ECHA PROPOSES A RESTRICTION ON INTENTIONALLY ADDED MICROPLASTICS[1]

Summary[2]

The Annex XV report outlines a proposal to restrict the placing on the market of polymers (as defined by Article 3(5) of REACH) as a substance or in a mixture in a concentration equal to or greater than 0.01% w/w when present in a physical form consistent with a 'microplastic'. Microplastics are solid-polymer-containing particles, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 1nm ≤ *x* ≤ 5mm, or (ii), for fibres, a length of 3nm ≤ *x* ≤ 15mm and length to diameter ratio of >3. Microplastics have diverse applications, including in agriculture, horticulture, cosmetic products, paints, coatings, detergents, maintenance products, medical and pharmaceutical applications. Derogations are proposed for polymers that occur in nature, polymers that meet criteria for minimum (bio)degradability, uses of microplastics at industrial sites as well as certain uses by consumers or professionals that would not inevitably lead to a release of microplastics to the environment. Certain derogated uses are accompanied with requirements to provide additional information on packaging or safety datasheets and to report certain information annually to ECHA. The proposal includes transitional arrangements for specific applications, such that the restriction enters into effect progressively over a period of six years after entry into force. Uses of 'microbeads' (microplastics used as an abrasive) would be prohibited immediately after the entry into force of the restriction.

The public consultation on this proposed restriction will start on 20/03/2019 and end on 20/09/2019.

When responding to the public consultation, stakeholders should take into account when certain aspects of the proposal are planned to be discussed in the plenary meetings of the Committees and time their submissions accordingly:

	Committee	
Plenary meeting of the Committee (timing)	**Risk Assessment Committee (RAC)**	**Socio-Economic Assessment Committee (SEAC)**
1 (2.5 months after PC starts)	Verify the proposed scope. Conclude on hazard and hold preliminary discussion on exposure/risk.	Verify the proposed scope. Conclude on costs of the proposed restriction and hold preliminary discussions on its benefits.
2 (5.5 months after PC starts)	Conclude on exposure/risk and hold preliminary discussion derogations.	Conclude on benefits and hold preliminary discussions on proportionality and derogations.
3 (8.5 months	Finalise the derogations. Finalise the opinion plus	Conclude on proportionality and derogations. Finalise the opinion

[1] The information note has been prepared based on the Annex XV report submitted by ECHA.

[2] An elaborated summary of the proposal is presented on pages 8 to 18 of the Annex XV report.

after PC starts)	justification text and adopt the final opinion.	plus justification text and agree the draft opinion.
4	Not relevant.	Conclude on issues raised during the SEAC draft opinion public consultation. Adopt the final opinion.

Information on the hazards of the substance(s) and the costs of the proposal would make the most impact if submitted by month two and exposure/risk, benefits and derogations by month four of the public consultation. This early submission would also allow the information to be considered at the appropriate time. This timing takes into account that stakeholders have access to the dossier much earlier than in the past, as it is published two weeks after submission or more than six weeks in advance of the start of the public consultation.

It is possible to submit more than one consultation response during the six month period so please take this into account when deciding when to submit information.

Please note that alongside the Annex XV report and annexes, a supplementary document has been prepared by the Dossier Submitter outlining the potential overlap between the proposed restriction on intentionally-added microplastics and the proposed restriction on the use of D4, D5 and D6, which was also submitted in January 2019.

How to submit a comment in the Consultation on the proposed restriction

Firstly please read the consultation guidance that describes the relevant information that should be submitted. It is available here: https://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf/7c4705d5-ad01-43ed-a611-06f1426a595c.

When you are ready to make your comments, click on the appropriate link on the ECHA website. Please be aware that it is not possible to save your submission and come back to it, so you should already have your comments prepared in an attachment or saved in some other format in advance.

The web form contains five main parts:

- Introduction: containing some general information on the restriction and a link to this note and the PC guidance.
- Section 1: Personal information
- Section 2: Organisational information
- Section 3: Non-confidential comments on the proposal - both general comments and information on specific issues (see below). Your responses can be entered directly into the form or through section 4 as an attachment. However, please do not submit the same comments via both means. General comments can be on any aspect of the Annex XV restriction proposal, including on issues related to socio-economic analysis.
- Section 4: Non-confidential attachments can be added here.

- Section 5: Confidential attachments can be added here. Confidential information will only be available to the ECHA Secretariat, the Committees and Member State Competent Authorities. However, if ECHA receives an Access to Documents request, we may come back to you for justifications why the information is confidential. You can also add this information already in the relevant part of the webform.

Once you have finished your submission press the submit button and your comments will be submitted. You will receive a submission number via e-mail and you should refer to this in any communication with ECHA on this issue.

It is not possible for you to retrieve your submission so you may want to take a screen shot, or printed copy for your future reference.

Specific information requests

In addition to the general comments, outlined above, the consultation includes several specific questions to gather information that is considered to be particularly relevant to the evaluation of the proposal, as follows:

1. Paragraph 3(b) of the proposed restriction sets out that *'polymers that are (bio)degradable'* are not considered to be microplastic for the purposes of the restriction. A tiered approach for establishing if a polymer-containing particle can be considered as (bio)degradable are detailed in Section 2.2.1.6 of the Annex XV report (Table 21 – Appendix X).

   Please provide feedback on the approach, test methods and pass/fail criteria that have been proposed, particularly in relation to their clarity, appropriateness, practicality and predictability for assessing the (bio)degradation of microplastics, including any practical experience of applying the proposed criteria to microplastics. Please tell us if further modifications or adaptations, or alternative test methods, pass/fail criteria or guidance should be considered, providing supporting justification.

2. The Dossier Submitter has identified that granular infill material used in synthetic turf (i.e. the granules produced from end-of-life tyres or other synthetic elastomeric materials) is consistent with the definition of an intentionally-added microplastic. Further information is needed in order to assess the implications of the restriction on these materials and to assess the possible need for a derogation. The specific information needed is:

   a. The quantity of microplastics used as synthetic turf infill material in individual Member States or the EU/EEA (Tonnes/yr).

   b. The quantity of microplastics released to the environment (Tonnes/yr, all relevant compartments), and an assessment of the different pathways by which microplastics can be released into the environment and an evaluation of their relative importance.

   c. Examples of 'best practice' operational conditions (OCs) and risk management measures (RMMs) to prevent or minimise the release of infill material to the environment, including an estimate of their effectiveness.

   d. Information on the costs of implementing 'best practice' OCs and RMMs

e. Information on the impacts to society of restricting the use of microplastics as synthetic turf infill material, i.e. consequences for the availability of sports fields, impacts on producers, installers and users as well as possible broader impacts of emissions associated with the management of rubber granulate waste (e.g. incineration), other externalities such as greenhouse gas emissions, etc.

3. The proposed concentration limit of 0.01% weight by weight (w/w) is intended to prevent the intentional use of microplastics and was based on the information available to the Dossier Submitter on the minimum concentration of microplastics added to products to achieve their technical function. For the concentration limit to be considered further, please tell us:

   a. What is the minimum concentration of microplastics (expressed as the w/w concentration of polymer-containing particles) in end products required to fulfil their intended technical function?

   b. In addition, please tell us what proportion of products in each of the categories below contain microplastics to achieve their intended function in concentrations: a) less than 0.001% w/w; b) between 0.001% w/w and 0.01% w/w; c) between 0.01% w/w and 0.1% w/w; d) between 0.1% w/w and 1% w/w; and e) greater than 1.0% w/w. When answering this question, please consider that, as defined in Paragraph 2d of the proposal, a 'polymer-containing particle' means either (i) a particle of any composition with a continuous polymer surface coating of any thickness or (ii) a particle of any composition with a polymer content of ≥ 1% w/w. We are interested in information differentiated between the following product categories/functions:

      - Agriculture and horticulture
      - Rinse-off cosmetic products
      - Leave-on cosmetic product
      - Detergents containing fragrance encapsulates
      - Other detergents
      - Waxes and polishes
      - Medical devices, *in vitro* diagnostic medical devices and medicinal products for human and veterinary use
      - Food supplements and medical food
      - Paints and coatings
      - 3D printing
      - Printing inks
      - Construction products
      - Products used in the oil & gas sector

      You may specify additional functions or uses, if necessary

   c. Please tell us about the availability of analytical methods that could be used to detect and quantify microplastics in the products above.

   d. Are you aware of microplastics corresponding to the definition proposed in the restriction being present in a substance or a mixture as an impurity? If so, at what concentrations (% w/w) do these occur?

4. According to Paragraph 5b of the proposed restriction (See Table 3, Annex XV report), a derogation is proposed for substances or mixtures containing microplastic where the microplastics is both (i) contained by technical means throughout their whole lifecycle and (ii) any microplastic containing wastes arising are incinerated or disposed of as though they were hazardous waste.

   This derogation is primarily intended to be applicable to professional uses of microplastics in medical devices and *in vitro* diagnostic medical devices (e.g. in hospitals and healthcare facilities), although could also be applicable to other laboratory equipment/consumables. Please provide information on the feasibility and practicalities of implementing the containment of microplastics by technical means and disposal of any microplastic containing wastes by incineration or as though they were hazardous waste for these uses, and any similar uses that would also be permitted on the basis of this proposed derogation.

5. The Dossier Submitter has assessed the socio-economic impacts of the proposed restriction based on its understanding of the uses of microplastics. Please provide (i) information on **other sectors or uses,** beyond those analysed by the Dossier Submitter, that may be affected by the proposed restriction or (ii) additional information to refine the assessment of sectors/uses already presented by the Dossier Submitter. Please bear in mind that the definition of microplastics used in the proposed restriction is substantially broader than the more commonly known "microbeads". Evidence of these impacts and supporting justifications can be provided on the following topics among others. Where relevant, please distinguish between the impacts of the different elements of the proposed restriction e.g. ban on placing on the market, labelling or instructions for use, reporting.

   a. tonnages of microplastics used, technical function, releases to the environment, including pathways for such releases;

   b. costs and benefits to producers (including of alternatives), professionals, consumers, etc.; Please indicate the actors affected (e.g. producers, formulators, professional users, consumers), including key economic parameters such as profits, number of people employed, etc.

   c. technical and economic feasibility of potential alternatives, including information on product performance, the price differences between microplastics and their alternatives, the number of products that could require reformulation, expected costs and timelines for reformulation and transitioning to a full-scale production using the alternatives, other potential impacts stemming from the transition to alternatives, e.g., discontinuation of certain products, etc; Please indicate critical uses, for which no alternative currently exists and how long it would take to identify such alternatives.

   d. hazard and risk of the alternatives.

6. The Dossier Submitter has received information that the 19 polymers in **Table 1** below are used in cosmetic products. Table 88 in the annexes to the report includes a non-exhaustive list of further polymers that may or may not be impacted by the proposed restriction. This information was used by the Dossier Submitter to estimate the impacts of the restriction on cosmetic products in 'low' and 'high' scenarios. These estimates can be refined should additional data be provided in the consultation. If the response

to this question is submitted as a confidential attachment, the data will be anonymised and reported in aggregate form only.

a. Using the template provided (available on the website alongside the information note), please tell us which polymers (specify the INCI name) used in cosmetic products would be impacted by the proposed restriction (those included below and any other relevant polymers). When answering this question, please consider: i) if the physical form of the polymer is consistent with the proposed definition of a microplastic in the cosmetic mixture at point of release or use by end-users, ii) that (bio)degradable polymers are not considered to be microplastics (see Paragraph 3b of the restriction proposal in Table 3 of the report), iii) that certain uses of microplastics in cosmetic products are proposed to be derogated (e.g., polymer-containing particles that form films are not considered to be microplastics at the point of use, see Paragraph 5b of the restriction proposal in Table 3 of the report).

b. Please provide information on the formulations containing each INCI that fulfil the microplastic definition or not, i.e., the polymers (specify the INCI name) listed in the table below and any additional polymers identified in a). Please answer in the template provided for each INCI name and differentiate between rinse-off and categories of leave-on cosmetic products. Please provide information on the kilogrammes used in the template.

Table 1. List of 19 polymers used in cosmetic products

Polymer (as identified by Industry)	Associated INCI name
Polyethylene	POLYETHYLENE
Polypropylene	POLYPROPYLENE
Polymethylmethacrylate	POLYMETHYL METHACRYLATE
Polytetrafluoroethylene	POLYTETRAFLUOROETHYLENE ACETOXYPROPYL BETAINE
Polyurethane crosspolymer – 1	POLYURETHANE CROSSPOLYMER-1
Polyurethane crosspolymer – 2	POLYURETHANE CROSSPOLYMER-2
Polyamide (nylon) 5	POLYAMIDE-5
Polyamide (nylon) 6	NYLON-6 NYLON 6/12
Polyamide (nylon) 12	NYLON-12 NYLON-12 FLUORESCENT BRIGHTENER 230 SALT NYLON 12 (not INCI, but encountered on the labels) NYLON 6/12
Styrene acrylate copolymer	STYRENE/ACRYLATES COPOLYMER
Polyethylene terephthalate	POLYETHYLENE TEREPHTHALATE
Polyethylene isoterephthalate	POLYETHYLENE ISOTEREPHTHALATE
Polybutylene terephthalate	POLYBUTYLENE TEREPHTHALATE
Polyacrylates, acrylates copolymer	ACRYLATES COPOLYMER ACRYLATES CROSSPOLYMER
Ethylene/Acrylate copolymer	ETHYLENE/ACRYLIC ACID COPOLYMER
Polystyrene	POLYSTYRENE
Methyl methacrylate crosspolymer	METHYL METHACRYLATE CROSSPOLYMER
Polymethylsilsesquioxane	POLYMETHYLSILSESQUIOXANE

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Polymer (as identified by Industry)	Associated INCI name
Poly lactic acid	POLYLACTIC ACID

The final opinions of both Committees are scheduled to be available by March 2020. ECHA will send the joint opinion of the Committees to the European Commission, which will take the decision whether to include the proposed restriction in Annex XVII of the REACH Regulation.

The Dossier Submitter and the Rapporteurs will all respond to the issues raised in the public consultation and these responses will be published with the launch of the consultation on the SEAC draft opinion in month nine of the process.