ECHA(*)
    - CAS Name(*)
    - CAS number(*)
    - Other identity code, such as customs number(*)
    - Molecular formula
    - Structural formula (including SMILES is available) or crystal structure(*)
    - Optical activity and typical ratio of (stereo) isomers(*)
    - Molecular weight or molecular weight range
    - Qualitative analytical data – UV-VIS, IR, NMR, MS or diffraction data
    - Quantitative analytical data – chromatographic, titrimetric, elemental analysis or diffraction data
    - Description of analytical methods
    - Experimental protocols
    - Relevant interpretation of the results

    (*) if available / appropriate

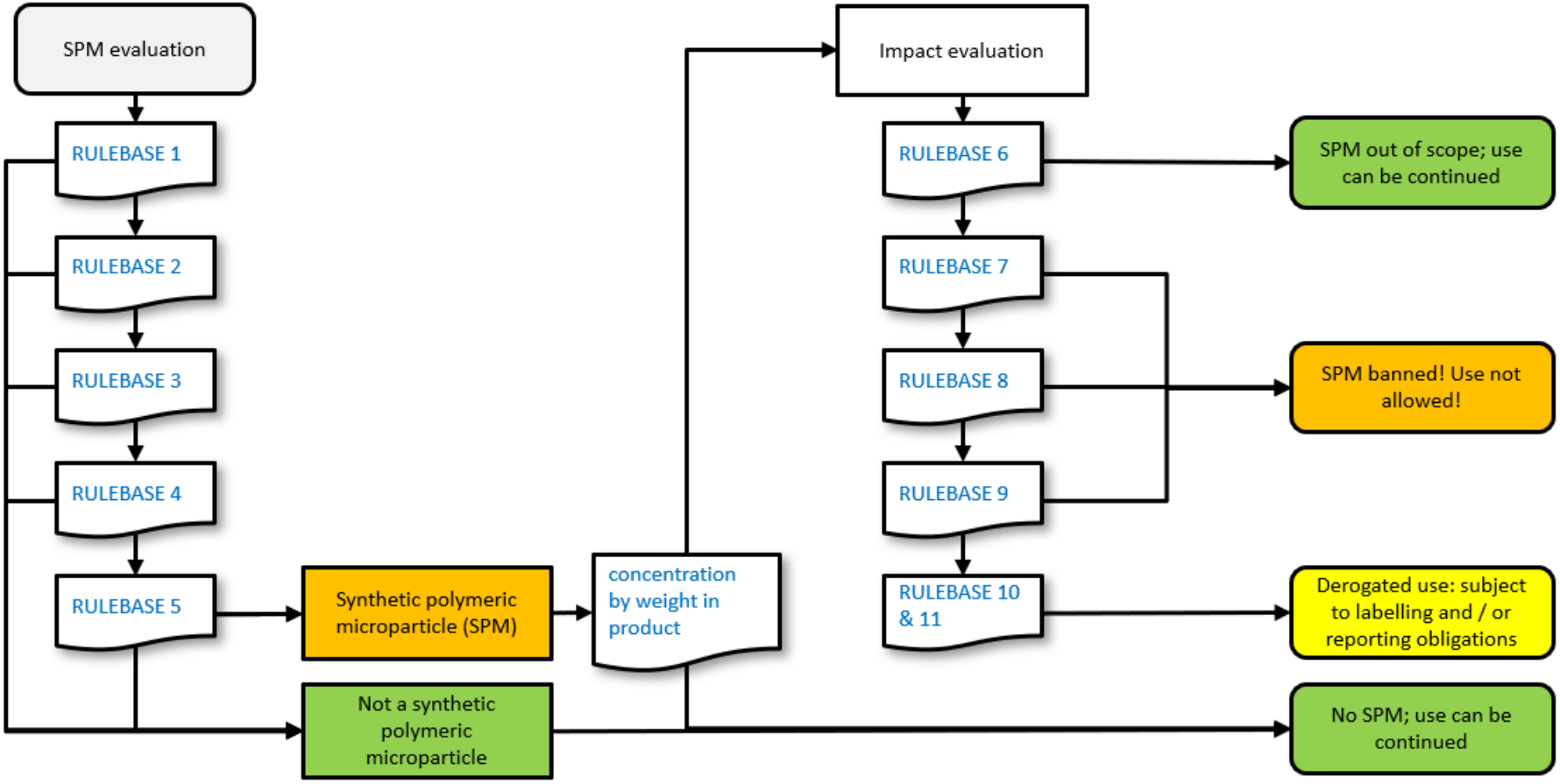
12. PARAGRAPH 15 – DEMONSTRATION OF COMPLIANCE WITH EXEMPTION CRITERIA – SECTION 2

- Where SPM fall out of scope of this restriction due to their biodegradability or solubility, regulatory authorities can request supporting reports according to the methodologies cited as reference in appendix of the restriction.
- Data must be provided without undue delay.

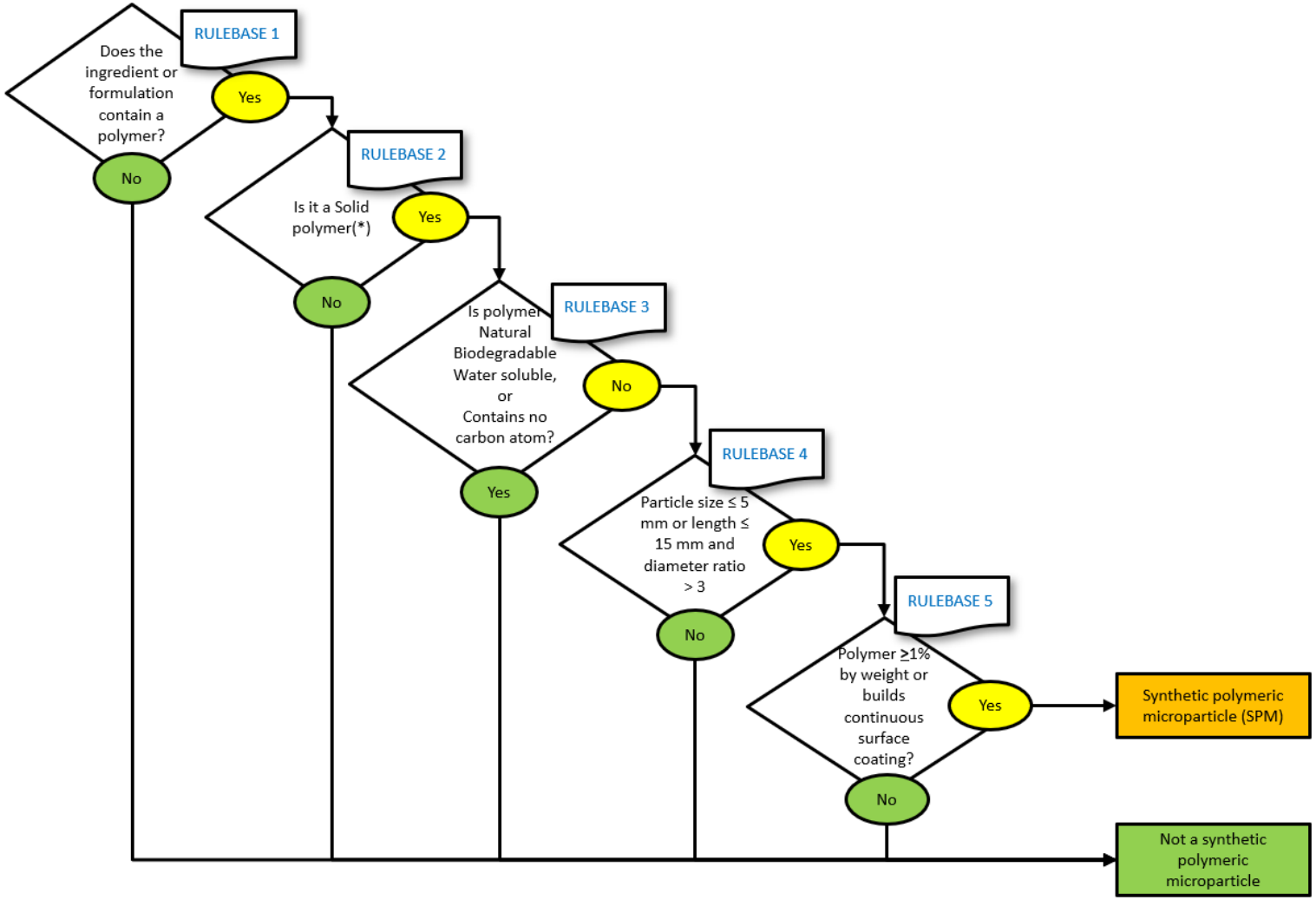
Key points to note:

- Literature data should be validated and may not be sufficient when cited without an approved method origin.

How to decide if your polymer is a synthetic polymer microparticle (SPM)



Is the ingredient a synthetic polymer microparticle (SPM) or does the formulation contain a synthetic polymer microparticle (SPM)?



RULEBASE 1 – DOES MY INGREDIENT OR FORMULATION CONTAIN A POLYMER?

The first question in the flow chart addresses whether or not polymers are present in our ingredient or formulation:

- If yes, you need to move to the next section of the flow chart to understand if the polymer meets the criteria laid out in the Restriction
- If no, then your ingredient or formulation is out of scope of the Restriction – no further action is required

Please note: ECHA's preferred analytical method for determining whether a substance is a polymer or not is GPC as per section 4 of the ECHA Guidance on Monomers and Polymers (v.3, February 2023).

Not all polymers are classified as Synthetic Polymer Microparticles (SPM). Only polymers meeting the specific criteria laid out in the Restriction are in scope.

The next four steps in the flowchart will help determine if the polymer contained in the ingredient or formulation is classified as a Synthetic Polymer Microparticle (SPM).

RULEBASE 2 – IS THE POLYMER SOLID?

Solid is defined within the Restriction as "not a liquid or gas". Conditions for determining whether a material is a liquid or gas are explicitly detailed in the Annex:

- GAS:
  - A substance or mixture which at 50 °C has a vapour pressure greater than 300 kPa (absolute), or is completely gaseous at 20 °C at a standard pressure of 101,3 kPa;
- LIQUID:
  - A substance or mixture that meets any of the following conditions:
    i. The substance or mixture at 50 °C has a vapour pressure of not more than 300 kPa, is not completely gaseous at 20 °C and at a standard pressure of 101,3 kPa, and has a melting point or initial melting point of 20 °C or less at a standard pressure of 101,3 kPa;
    ii. The substance or mixture fulfils the criteria in the American Society for Testing and Materials (ASTM) D 4359-90 Standard Test Method for Determining Whether a Material Is a Liquid or a Solid;
    iii. The substance or mixture passes the alternative fluidity test (penetrometer test) described in chapter 2.3.4 of Part 2 of Annex A to the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) concluded at Geneva on 30 September 1957;

If your polymer meets the definition of a liquid or gas it is out of scope of the Restriction

- SUSPENSION / DISPERSION / MIXTURE:
  - Some substances are in solid form – need to determine if the polymer is in liquid or solid form
    - Test methods to do this are not specified in the Restriction – it is at the discretion of industry to determine a scientifically credible methodology

Points for further deliberation / agreement moving forward:

Determination of physical state of polymers in suspensions / dispersions / mixtures:

- Industry to agree methodologies to determine if the polymer is in a solid state (cf. Ch 5)

RULEBASE 3 - SUBSTANCES OUTSIDE THE SCOPE OF THE BAN

1. Natural Polymers

The term "natural polymer" is defined in the Restriction as a substance:

- Where polymerisation took place in nature (before extraction occurred)
- That is not chemically modified

The Restriction does not contain guidance on what is meant by "extraction" or "chemical modification". However, EU REACH contains definitions for the following terms:

- Substances that occur in nature (i.e. natural substances)
  - a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means;
- Not chemically modified substance:
  - 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

In the EU Restriction, substances that occur in nature, are described slightly differently:

- 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;

Points for further deliberation / agreement moving forward:

Determination of how to interpret the potentially different definitions:

- Develop common understanding of methods of extraction are permitted under the Restriction
- Polymers obtained by fermentation (a biotechnology process) are currently not considered natural polymers, since they are subject to registration under REACH (per ECHA (2012) Guidance for Annex V Exemptions from the obligation to register, page 18[1])

[1] https://echa.europa.eu/documents/10162/2324906/annex_v_en.pdf/8db56598-f7b7-41ba-91df-c55f9f626545

2. Water soluble polymers

Water soluble polymers are defined as polymers with a water solubility of >2g/L.
Appendix 16 of the Restriction details specific test guidelines, test conditions and pass criteria that must be followed to prove solubility in water:

Permitted test methods	Test conditions	Pass criteria
OECD 105 OECD 120	○ Temperature – 20°C ○ pH – 7 ○ Loading – 10g/1000ml ○ Test time – 24 hours	>2g/L

Key points to note:

- Tests must be performed by labs compliant with GLP, ISO 17025 or other international standards accepted by ECHA
  - Currently GLP is not a requirement for some phys-chem endpoints under EU REACH, including water solubility
- Testing should be carried out on material comparable in terms of composition, form, size and surface area to the polymer particle present in the product.

- If this isn't technically feasible to test the particle, a test can be performed on the polymer itself
- Authorities can request information proving that those polymers are soluble in accordance with Appendix 16 without delay.
- Literature data should be validated and may not be sufficient when cited without an approved method origin

3. Polymers without carbon atoms in their structure

Polymers that do not contain carbon atoms are out of scope of this Restriction

4. Biodegradable Polymers

Polymers that are biodegradable are not in scope of the Restriction. The exact methodologies, test conditions and pass criteria are detailed in Annex 15 of the Restriction.

The test methodologies permitted have been grouped together based on their ultimate endpoint. There are 5 groups in total. **If performing tests from groups 4 and 5, the polymer must pass a test in each of the 3 compartments to be considered out of scope.**

A summary of the test methods permitted, the groups they belong to and the pass criteria are show in the table below:

Group #	Permitted test methods	Test duration	Pass criteria	# tests required to be out of scope
1	OECD 301B OECD 301C OECD 301D OECD 301F OECD 310	28d	60%	1
2	OECD 301B OECD 301C OECD 301D OECD 301F OECD 310 OECD 306	28 – 60d	60%	1
3	OECD 302C	14d	≥70%	1
4	EN ISO 14852:2021 EN ISO 14851:2019 EN ISO 19679:2020 EN ISO 18830:2016 EN ISO 17556:2019 ISO 22404:2019	1. Aquatic – 6mo 2. Soil – 24mo 3. Sediment – 24mo, or; Water/sediment – 24mo	≥90%	3 – one from each compartment
5	OECD 307 OECD 308 OECD 309	1. Water – <60d 2. Sediment – <180d 3. Soil <180d	Degradation half life	3 – one from each compartment

Note: this table is a summary only. For full details on specific test conditions, please refer to the legal text

Key points to note - accepted test methodologies:

- OECD 301A and E are not considered acceptable test methods
- OECD 302C pass criteria has been modified – testing period is **14 days** (not 28 as per the guideline)

Key points to note - how tests should be carried out:

- Tests must be performed by labs compliant with GLP, ISO 17025 or other international standards accepted by ECHA
- Testing should be performed under conditions that are comparable in terms of:
  - Composition, form, size and surface area in the product or,
  - If not feasible, the polymer particles as disposed of / released to the environment
- Polymers used in encapsulation 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
- Where the polymer is part of a mixture:
  - The test material contains more than one polymer
    - The test material and each polymer requires its own test; or
    - The test material can be tested as a whole as long as you can prove each of the polymers passes the criteria of the test carried out
  - The mixture contains a single polymer and non-polymeric organic components at >10%
    - The test material for the polymer requires its own test; or
    - The test material can be tested as a whole as long as you can prove each of the polymers passes the criteria of the test carried out
- Authorities can request information proving the polymers are degradable in accordance with Appendix 15 without delay.

Points for further deliberation / agreement moving forward:

Biodegradability testing capacity is limited.

- Consider the use of read-across as per EU REACH permissions
- Consider the application of interpolation principles as per EU Detergents Regulation
- Review and interpret exactly how SPM should be tested

RULEBASE 4 – PARTICLE SIZE & PARTICLE SIZE DISTRIBUTION

Particle size

For a particle to be in scope of the Restriction, **all dimensions** must be equal to or less than 5mm.
This means:

- A particle with at least one dimension >5mm is not a SPM
- If material is a solid, block it does not meet the size criteria required to define the substance or mixture as a Synthetic Polymer Microparticle (SPM) and therefore is out of scope of the Restriction

The Restriction does not specify test methods to use for particle size determination.

Section R.7.1.1.4 of the Guidance on Information Requirements and Chemical Safety Assessment[2], published by ECHA lists test methods to determine particle size measurements of solids and solids suspended in liquids. None of the methodologies listed cover the particle size range covered by this Restriction.

It is at the discretion of industry to determine a scientifically credible methodology.

Particle size distribution

The definition states that*:*

> *Synthetic polymer microparticles are 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*
>
> *Where the concentration of synthetic polymer microparticles covered by this entry cannot be determined by available analytical methods or accompanying documentation, in order to verify the compliance with the concentration limit referred to in paragraph 1, only the particles of at least the following size shall be taken into account:*
> *0,1 µm for any dimension, for particles where all dimensions are equal to or smaller than 5 mm;*
> *(b) 0,3 µm in length, for particles that have a length that is equal to or smaller than 15 mm and a length to diameter ratio greater than 3.*

Points for further deliberation / agreement moving forward:

Particle size measurement:

- Industry to agree methodologies for measurement of particle size
  - Solids
  - Solid matter in suspensions

Particle size distribution:

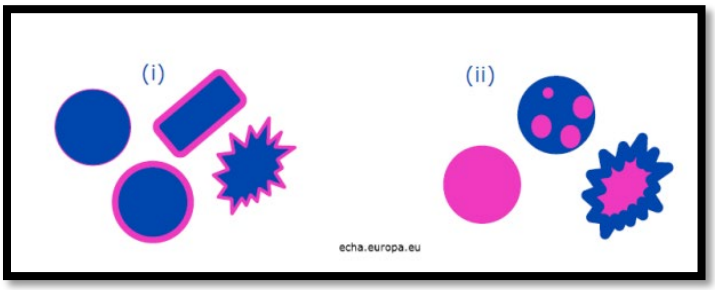
- Review the potential pitfalls of adopting the “nano approach” to particle size distribution?

[2] Guidance on Information Requirements and Chemical Safety Assessment - ECHA (europa.eu)

RULEBASE 5 - % INCLUSION AND SURFACE COATING

If the polymer **does not** meet the following criteria, it is out of scope:

- Forms a continuous surface coating of any thickness on particles or
- Present at ≥ 1% in the particle

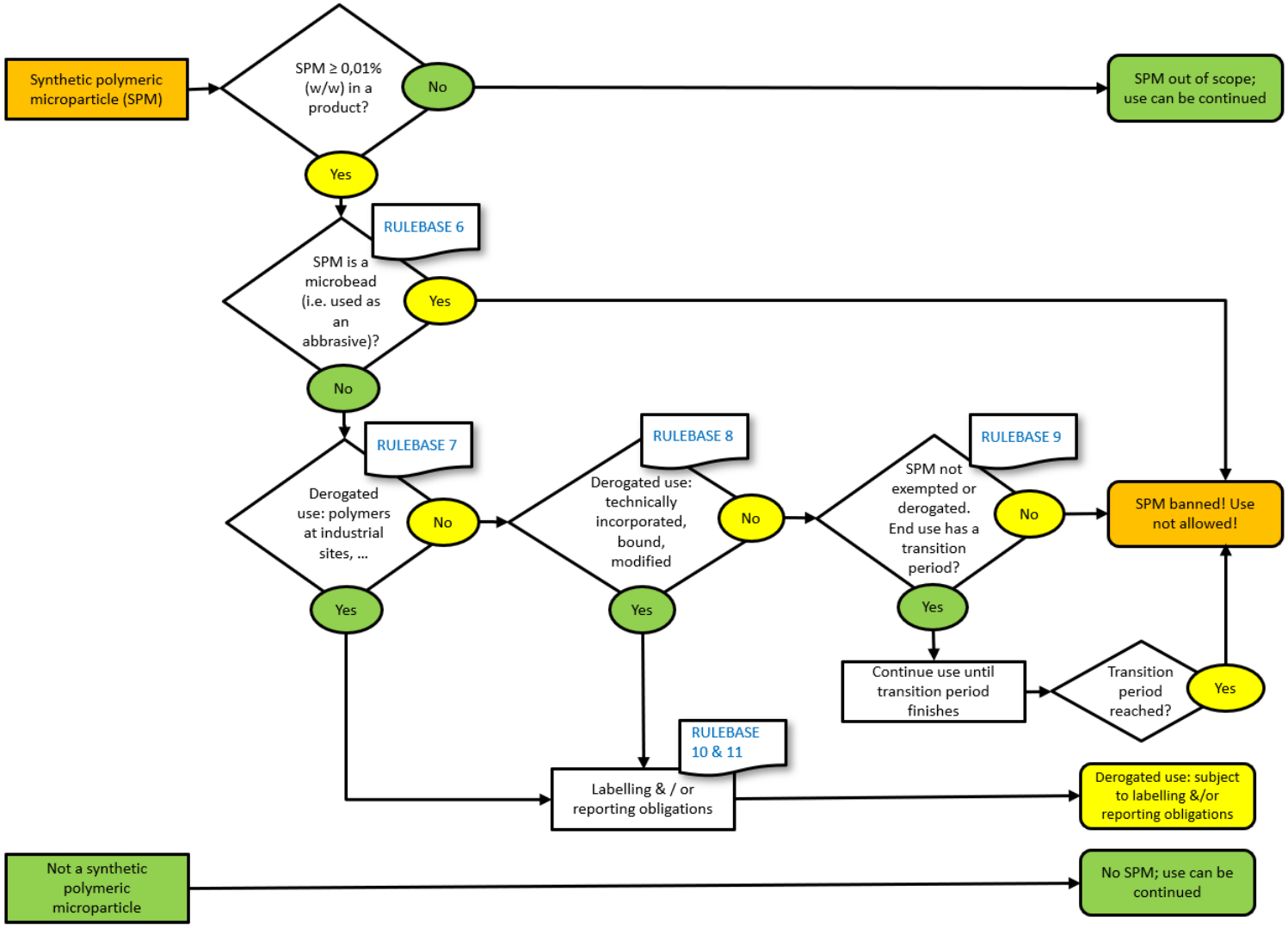


By this point in the flow chart, you will have determined whether or not you have an SPM.
The next part of the flow chart navigates the use of potential derogations.
If your product does contain a SPM, then what happens next is concentration dependent:

- If the SPM is present at less than 0.01%, you can continue to use the material and Have no further obligations
- If the SPM is present at greater than or equal to 0.01%, continued use depends on Compliance with any of the listed derogations.

The next part of the flow chart navigates through the use of potential derogations

My product contains SPM. Do any of the derogations apply?



RULEBASE 6 – IS MY SPM A MICROBEAD?

Microbeads are defined within the text of the legislation as:

- Synthetic polymer microparticles for use as an abrasive, i.e. namely to exfoliate, polish or clean, mainly used in rinse-off cosmetic products or detergents

SPM meeting this definition are already banned at >0.01%. Entry into force was 17 October 2023.

RULEBASE 7 - THE 'USE AT INDUSTRIAL SITES' DEROGATION

Companies are allowed to manufacture and use SPM in an industrial setting at ≥0.01%

However, there is an obligation for manufacturers of the SPM to report *and* to provide instructions for use and disposal to avoid release to the environment (even if the SPM loses its solid-state during formulation). Formulators can apply the IFUD given by the manufacturer, but still need to report on industrial use of SPM.

(**Note**: new instructions for use and disposal are not required if the formulation no longer contains SPM for the subsequent uses - **see Rulebases 10 and 11.)**

RULEBASE 8 – OTHER DEROGATED USES

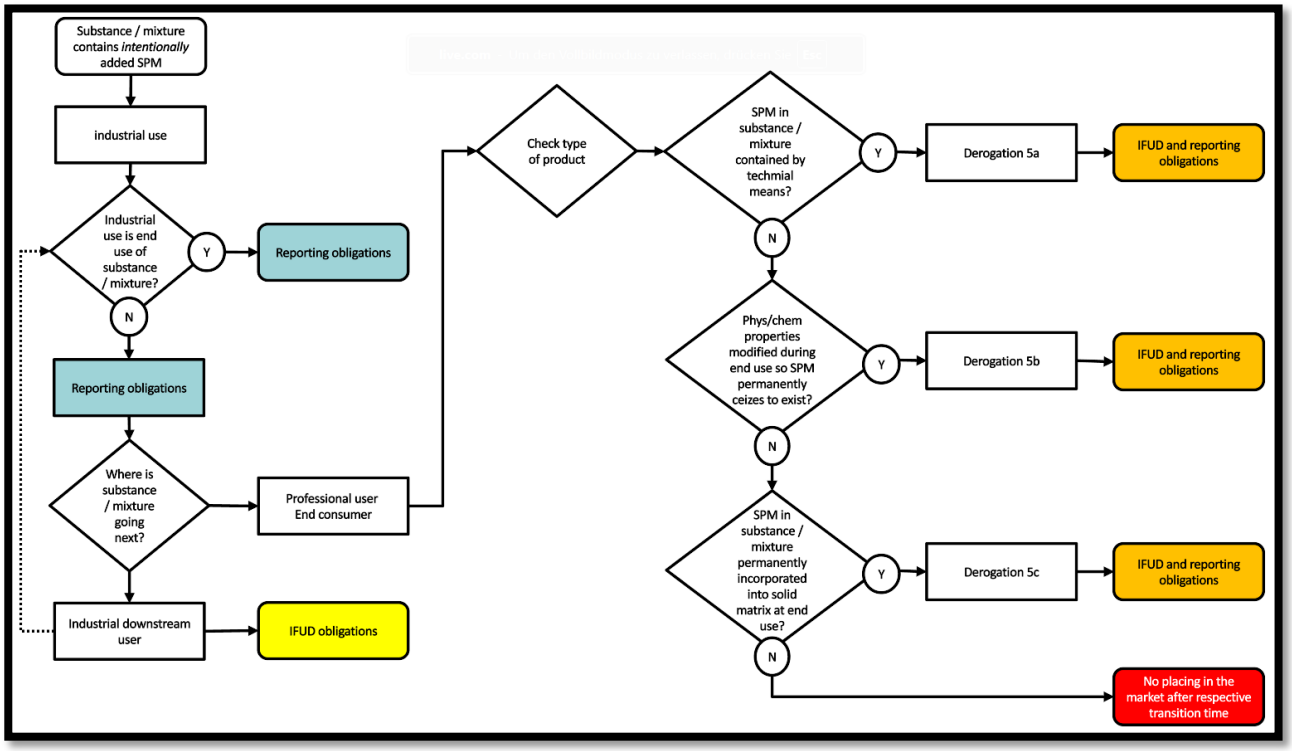
Derogated end uses allow the use of an SPM at ≥0.01% and apply to the SPM as it enters the environment.

There are derogations for 3 different scenarios listed in the Annex to the Restriction:

- If during end use there is no release of the SPM to the environment due to containment by technical means (paragraph 5a)
- If during the use of the product by the consumer the physical properties of the SPM change so it no longer meets the definition of SPM (paragraph 5b)
    - i.e. the SPM is no longer a solid, or is >5mm in at least one dimension etc.
    - An example of this could be an SPM that forms a film in use or a swellable polymer that changes its size and shape in use.
- If during use the SPM are incorporated into permanent solid matrix (paragraph 5c)

Under the current proposal, these products need to be labelled with Instructions for Use and Disposal - **see Rulebases 10 and 11**.

Following flow chart should help to make this more transparent:



Key points to note:

- Test methodologies to demonstrate physical properties of the SPM have been permanently modified are not listed in the Restriction.
- It is at the discretion of industry to determine a scientifically credible methodology

Points for further deliberation / agreement moving forward:

Proving physical state properties of the SPM are modified:

- Industry to agree methodologies to demonstrate modification of physical properties for the following applications / scenarios
    - Film formers
    - Swellable polymers
    - SPM dissolution in solvents other than water
    - SPM melting
    - Others?

RULEBASE 9 – TRANSITION TIMES

If an SPM is neither out of scope nor falls under a derogated use, then ultimately, use will be restricted to less than 0.01% by weight.

Paragraph 6 of the Annex to the legal text details the number of years after which the use of SPM at >0.01% will be banned based on intended application. These are referred to as transition periods.

Transition periods are as follows:

APPLICATION	# YEARS IN TRANSITION PERIOD	TRANSITION PERIOD END DATE
• Microbeads used in any application	0	16 October 2023
• Rinse off cosmetic products	4	16 October 2027
• Detergents, waxes, polishes and air care products • Fertilisers	5	16 October 2028
• Leave on cosmetic products (excluding lip, nail and make-up applications) • Fragrance encapsulates used in any application • Medical devices	6	16 October 2029
• Agricultural and horticultural uses that are not plant protection products, seeds or biocides • Granular infill on sports field	8	16 October 2031
• Make up, Lip and Nail leave on cosmetic products	12	16 October 2035

Note that for Make-up Lip and Nail products, from 17 October 2031 such products must be labelled 'Contains Microplastics' if they contain SPM.

RULEBASE 10 – LABELLING OBLIGATIONS

The exact labelling obligations are dependent on who is going to use the substance or mixture containing the SPM:

- Workers at an industrial site
- Professional users or consumers

Workers at an industrial site:

From 17 October 2025, suppliers of SPM will provide the following:

- Instruction for use and disposal for industrial downstream user explaining how to avoid releases into the environment
- SPM statement
- The quantity or concentration of SPM
- Generic identity details required to comply with reporting requirements

How to identify the SPM for the purpose of reporting is not specified. However, Paragraph 14 of the Restriction does highlight additional information that could be requested by the authorities – **see section 10 of The Key elements of the Restriction for the Cosmetics industry**.

Ingredients suppliers will provide downstream users with the following generic data:

- Name
- EC Number or number assigned by ECHA
- CAS Name
- CAS number

Information can be provided on the MSDS, primary or secondary packaging.

Professional users or consumers:

Cosmetics Europe recommends that Instructions for use and disposal (IFUD) should consist of the message '*Do not rinse packaging before disposal',* using the following pictogram:

Key points to note:

- IFUD do not need to be added to sealed packaging such as aerosols where there is no possibility of the consumer accessing the residue.
- The pictogram can be on secondary or primary packaging, or the package leaflet
- The pictogram should appear in the area where the other 'end of life' information is communicated
- It can be supplemented (but not replaced) by digital means
- This is a CE recommendation only

RULEBASE 11 – REPORTING OBLGATIONS

If the SPM you are using falls under one of the derogations contained in the legal text, you are allowed to use it at >0.01% in your product, but you will have reporting and / or labelling obligations.

The data that needs to be provided depends on the derogation you are using for your product:

Derogation Paragraph	Description	First reporting deadline	Data required for submission
4(a)	Use of SPM at industrial sites as a substance or in a mixture	31 May 2027	• Uses of SPM in previous calendar year • Generic information on identity • For each use estimate of environmental releases (including transportation) • Reference to 4(a) derogation
5(a)	SPM contained by technical means	31 May 2027	• Description of end uses • Generic information on identity • Estimate of environmental releases for each end use(including transportation) • Reference to applicable derogation
5(b)	SPM physical properties permanently modified in use		
5(c)	SPM is permanently incorporated into a solid matrix		

Some key points to note include:

- Reporting to ECHA is mandatory annually and must be submitted by 31 May each year
- **Please note:** if making plastics using pellets, powders or flakes, reporting starts from 2026. Data requirements are as per paragraph 4(a)

Frequently Asked Questions

1. Who determines if a raw material is an SPM?

Both raw material manufacturers and downstream users of the SPM have a role to play in the assessing if a raw material is an SPM.

Whilst raw material manufacturers will be able to confirm polymeric status, water solubility, degradation of the polymer as supplied and / or particle size, the Restriction focuses on end use of the SPM. Derogations require a knowledge of how the SPM behaves within the formulation and when used by the consumer. This knowledge lies with the downstream user.

It is likely raw material suppliers and downstream users will be required to work closely together to answer this question.

2. Is the statement on physical state and solubility in a substance SDS (ch 9.1) and on biodegradability (ch 12) sufficient to exclude a polymer from the SPM restriction?

Yes, statement is sufficient in case a dedicated / approved method is given (according to the restriction annex 15 and 16). The downstream user may request for detail / confirmation on the test method.
It remains the responsibility of the SDS provider in case of authority requests to send proof of a GLP test.

3. Is a list of INCI names available for SPMs which are covered by Restriction?

No such list is available

4. Who determines if derogation 4a or 5b applies?

Derogation 4(a) refers to use of SPM at industrial sites, whereas derogation 5(b) refers to the changing of physical properties at the time of use.

For derogation 4(a), use at an industrial site can be >0.01%.

However, when as part of derogation 4(a) and 5(b), the SPM ceases to meet the definition of SPM, it is the responsibility of the user/formulator to prove compliance with these derogations. For example, where a SPM loses its defined character during the formulation and ceases to exist in the end-product, the final formulation does not contain SPMs and the formulation process therefore bring former SPMs out of the scope of the restriction. In this case only derogation §4(a) applies.
Guidance on how a SPM behaves in formulation may be available from the raw material supplier. However, how the molecule behaves in the formulation and at the point of end use is influenced by the formulation itself. Formulations are varied by the ingredients they contain, which in turn influences the properties of the formulation and could in turn impact how the SPM behaves in the formulation.

5. What if a polymer is sold in a solvent other than water and neither the state of the polymer itself (solid or not) nor the solubility in water is known.

If the polymer is solubilised in the solvent when sold, and as a result of solubilisation, the polymer is a liquid, it would be outside the scope of the Restriction.

However, it is important to understand what happens to the polymer in formulation to ensure there are no implications under the Restriction. The further work proposed on analytical methods to determine the physical form of the polymer in formulation will be useful in determining the physical state of the polymer after solubilisation in the solvent.

6. Are Acrylates used as rheology modifier derogated under paragraph 5(b)?
Example: An Acrylate which is solid as a raw material is given into water at 1%. The resulting pH is 2.5-3 (info from MSDS). If adjusted to pH7 with NaOH, a gel network is formed, and the phase thickens.

Not all acrylates are classified as SPM. Only acrylates meeting the specific criteria laid out in the restriction are in scope. If in the scope, derogation 4a will apply and the forming of a gel during formulation would come along with the change of the particulate state of the SPM (for example seen by microscopy). As the phys./chem. properties changes during formulation and the final product does not contain SPM it is therefore out of scope in its end use.

If the gel is formed during consumer use, on nails for example, derogation 5b would apply. Prerequisite is, that the gel remains stable when applied.

7. Are coated particles in scope?

Coated particles (<5mm) are in scope if they:

- if the polymer forms a solid continuous surface coating of any thickness or,
- Contain ≥1% of a solid polymer

What about polymer coated inorganic particles, where liquid polymer is not covalently bound to the inorganic particle? à to answer this question, some more details are required for better understanding. As soon as these details are clarified, we can provide an answer here.

8. How is double Reporting avoided?

The text of the Restriction states it is the responsibility of the first actor in the supply chain to report data to avoid double reporting. The term "actors in the supply chain" not defined in the Restriction. It is however, defined in the text of EU REACH Regulation as:

All manufacturers and/or importers and/or downstream users in a supply chain;

If the SPM is manufactured in the EU, then this manufacturer is arguably the first actor in the supply chain. If they were to report all uses, it would require downstream users to report their uses to the manufacturer.

This notion is not totally alien in REACH, as downstream users today are required to notify Process Categories (PROCS), and Environmental Release Categories (ERCS) applicable to their uses to the manufacturer.

However, Paragraphs 11 and 12 state all manufacturers and industrial users must report their release to the environment, and for professional and consumer uses, release to the environment must be estimated by the product manufacturer. More clarification on how this will work in practice is required here.

9. Are hydrocarbon waxes in scope if in particle size range?

If in the particle size range for inclusion in the Restriction, the wax would also need to meet the definition of "polymer" and "solid" to be in scope of the Restriction. "Solid" means a substance or mixture other than a liquid or gas according to the legal text.

10. Are there reporting obligations for products with transition periods?

Yes, for SPM used at industrial sites, and for SPM used in derogated products the first reporting deadline is 31 May 2027.

To note: Reporting for SPM containing products derogated under paragraph 5 starts in 2027. **This applies to products placed on the market for the first time**. This can be interpreted as reporting is only required for "new" products offered the previous year. However, ECHA's intentions are clear – they would like a full overview of what is placed on the market, and therefore it is possible that the legal text will change in the future. The first reporting deadline is 31 May 2027.

11. Are there IFUD obligations under derogation 5(b) for products with transition periods?

This has been debated and there is some uncertainty about the practical benefit of this labelling but the current view of the EU Com is that the IFUD obligations still apply .

12. Is there a threshold limit in quantity for reporting of SPM?

No. There is no volume threshold limit specified in the Restriction that triggers reporting obligations.

13. How should products containing glitter be treated?

The EU Commission has provided guidance on this question: https://single-market-economy.ec.europa.eu/commission-regulation-eu-2023205-restriction-microplastics-intentionally-added-products_en

14. What are the reporting obligations under Paragraph 11 and 12 if a product is manufactured e.g. by a third-party manufacturer) outside of the EU?

Under REACh, importing is regarded as placing on the market. Based on this, the first use at an industrial site has the reporting and / or labelling obligations.

If the SPM fall under one of the derogations in paragraph 5 and is imported as part of a finished formulation for use at an industrial site, under paragraph 12, the responsible person placing the product on the market would be responsible for complying with reporting obligations.

15. Does a glitter containing peel-off mask (or other SPM containing masks) which must be peeled off after 20 minutes and is usually disposed of in the residual waste fall under §5(b) or 5(c) ?

SPM only fall under §5(b) if they lose their particulate form. Glitter remain SPM in the product and is usually not ceasing to exist as such. It is not derogated under §5(c) either, because cosmetic uses are not permanent. Therefore, there is no derogation of such products and is banned after its transition period.

16. **Will products containing non-derogated SPMs be exempted from labelling and reporting during the transition period, i.e. before they are banned?**

If SPM is not derogated IFUD and reporting is not necessary. Note that non-derogated SPMs are banned as the transition period ends.

Areas for further work

There are some areas of the Restriction that require further consideration for us to develop mutually agreed guidance. These are:

- **Test methods to determine the physical state of polymers in particles / suspensions / dispersions / mixtures / solvents other than water**
  - Industry to share knowledge and agree on a set of scientifically suitable test methodologies where possible.

- **Definition of "natural"**
  - Agree common interpretation on what extraction methods are permitted for the extraction of natural polymers
    - Compare wording of the main text of REACH with that of the restriction

- **Biodegradability**
  - The wording of Appendix 15 paragraph 3 is complex
    - Industry to review and determine exactly what needs to be tested to ensure compliance with the Restriction
    - Particular attention to be given to "The degradation of the test material and the polymer(s) need testing separately" and testing at "in use" conditions
  - Biodegradability testing capacity is limited.
    - Consider the use of read-across as per EU REACH permissions
    - Consider the application of interpolation principles as per EU Detergents Regulation

- **Test methods to determine particle size and particle size distribution**
  - Industry to share knowledge and agree on a set of scientifically suitable test methodologies where possible for:
    - Solids
    - Solid matter in suspensions
  - Industry to investigate the potential for adopting a particle size distribution cut-off level, e.g. nanomaterials. What are the potential pitfalls of adopting such an approach?

- **Test methods to demonstrate compliance with Paragraph 4a and 5a-c derogations**
  - Industry to share knowledge and agree methodologies to demonstrate modification of physical properties for the following applications / scenarios
    - Film formers
    - Swellable polymers
    - SPM dissolution
    - SPM melting
    - Others?

- **Process for avoiding double reporting**
  - Industry to review how double reporting can be avoided when applying derogations given paragraphs 11 and 12 require reporting of the same figures by different actors in the supply chain

Appendix 1 – Assessment Template

This template is designed to record decisions made throughout the SPM assessment process. The final assessment will require input from both the SPM manufacturer and those who use the SPM in the manufacture of other goods. This template is intended to capture all decisions in a single form.

An intuitive assessment template has been developed using the free version of Microsoft Forms.
A copy is available from the EFfCI and Cosmetics Europe SharePoint page to be used within companies.

Appendix 2 – Link to legal text

Please see below link to the official legal text:

https://eur-lex.europa.eu/eli/reg/2023/2055/oj

Appendix 3 - Definitions and Abbreviations

Descriptor	Definition	Source
Actor in the supply chain	All manufacturers and/or importers and/or downstream users in a supply chain;	**Commission Regulation (EC) 1907/2006** EU REACH Article 3
Downstream user	Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user	**Commission Regulation (EC) 1907/2006** EU REACH Article 3 Based on definition of “Downstream user”
Gas	A substance or mixture which at 50 °C has a vapour pressure greater than 300 kPa (absolute), or is completely gaseous at 20 °C at a standard pressure of 101,3 kPa;	**Commission Regulation (EU) 2023/2055** Annex XVII restriction on synthetic polymer microparticles under EU REACH Annex: Paragraph 2(c)
Instructions for use and disposal	Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user	**Commission Regulation (EC) 1907/2006** EU REACH Article 3 Based on definition of “substances occurring in nature”
Liquid	A substance or mixture that meets any of the following conditions: (i) the substance or mixture at 50 °C has a vapour pressure of not more than 300 kPa, is not completely gaseous at 20 °C and at a standard pressure of 101,3 kPa, and has a melting point or initial melting point of 20 °C or less at a standard pressure of 101,3 kPa; (ii) the substance or mixture fulfils the criteria in the American Society for Testing and Materials (ASTM) D 4359-90 Standard Test Method for Determining Whether a Material Is a Liquid or a Solid; (iii) the substance or mixture passes the fluidity test (penetrometer test) described in chapter 2.3.4 of Part 2 of Annex A to the European Agreement concerning the	**Commission Regulation (EU) 2023/2055** Annex XVII restriction on synthetic polymer microparticles under EU REACH Annex: Paragraph 2(d)

	International Carriage of Dangerous Goods by Road (ADR) concluded at Geneva on 30 September 1957;	
Make-up product	Any substance or mixture intended to be placed in contact with specific external parts of the human body, namely the epidermis, eye brows and eye lashes, with a view to, exclusively or mainly, changing their appearance;	**Commission Regulation (EU) 2023/2055** Annex XVII restriction on synthetic polymer microparticles under EU REACH Annex: Paragraph 2(e)
Microbead	Synthetic polymer microparticles for use as an abrasive, i.e. namely to exfoliate, polish or clean, mainly used in rinse-off cosmetic products or detergents	**Commission Regulation (EU) 2023/2055** Annex XVII restriction on synthetic polymer microparticles under EU REACH Paragraph 21
Nanomaterial	A natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the following conditions: (a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm; (b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm; (c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm. In the determination of the particle number-based size distribution, particles with at least two orthogonal external dimensions larger than 100 µm need not be considered. However, a material with a specific surface area by volume of < 6 m2 /cm3 shall not be considered a nanomaterial. The following definitions apply in the context of the above: (a)‘particle’ means a minute piece of matter with defined physical boundaries; single molecules are not considered ‘particles’; (b) ‘aggregate’ means a particle comprising of strongly bound or fused particles;	**Commission Recommendation (2022/C 229/01)** 10 June 2022 - the definition of nanomaterial

	(c) 'agglomerate' means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components.	
Natural polymer	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 and not chemically modified substances	**Commission Regulation (EU) 2023/2055** Annex XVII restriction on synthetic polymer microparticles under EU REACH Annex: Entry 78 **https://echa.europa.eu/-/guidance-for-monomers-and-polymers** **(page 19 - point 3.2.1.3 Case of a natural polymer or a chemically modified natural polymer)**
Natural	A naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means	**Commission Regulation (EC) 1907/2006** EU REACH Article 3 Based on definition of "substances occurring in nature"
Not chemically modified	A substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities	**Commission Regulation (EC) 1907/2006** EU REACH Article 3 Based on definition of "not chemically modified substance"
Particle	A minute piece of matter, other than single molecules, with defined physical boundaries	**Commission Regulation (EU) 2023/2055** Annex XVII restriction on synthetic polymer microparticles under EU REACH Annex: Paragraph 2(a)
Placing on the market	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; Please note that the SPM restriction is a REACh related regulation, in contrast to the Cosmetic Products regulation: Article 3.12 of REACH defines the 'placing on the market' as [supplying or making available whether in return for payment or free of charge, to a third party" or importing within the customs territory of the EU.] It does not distinguish	**Commission Regulation (EC) 1907/2006** EU REACH Article 3 Based on definition of "placing on the market" Cosmetics Products Regulation 1223/2009 Article 2g and 2h Placing on the market

	between the "first" supply and the subsequent making available on the market of the substances and mixtures. One substance as such or in mixture could therefore be placed on the market in the sense of REACH several times within the same supply chain, i.e., anytime. At the due date of ban, substance, which already left the factory and are in the hands of distributors, could no longer be lawfully sold. The cosmetics Products Regulation 1223/2009 defines in articles 2.g and 2.h, the 'placing on the market' as the ["first making available of a cosmetic product on the [EU] market"] by opposition to the subsequent 'making available', i.e., the "supply of a cosmetic product for distribution, consumption or use on the [EU] market in the course of a commercial activity, whether in return for payment or free of charge".	
Polymer	A substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following: (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; (b) less than a simple weight majority of molecules of the same molecular weight. In the context of this definition a 'monomer unit' means the reacted form of a monomer substance in a polymer;	**Commission Regulation (EC) 1907/2006** EU REACH Article 3 Based on definition of "Polymer"
Solid	A substance or mixture other than a liquid or gas	**Commission Regulation (EU) 2023/2055** Annex XVII restriction on synthetic polymer microparticles under EU REACH Annex: Paragraph 2(e)
Synthetic Polymer Microparticle	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;	**Commission Regulation (EU) 2023/2055** Annex XVII restriction on synthetic polymer microparticles under EU REACH Annex: Entry 78

	(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.	

Abbreviations:

IFUD – Instructions for use and disposal

SPM – Synthetic polymer microparticle