Internal

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HelpNet Borderline Working Group Assessments of borderline cases from the Explanatory Guide Part III, Annex 3

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

General

The European Commission has published on 1 April 2025 an <u>Explanatory Guide</u> to help stakeholders and Member States implement the microplastics restriction under the REACH Regulation, called "*REACH restriction of synthetic polymer microparticles (Entry 78 of Annex XVII REACH, as introduced by Commission Regulation (EU) 2023/2055) – Explanatory Guide – Version 1".*

The 'Annex 3 – Borderline cases' of Part III of that Explanatory Guide contains a number of specific product examples where under the column 'In the scope/Out of the scope of the restriction' of the Table under section 3.1 of that Annex the following is mentioned: "This case is being assessed according to Chapter 2 of the ECHA guidance on requirements for substances in articles. The conclusions will be included here once available."

Future versions of the Explanatory Guide will be developed and published by ECHA.1

The HelpNet Borderline Working Group (BWG) agreed to prioritise the abovementioned cases for assessment, considering the number of questions received by the NHDs. Furthermore, the conclusions of those assessments may be used by ECHA to update the Explanatory Guide in the future.

This document, prepared at the intention of the National Helpdesks and National Enforcement Authorities, details the assessments and conclusions agreed upon by members of the Borderline Working Group for these specific cases as described in the Explanatory Guide.

¹ As stated in European Commission webpage on 'Commission Regulation (EU) 2023/2055 - Restriction of microplastics intentionally added to products': <a href="https://single-market-economy.ec.europa.eu/sectors/chemicals/reach/restrictions/commission-regulation-eu-20232055-restriction-microplastics-intentionally-added-products_en_added-products_en_added-products_en_added-products_en_added_products_en_adde



Table of Contents

1.	Objects covered with synthetic fibres, regenerated natural fibres, and natural fibres: A3.6 Fake fur on plush/stuffed toys; A3.23 Flock-coated products (flocked hangers, etc); A3.24 Fake polyester grass coating	3
2.	A3.25 Polyester pom-pom	3
3.	A3.13 Filling pellets and beads in soft-filled toys	4
4.	A3.14 Plastic gems	7
5.	A3.18 Sequins without holes	8
6.	A3.19 Stickers	9
7.	A3.20 Glitter gel pens	. 10
8.	A3.21 Water beads for gel blasters	. 11
9.	A3.22 - Styrofoam beads; - Slime containing styrofoam beads; - Playfoan	1 1 2
10.	A3.28 Bath Slime	. 13
11.	A3.27 Glittered candles	. 14
12.	A3.26 Snow globe	. 14



1. Objects covered with synthetic fibres, regenerated natural fibres, and natural fibres: **A3.6** Fake fur on plush/stuffed toys; **A3.23** Flock-coated products (flocked hangers, etc); **A3.24** Fake polyester grass coating







A3.6 Fake fur on plush/stuffed toys

Product description:
Polymeric fibres 15 mm and less in length on soft-filled toys and on figurines covered with micro nylon fibres.

A3.23 Flock-coated products (flocked hangers, etc)

Product description: Articles (e.g., hangers, decorations etc.) with elements of flock (made of viscose, polyester, micro nylon)

A3.24 Fake polyester grass coating

Product description: Decoration with grass effect (polyester) applied to the surface of products

Outcome of the discussion on fibres by the BWG:

Synthetic and regenerated natural fibres are regarded as articles (according to example 17 in Appendix 4 to the <u>Guidance on requirements for substances in articles</u>).

Conclusion: Objects (already fulfilling the definition of article under REACH) covered by synthetic fibres, regenerated natural fibres, and natural fibres are regarded as a complex object (as defined in chapter 2.4 of the Guidance) made of many articles.

Consequence: the SVHC content is calculated over the weight of the fibre.

[Therefore, these objects are out of the scope of the microplastics restriction (entry 78 of REACH Annex XVII)]

2. A3.25 Polyester pom-pom



A3.25 Polyester pom-pom

Product description: Pom-pom made



of polyester fibres

The polyester fibres in a pom-pom are textile fibres, which are articles according to example 17 in Appendix 4 to the <u>Guidance on requirements for substances in articles</u>. Therefore, a polyester pom-pom is a complex object made of many articles.

Conclusion: A polyester pom-pom is regarded as a complex object (as defined in chapter 2.4 of the Guidance) made of many articles (the polyester fibres).

[Therefore, these objects are out of the scope of the microplastics restriction (entry 78 of REACH annex XVII)]

3. **A3.13** Filling pellets and beads in soft-filled toys.



A3.13 Filling pellets and beads in soft-filled toys

Product description: Polymeric pellets and expanded polystyrene (EPS) filling beads are used for toy shape retention.

They are entirely embedded in the toy and cannot be accessible for safety reasons (to prevent possible choking). Toy Safety Directive requires toys to pass tension test on seams and materials (EN 71-1).

Polymeric pellets and beads

Polymeric pellets and beads are regarded as a substance or as such or mixture under REACH.

Reasoning:

According to Chapter 2.2 of the *Guidance on requirements for substances in articles* (SiA Guidance): "Manufactured solid materials are by definition obtained in specific shapes and surfaces (e.g. granules, crystals, flakes, powders, etc.). These shapes and surfaces may be inherent to the physical properties of the manufactured materials. They may also be solely determined by the chemical starting materials used and the manufacturing process conditions applied. In both these cases, the manufactured materials are most likely to be substances (as such or in mixtures), even though the shapes and surfaces may also be deliberately controlled for the main purpose of optimising the further processing and/or the handling of the solid materials."

The solid polymer, including expanded polystyrene (EPS), is obtained, in the



manufactured process, in specific shapes and surfaces, in this case as pellets or beads/granules. The polymeric pellet or bead shape and surface obtained:

- may be inherent to the physical properties of the manufactured materials; or
- may be determined by the
 - chemical starting materials used and the
 - manufacturing process conditions applied.

In both these cases, as mentioned in Chapter 2.2 of the SiA Guidance, the manufactured materials – the polymeric pellets or beads - are a substance as such or in a mixture. I.e. the shape or surface of each pellet or bead/granule is a result of the chemical manufacturing process and is not especially given to the pellets or beads/granules. Those polymeric pellets or beads/granules have in principle significant variations in terms of sizes, shapes and surfaces. No special shape, surface or design has been deliberately determined and given during the manufacture process – a chemical process – and therefore the pellets or beads/granules do not fulfil one of the conditions of the definition of article under REACH.

Shell casing or outer cover of a soft-filled toy

A soft-filled toy has a shell casing or outer cover, which is usually made by an object or objects fulfilling the definition of article under REACH, like a (natural or synthetic) leather cloth, nonwoven cloth or a fabric made of natural fibres, regenerated natural fibres or synthetic fibres.

According to example 17 in Appendix 4 to the SiA Guidance, a woven fabric is a complex object made of many articles (fibres).

Soft-filled toy

The assessment of the soft-filled toy is carried out according to the workflow in chapter 2.2 of the SiA Guidance.

A soft-filled toy is made by inserting a filling (filler) into a shell, usually a outer fabric made of fibres.

Step 1. Function(s):

- To bear a resemblance, namely to a real object, animal or fictional character;
- For use in play by children.

Step 2: Are shape/surface/design of the object more relevant for the function than the chemical composition?

It is not possible to conclude unambiguously yes or no as an answer to this question. The soft-filled toy bears a resemblance (function) both due to shell casing or outer cover and the filling for the toy shape retention.

Step 3. Does the object contain a substance/mixture that can be separated from the object?

The pellets or beads filling which is a substance/mixture (the relevant chemical composition) can be separated from the soft-filled toy.

When using steps 4 and 5 of the workflow, by answering to the indicative questions, it



is concluded that a **soft-filled toy** with a substance/mixture as the filler/content **is regarded as an article or articles** (complex object) **with an integral substance/mixture** (content/filler: the polymeric pellets or beads)

⇒ Step 4

Step 4.

Question 4a: If the substance/mixture were to be removed or separated from the object and used independently from it, would the substance/mixture still be capable in principle (though perhaps without convenience or sophistication) of carrying out the function defined under step 1?

No

The pellets or beads are not able to bear a resemblance, namely to a real object, animal or fictional character, for use in play by children.

Question 4b: Does the object act mainly (i.e. according to the function defined under step 1) as a container or carrier for release or controlled delivery of the substance/mixture or its reaction products?

No.

The soft-filling toy is not used to release or make a controlled delivery of the pellets or beads filling which is a substance/mixture (the relevant chemical composition).

Question 4c: Is the substance/mixture consumed (i.e. used up e.g. due to a chemical or physical modification) or eliminated (i.e. released from the object) during the use phase of the object, thereby rendering the object useless and leading to the end of its service life?

Nο

The pellets or beads filling which is a substance/mixture (the relevant chemical composition) are not consumed or eliminated during the use phase of the soft-filling toy. They can be deformed or inadvertently be spilled, which is an unwanted result, during the use phase of the soft-filling toy

⇒ All answered with 'No'. Go to step 5.

Step 5.

Question 5a: If the substance/mixture were to be removed or separated from the object, would the object be unable to fulfil its intended purpose?

Yes.

Without the pellets or beads filling, the toy is not able to retain its shape and therefore to bear the resemblance, namely to a real object, animal or fictional character, for use in play by children.

Question 5b: Is the main purpose of the object other than to deliver the substance/mixture or its reaction products?

Yes.



(See step 1)

Question 5c: Is the object normally discarded with the substance/mixture at the end of its service life, i.e. at disposal?

(In principle) yes.

Usually, the soft-filled toy is discarded (at least partially) with the pellets or beads filling which is a substance/mixture (the relevant chemical composition).

⇒ All answered with 'Yes'.

Conclusion: The object, a soft-filled toy with polymeric pellets or beads - a substance/mixture as the filler/content (the relevant chemical composition), is regarded as an article or articles (complex object) with an integral substance/mixture (content/filler: the polymeric pellets or beads).

Conclusion: The soft-filling toy is regarded as an article or articles (complex object) with an integral substance/mixture - the polymeric pellets or beads.

The conclusion applies only to filling pellets in non-refillable soft-filled toys.

[Therefore, these objects are out of the scope of the microplastics restriction (entry 78 of REACH annex XVII)]

4. **A3.14** Plastic gems



A3.14 Plastic gems

Product description: Standalone, shiny, faceted gems, used e.g. for art decorations.

Description of the object:

A plastic gem is a faceted bead which may have a size less than 5 mm. They are commonly made from an acrylic or methacrylic (co)polymer (thermoplastic). Dyes are



added to the polymeric pre-mixtures to provide the desired shades and hues. Extrusion or moulding are used to obtain a specific profile (e.g. cylinder, regular prismatic shape) from the pre-mixture, which may then undergo a faceting process (involving cutting and similar mechanical processes).

The plastic gems have been used on costumes, apparel, jewellery and art decorations.

Step 1. Function: decoration and further processing – incorporation into costumes, apparel, jewellery and art objects.

Step 2. Are shape/surface/design more relevant for the function than the chemical composition?

Yes.

The shape and surface are key to construct the faceted object with uniform pattern to look like a shiny faceted mineral crystal gem. The shape and surface and more important (than the chemical composition) to make them shiny and faceted, to be used as decoration objects and decorative adornments in costumes, apparel, jewellery and art objects. Therefore, a plastic gem is regarded as an article.

Furthermore, example 18 of Appendix 4 to the <u>Guidance on requirements for substances in articles</u> supports this conclusion.

Conclusion: A plastic gem is regarded as an article.

[Therefore, these objects are out of the scope of the microplastics restriction (entry 78 of REACH annex XVII)]

5. A3.18 Sequins without holes



A3.18 Sequins without holes

Product description: Set of flat sequins without holes to stick on a selfadhesive backing to create a picture.

Description of the object:

The hardened flat polymer piece is assembled into a canvas with an adhesive to obtain a painting assembly.



Step 1. Function: further processing – incorporation into a painting assembly (component of a painting assembly)

Step 2. Are shape/surface/design more relevant for the function than the chemical composition?

Yes.

The shape is key to construct the painting since the shape needs to fit into the empty spaces in the canvas with an adhesive. Therefore, the shape of the flat polymer piece is more important to make the painting assembly than the chemical composition. Therefore, hard flat polymer piece is regarded as an article. Example 18 of Appendix 4 to the Guidance on requirements for substances in articles supports this conclusion.

Conclusion: A sequin without hole is regarded as an article.

[Therefore, these objects are out of the scope of the microplastics restriction (entry 78 of REACH annex XVII)]

6. **A3.19** Stickers



A3.19 Stickers

Product description: Polymer/plastic sticker is a solid piece of plastic with a pressure sensitive adhesive coating/layer on one side.

Description of the object:

Polymer/plastic sticker is a solid piece of plastic with a pressure sensitive adhesive coating/layer on one side.

Typically, the plastic stickers are obtained by die-cutting a printed plastic film or sheet, with a pressure sensitive adhesive coating on the backside, into the desired shapes and sizes using specialized machinery. The production process comprises the making of the plastic film or sheet, the printing (e.g. digital printing, flexography, screen printing), possibly a coating on the front side to enhance certain properties, such as resistance to wear and tear or aesthetic appearance, application of pressure sensitive adhesive on the backside, and finally die-cutting.

Step 1. Function: sticking onto a surface

Step 2. Are shape/surface/design more relevant for the function than the chemical composition?

Yes, either if we are looking to the chemical composition of the solid plastic part or to



the pressure adhesive layer (article with an integral substance/mixture – the adhesive layer) of the polymer sticker.

This conclusion is achieved based on the principles laid down on Chapter 2 and

- · examples 18 for the backing polymer sheet,
- examples 18 and 19 for further processing (e.g. printing, coating),
- and 'adhesive tape for fixing carpets' example (appendix 3) for the sticker sheet in Tables 11 and 12,
- as well as examples 18 and 19 for further cutting process of the sticker sheet to make the individual stickers,

of the Guidance on requirements for substances in articles.

Conclusion: A sticker is regarded as an article with an integral substance/mixture (the adhesive layer).

[Therefore, these objects are out of the scope of the microplastics restriction (entry 78 of REACH Annex XVII)]

7. A3.20 Glitter gel pens



A3.20 Glitter gel pens

Product description: Pens containing coloured gel inks mixed with polymeric glitter

A pen, which is used to write, draw, sketch or paint on paper (or other suitable base material or surface), is regarded as a combination of articles (functioning as container, enabling controlled release, and handling facilitator) and a substance/mixture (the ink or paint, including those that incorporate glitter in their composition).

Step 1. Function

The main function of a pen is to write, draw, sketch and paint on paper (or other suitable base material or surface), i.e. bring ink/paint onto paper or other suitable surface.

Step 2. Are shape/surface/design more relevant for the function than the chemical composition?

The ink or paint (or other suitable mixture), with or without glitter in its composition, is the essential component of a pen, without it, the function is not achieved. The object used to carry and transfer the ink or paint (container and handling facilitator) is the other main component of a pen. The whole "container" device or object that releases the mixture in a controlled manner, is an article or a combination of several articles (complex object). The degree of sophistication of the mixture container, barrel,



etc. of the pen only contributes to improve the quality of the traces made when writing, drawing, sketching, painting, etc, and does not change the function in itself (of transferring the ink/paint from the container onto paper or other suitable surface). From these considerations, one can conclude already in step 2 of the decision-making workflow included in chapter 2.3 of the <u>Guidance on requirements for substances in articles</u> that a pen is regarded as a combination of articles (e.g. ink container, barrel) - complex object - and a substance/mixture (ink or paint, including those that incorporate glitter in their composition).

This conclusion is in line with the examples of the 'spray can with paint', 'printer cartridge' and 'printer ribbon' in Tables 7 and 10 of Appendix 3 of the <u>Guidance on requirements for substances in articles</u>

Conclusion: A glitter gel pen is regarded as a combination of articles (functioning as container, enabling controlled release, and handling facilitator) and a substance/mixture (the ink with polymeric glitter).

[Therefore, the ink in a glitter gel pen is within the scope of the microplastics restriction (entry 78 of REACH Annex XVII)]

8. **A3.21** Water beads for gel blasters



A3.21 Water beads for gel blasters

Product description: Beads made of superabsorbent (swellable) polymers and used as ammunition for "gel blaster" guns

Water beads for gel blaster are polymer particles made of cross-linked water-absorbing hydrophilic homopolymers or copolymers (e.g. cross-linked polyacrylates and polyacrylamides; graft-modified polysaccharides, cross-linked maleic anhydride copolymers). They can absorb and retain large amounts of water or aqueous solutions through hydrogen bonding between the polymer functional groups and water molecules. They are therefore hydrogels, i.e. they are not solid. They do not have a specific or special shape or even size, i.e. their dimensions depend on the quantity of water absorbed or on the aqueous solution used.

When hydrated, the water beads are regarded as a mixture. In the dehydrated form, they are regarded as a substance or mixture, depending on their composition.



The most important properties of a water bead to perform its function (depending on the use) are high swelling capacity, high swelling rate, and good strength of the swollen gel. These properties are related with the chemical composition and microstructure and not with the shape, surface or design.

Conclusion: A water bead for gel blasters is regarded as a substance/mixture.

[Therefore, the water beads for gel blasters, provided that they fulfil the dimensions criteria, are within the scope of the microplastics restriction (entry 78 of REACH Annex XVII)]

 A3.22 - Styrofoam beads; - Slime containing styrofoam beads; -Playfoam



A3.22 - Styrofoam beads

Product description: Styrofoam beads or similar polymeric beads with a diameter <5 mm, often mixed with slime or other fluids (e.g. in Playfoam) for crafts projects.

According to Chapter 2.2. of the <u>Guidance on requirements for substances in articles</u>: Manufactured solid materials are by definition obtained in specific shapes and surfaces (e.g. granules, crystals, flakes, powders, etc.). These shapes and surfaces may be inherent to the physical properties of the manufactured materials. They may also be solely determined by the chemical starting materials used and the manufacturing process conditions applied. In both these cases, the manufactured materials are most likely to be substances (as such or in mixtures), even though the shapes and surfaces may also be deliberately controlled for the main purpose of optimising the further processing and/or the handling of the solid materials.

Styrofoam beads have a shape, surface and microstructure which result from:

- the material they are made of,
- and the manufacturing process conditions applied.

It seems that the shapes and surfaces of Styrofoam beads are, in general, deliberately controlled for the main purpose of optimising the further processing and their handling. Therefore, they are considered as a substance or mixture.

The Styrofoam beads are to be seen as a substance/mixture ingredient when mixed with slime or other fluids (e.g. in Playfoam) for crafts projects.



Conclusion: Styrofoam beads are, in principle, regarded as a substance/mixture.

[Therefore, the Styrofoam beads are within the scope of the microplastics restriction (entry 78 of REACH annex XVII), as well as a mixture containing Styrofoam beads as a chemical ingredient (e.g. slime containing styrofoam beads; playfoam].

10.A3.28 Bath Slime



A3.28 Bath Slime

Product description: Polymeric powder or small granules that can be added to bath water to turn it into "slime" in water

According to Chapter 2.2. of the <u>Guidance on requirements for substances in articles</u>: Manufactured solid materials are by definition obtained in specific shapes and surfaces (e.g. granules, crystals, flakes, powders, etc.). These shapes and surfaces may be inherent to the physical properties of the manufactured materials. They may also be solely determined by the chemical starting materials used and the manufacturing process conditions applied. In both these cases, the manufactured materials are most likely to be substances (as such or in mixtures), even though the shapes and surfaces may also be deliberately controlled for the main purpose of optimising the further processing and/or the handling of the solid materials.

Polymeric powder or small granules used to make slime have a shape and surface which result from:

- the material they are made of,
- and the manufacturing process conditions applied.

Therefore, they are considered as a substance.

The polymer, in the form of powder or granules, to make slime, is to be seen as a substance. When making slime, the powder particles or granules lose their shapes and surfaces.

Conclusion: Bath slime – polymer in the form of powder particles or granules - is regarded as a substance.

[Therefore, bath slime – polymer in the form of powder particles or granules - is within the scope of the microplastics restriction (entry 78 of REACH annex XVII)].



11.A3.27 Glittered candles





A3.27 Glittered candles

Product description: Candles where glitter is either inside the wax or is affixed to the external surface of the candle.

A glittered candle is a combination of an article (the wick) and a mixture (the wax with polymeric glitter, either in the wax or on its surface), according to Appendix 3 to the Guidance on requirements for substances in articles, and the example of 'coated conventional candle' in the <u>Catalogue of borderline cases between articles and substances/mixtures.</u>

Conclusion: A glittered candle (either with glitter within the wax or on its surface) is regarded as a combination of an article (the wick) and a mixture (the wax with polymeric glitter, either in the wax or on its surface).

[Therefore, a glittered candle is within the scope of the microplastics restriction (entry 78 of REACH annex XVII)].

12.**A3.26** Snow globe



A3.26 Snow globe

Product description: Decorative object containing a mixture with polymeric artificial snow

(Workflow in section 2.3 of the Guidance on requirements for substances in articles)

Step 1. Function: decoration

Step 2. Are shape/surface/design more relevant for the function than the chemical composition?



When taking into consideration the relevant chemical composition - liquid with polymeric artificial snow (mixture) - it is not possible to answer to the question unambiguously.

Step 3. Does the object contain a substance/mixture that can be separated from the object?

The relevant chemical composition, the mixture - liquid with polymeric artificial snow - can be separated from the globe.

⇒ Step 4

Step 4.

Question 4a: If the substance/mixture were to be removed or separated from the object and used independently from it, would the substance/mixture still be capable in principle (though perhaps without convenience or sophistication) of carrying out the function defined under step 1?

No. The decorative effect is only provided when the mixture is incorporated in the globe, on its own it does not work for that function.

Question 4b: Does the object act mainly (i.e. according to the function defined under step 1) as a container or carrier for release or controlled delivery of the substance/mixture or its reaction products?

No. The liquid with polymeric artificial snow is not released or controlled delivered – It is kept enclosed in the globe.

Question 4c: Is the substance/mixture consumed (i.e. used up e.g. due to a chemical or physical modification) or eliminated (i.e. released from the object) during the use phase of the object, thereby rendering the object useless and leading to the end of its service life?

No. The liquid with polymeric artificial snow is not consumed or eliminated during the use phase.

⇒ **Mostly No**. Step 5.

Step 5.

Question 5a: If the substance/mixture were to be removed or separated from the object, would the object be unable to fulfil its intended purpose?

No. It could still be used as a decorative object.

Question 5b: Is the main purpose of the object other than to deliver the substance/mixture or its reaction products?

Yes. The liquid with polymeric artificial snow improves the decorative function and the object is constructed to keep that mixture enclosed during its entire use phase.



Question 5c: Is the object normally discarded with the substance/mixture at the end of its service life, i.e. at disposal?

Yes.

Unless it breaks or the liquid with polymeric artificial snow leaks out from the globe (unwanted).

⇒ Mostly Yes.

Conclusion: The function of the object (globe containing a mixture with polymeric artificial snow) – decoration - is likely to be determined rather by the physical properties shape, surface and design, than by the chemical composition (mixture with polymeric artificial snow). The object is then regarded as an article with an integral mixture (i.e. the mixture forms an integral part of the article).

Conclusion: Snow globe to be regarded as an article with an integral mixture (mixture with polymeric artificial snow as an ingredient).

[Therefore, these objects are out of the scope of the microplastics restriction (entry 78 of REACH Annex XVII)]