Response to comments document (RCOM)
on the Annex XV dossier
proposing restriction on
intentionally-added microplastics

Non-confidential

ECHA/RAC/RES-O-0000006790-71-01/F

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

Substance name	EC number	CAS number
Intentionally-added microplastics	-	-

11 June 2020

1. General comments and answers to specific information requests

1.1. Specific information requests

In addition to providing an opportunity for interested parties to submit general comments on the proposed restriction, the Dossier Submitter and RAC/SEAC Rapporteurs posed a series of specific information requests as part of the consultation. These requests were, 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 (https://echa.europa.eu/documents/10162/0bab188e-cf32-4f21-e13d-689721908c2f), 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).

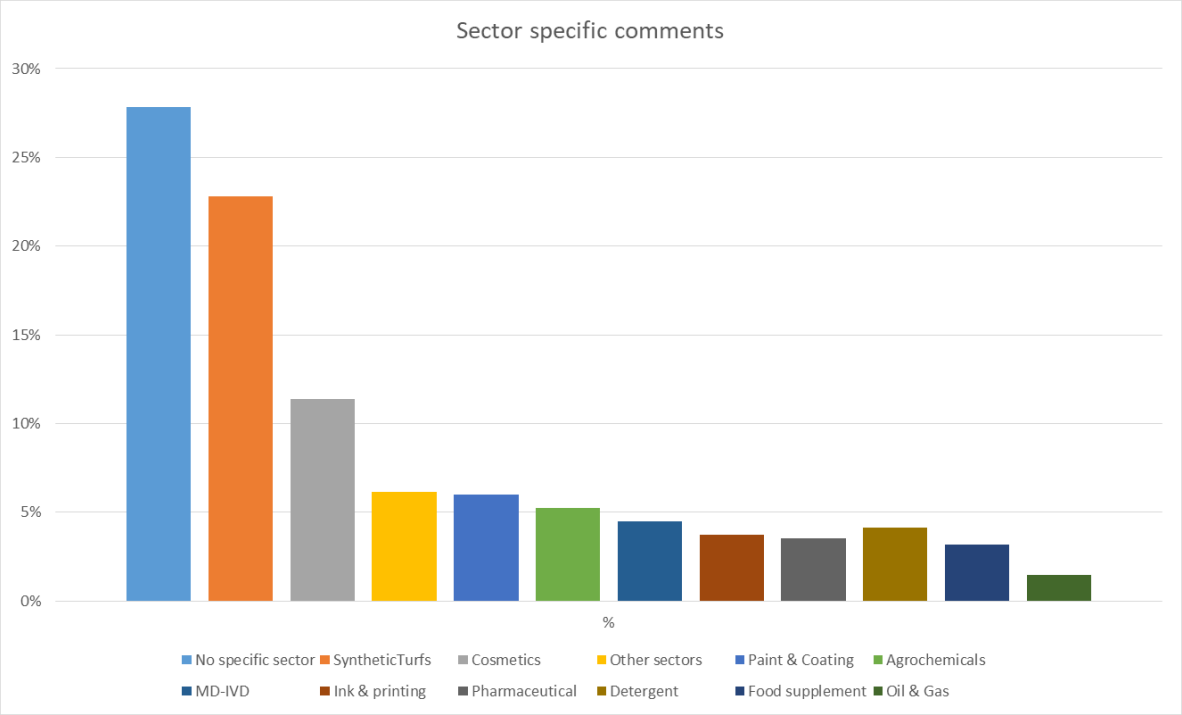
b. Please provide information on the formulations containing each INCI that fulfil the microplastic definition or not, i.e., the polymers (specify the INCI name) listed in the table below and any additional polymers identified in a). Please answer in the template provided for each INCI name and differentiate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

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
Poly lactic acid	POLYLACTIC ACID

1.2. Overview of the comments received

477 comments received.

Main areas of interest:



2. Response to comments

The Dossier Submitter would like to thank the many interested parties that submitted comments and information to the consultation.

In July 2019, during the consultation period, the Dossier Submitter published a 'Questions and Answers (Q&A)' document to address frequently-asked questions or comments received in relation to the proposal[1]. This document is one element of the Dossier Submitter's response to comments. Parts of the Q&A document have been brought forward to the Background Document or the Annexes to the Background Document to clarify the proposal, notably the decision trees that are reported in Section 2.6 of the Background Document for (i) the identification of microplastics and (ii) for stakeholders to identify their obligations under the proposed restriction. In addition, the entire Q&A document will be included as a new Annex (Annex F) to the Background Document.

The Dossier Submitter notes that many of the comments received were similar in nature and concerned a limited number of common themes. Given the large number of

[1] https://echa.europa.eu/documents/10162/13641/rest_microplastics_qa_v1.0_en.pdf

comments received, and to improve the clarity of the Dossier Submitter's responses to them, the Dossier Submitter has prepared a set of general responses to common themes. These general responses summarise the nature of the comments received and how the Dossier Submitter has responded to them, typically by undertaking revisions to the Background Document. These general responses should be read alongside responses to specific comments below.

In some cases the Dossier Submitter has responded to comments by revising the wording of the 'conditions of the restriction' (i.e. the wording of the restriction presented in Tables 3 and 17 in the Background Document). Respondents should note that the wording of the conditions of the restriction in the Background Document is intended to express the intention of the Dossier Submitter. The European Commission would ultimately decide on the precise legal wording used to update Annex XVII of REACH in the event that a restriction was adopted.

The comments received have been grouped into the following topics:

1. Microplastic definition, including considerations regarding substance identity, relevant size limits, physical properties, natural polymers and solubility

2. Scope of the proposed restriction

3. Hazard and risk

4. Derogation for (bio)degradable polymers

5. Derogations 5a, 5b and 5c

6. Plant protection and fertilising products (incl. coated seeds)

7. Cosmetic products

8. Detergents and household products

9. *In vitro* diagnostic devices and medical devices

10. Medicinal products for human and veterinary health

11. Food additives

12. Ink-printing, paint and coatings and construction products

13. Oil and gas sector

14. Polymeric infill material for synthetic sports pitches

15. Additional (newly reported) uses

16. Paragraph 7 'Instruction for use and disposal' requirements for derogated uses

17. Reporting requirements for derogated uses

18. Implementation and enforcement, including the availability of analytical methods

2.1. Microplastic definition, including considerations regarding substance identity, relevant size limits, physical properties, natural polymers and solubility

2.1.1. Dossier Submitter response to comments

Numerous comments were received from stakeholders on the elements used by the Dossier Submitter to identify microplastics and establish the scope of the proposed restriction, the so-called 'microplastics definition'. For example, comments #2010, #2014, #2015, #2016, #2028, #2044, #2057, #2058, #2061, #2069, #2070, #2072, #2074, #2077, #2085, #2087, #2095, #2096, #2097, #2098, #2103, #2105, #2107, #2108, #2111, # 2115, #2117, #2118, #2124, #2125, #2138, #2142, #2144, #2147, #2149, #2153, #2162, #2163, #2166, #2167, #2168, #2169, #2171, #2172, # 2176, #2181, #2183, #2184, #2186, #2187, #2188, #2189, #2190, #2192, #2193, #2194, #2195, # 2199, #2202, #2204, #2205, #2209, #2210, #2212, #2215, #2216, #2218, #2221, #2222, #2228, #2230, #2234, #2236, #2237, #2238, #2240, #2241, #2243, #2244, #2254, #2256, #2259, #2264, #2266, #2271, #2335, #2343 #2345, #2352, #2351, #2361, #2362, #2363, #2364, #2365, #2369, #2370, #2371, #2374, #2375, #2376, #2381, #2382, #2386, #2392, #2406, #2418, #2421, #2422, #2429, #2431, #2432, #2434, #2438, #2440, #2441, #2443, #2446, #2447 #2448, #2458, #2464, #2465, #2467, #2468, #2473, #2474, #2476, #2477, #2480, #2482, #2485, #2486, #2489, #2492, #2495, #2500, #2502, #2503,#2504, #2506, # 2508, #2510, #2511, #2514, #2515, #2523, #2524, #2525, #2528, #2529, #2530, #2531, #2536, #2537, #2538, #2539, #2540, #2541, #2542, #2544, #2548, #2551,#2553, #2554, #2556, #2558, #2559, #2564, #2565, #2566, #2574, #2576, #2578, #2581,#2585, #2586, #2587, #2588, #2593, #2594, #2596, #2598, #2603, #2606, #2607, #2609, #2611, #2613,#2616, #2618, #2619, #2621, #2623, #2624, #2645, #2647, #2652, #2653, #2656, #2655, #2658, #2663, #2664, #2669, #2670, #2674, #2678, #2680, #2681, #2685, #2691, #2697, #2687, #2698, #2699, #2700, #2701, #2706, #2709, #2710, #2713, #2717, #2719, #2720, #2721, #2727, #2729 and #2735, #2738, #2739. Some of the comments have been handled as confidential as per the respondent's request.

Since the 'microplastic' definition includes multiple elements, the most frequently received comments on each are listed below separately.

2.1.1.1. ISO definition of plastic

Multiple respondents proposed that the ISO definition (ISO 472 (2013)) of plastic should be used as the basis for the proposed REACH restriction, rather than the definition proposed by the Dossier Submitter. The definitions are different and have been derived based on different considerations. The regulatory definition as proposed by the Dossier Submitter, is underpinned by physical, chemical and persistence properties that are associated with hazard/risk concerns (the so-called 'microplastic concern'). In contrast, the ISO definition of plastics is primarily based on process considerations. A comparison of the ISO and proposed regulatory definitions of microplastics has been elaborated in the Background Document. Although there are some elements of the two definitions in common, the substances/mixtures that will be covered by the different definitions are

likely to be different. Therefore, the Dossier Submitter has concluded that the definitions cannot be used interchangeably. The ISO definition of plastic is not sufficiently inclusive to identify all synthetic polymeric substances that are associated with the 'microplastic concern' (i.e. solid minute particles comprised of synthetic polymers that are persistent in the environment). For example, the ISO definition would explicitly exclude elastomeric materials whilst particles from tyres and synthetic infill material on artificial sports surfaces, for instance, are clearly associated with the microplastics concern. There are further examples of substances/mixtures that would be excluded by the ISO definition of plastic that are associated with the microplastic concern. The Dossier Submitter notes that the proposed restriction does not need to explicitly refer to the term 'microplastic' in the conditions of the restriction if all the elements describing the substances/mixtures of concern are included. The term 'microplastic' is simply a convenient label for a group of substances/mixtures with defined physical, chemical and persistence properties that are consistent with an identified hazard and risk for the environment.

More information can be found in Section 1.2 of the Background Document and section B.1. Substance of the Annex to the Background Document.

2.1.1.2. Size limits

In the Annex XV report, the Dossier Submitter proposed the following size limits to define a 'microplastic':

- ≥ 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.

Respondents to the consultation raised concerns with these proposed limits based on the availability of analytical techniques that could be used identify, characterise and quantify nanoscale 'microplastic' particles in complex mixtures. The Dossier Submitter has considered the concerns. As a result of this consideration, the Dossier Submitter considers that while the size limits for the definition of Microplastic should remain as they have been outlined above, there should be a consideration how the restriction proposal can be enforced. Therefore, for the purpose of enforcement the Dossier Submitter proposes that the size limits would be set as follows:

- ≥ 1% w/w of particles have (i) all dimensions 0.1µm ≤ x ≤ 5mm, or (ii) a length of 0.3µm ≤ x ≤ 15mm and length to diameter ratio of >3.

More details on the revision is provided in Section 2.2.1.1 of the Background Document

2.1.1.3. Concentration limit

Some comments discussed the proposed concentration limit of 0.01% w/w set in the microplastic definition. On one hand, some respondents considered that the proposed concentration limit is too high and requested a total ban, while on the other hand, other respondents argued that a concentration threshold at 0.1 or 1% w/w would be more reasonable, and that 0.01% w/w concentration would be difficult to verify (cf. also topic on enforceability).

In addition, some comments reported the presence of intentionally added microplastics in concentration lower than 0.01% w/w, for example in IVD application. The Dossier Submitter has updated the Background Document accordingly (cf. Annex D7 to the Background Document) but has not revised the proposed concentration limit of 0.01%.

2.1.1.4. Definition of solid

Based on the comments received in the consultation, there is a need to address the definition of 'solid' with regards to fully amorphous polymers. This is due to the definition of solid proposed by the Dossier Submitter which defines solid as 'not gas or liquid'. This issue was discussed during the RAC opinion making. In the initial Annex XV report gas and liquid were defined, based on the CLP definition, as:

> • 'gas' means a substance which (i) at 50 °C has a vapour pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at 20 °C at a standard pressure of 101.3 kPa.
>
> • 'liquid' means a substance or mixture which (i) at 50 °C has a vapour pressure of not more than 300 kPa (3 bar); (ii) is not completely gaseous at 20 °C and at a standard pressure of 101.3 kPa; and (iii) which has a melting point or initial melting point of 20 °C or less at a standard pressure of 101.3 kPa.

The issue is with the point (iii) in the definition of a liquid.

Fully amorphous, or semi-crystalline, polymers do not exhibit T_m. Therefore, there is a need to be address this specifically. The Dossier Submitter proposes that the CLP definition of 'solid' is supplemented with additional criteria from the GHS definition for a liquid:

"A viscous substance or mixture for which a specific melting point cannot be determined shall be subjected to:

ASTM D 4359-90, or

Fluidity test (penetrometer test) described in section 2.3.4 of Annex A of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)."

The definition of solid has been updated accordingly by the Dossier Submitter in the Background Document.

2.1.1.5. Polymer solubility

Polymer solubility [in water] was discussed at length during the preparation of the proposal (detailed in the Annex XV report as well as in the note published prior to the submission of the Annex XV report on 'substance identification and the potential scope of a restriction on uses of microplastics'). Polymers that are soluble in water are not typically considered to be microplastics.

The Dossier Submitter initially concluded that 'solubility' [in water] would not be used as

a criterion to describe a microplastic but that, instead, the concept of the presence of a solid particle would be emphasised, as this was more relevant to the microplastic concern. During the opinion-making phase this rationale was revisited and a derogation for polymers with water solubility greater than 2 g/L was included as an additional derogation from the restriction. Background and justification for revisions on polymer solubility are provided in Sections 1.2.1, 2.2.1.1 and 2.2.1.7 of the Background Document and in Section B.1.1.4. of the Annex to the Background Document.

2.1.1.6. Natural polymers

In the Annex XV report, paragraph 3(a) referred to “Polymers that occur in nature that have not been chemically modified (other than by hydrolysis)”. This wording has now been changed to “natural polymers (as defined in the REACH Guidance for monomers and polymers) that have not been chemically modified (as defined in REACH Article 3(40)”.

The revised wording of paragraph 3(a) is closer to the original intention of the Dossier Submitter who had anticipated that any processing of a polymer obtained from nature could be derogated from the scope of the restriction as long as it did not result in chemical modification of the original polymer. The term ‘not chemically modified’ is set out in REACH Article 3(40) as “a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities”.

The derogation in paragraph 3(a)) “natural polymers that have not been chemically modified” are also elements of SUP Directive (2019/904). As the guidelines for SUP Directive is aimed at to be published in July 2020, there may be a need to ensure that alignment on the interpretation of these elements is made in both the microplastic restriction and the SUP Directive.

Further explanation on natural polymers has been provided in section B.1.1.10. Natural polymer of the Annex to the Background Document.

2.1.1.7. Swellable polymers

‘Swellable’ polymers are capable of absorbing water (or other liquid) in a quantity that can be several orders of magnitude larger than their original mass. During the absorption of the liquid the structure of the polymer changes to a gel-like structure.

Interpreting whether a swellable polymer meets the definition of a microplastic requires careful consideration, particularly if a derogation from the proposed restriction on the basis of conditions described in paragraph 5(b) (**permanent modification** at point of end use resulting in loss of microplastic form) is being considered.

view of the Dossier Submitter on ‘swellable polymers’ outlined in the Annex XV report was that these polymers would not fulfil the definition of a microplastic where they form gels in the presence of water (or other solvent) that are not comprised of particles. However, if a particulate form comprising solid particles is retained after swelling then

they are still considered as microplastics as long as the size of the particle does not exceed the relevant dimensions.

This concept has been further considered after the submission of the Annex XV report, and an elaborated interpretation is presented in Section B.1.1.9.4. of the Annex to the Background Document. This elaborated interpretation considers the potential for the reversibility of swelling, and the resultant recurrence of a particle with physical properties consistent with a microplastic, under certain conditions. This is particularly relevant to the interpretation of the derogation described in paragraph 5(b) of the conditions of the restriction, that requires the 'permanent modification' of the properties of a polymer at the point of end use such that it would no longer be considered to be a microplastic.

According to these considerations, the most straightforward way to assess whether a swellable polymer particle is a microplastic would be based on the 'original' physical state of the polymer particle prior to swelling taking place.

Therefore, the Dossier Submitter considers that an assessment of whether a swellable polymer meets the conditions of the proposed restriction should, initially, be based on their original physical state of the polymer particle.

2.1.1.8. Inorganic polymers

Respondents to the consultation requested clarification with regards to the status of 'inorganic polymers'. The microplastic definition used by the Dossier Submitter (throughout both the preparation and post-submission phases of the proposal) has consistently relied on the REACH definition of polymer, which includes all polymers. The polymer definition given in REACH does not differentiate substances based on the chemical composition, thus all polymers are included in the regulatory definition of 'microplastics' if all other criteria (such as size and water solubility) are met. The Dossier Submitter has addressed the case of 'inorganic polymers' in Section B.1 of the Annex to the Background Document.

2.1.1.9. Assessment of whether specific substances or materials are microplastics

Several respondents have provided information regarding substances or mixtures that they place on the market alongside an assessment as to whether they are 'microplastic' and on the applicability of the proposed derogations. The Dossier Submitter (or ECHA) does not endorse any assessment by a respondent of whether an individual substance or mixtures are microplastics according to the criteria included in the proposed restriction or whether or not specific derogations can be applied for these individual substances/materials in their specific uses.

2.1.1.10. Substances in articles – polymer fibres used in concrete and adhesive reinforcement

Some responders have raised the question whether polymer fibres used in concrete and adhesive reinforcement should be regarded as articles. The Dossier Submitter has

concluded, after taking all relevant considerations into account, that polymer fibres or filaments which are used in concrete and adhesive reinforcement materials for making objects of cured or dried reinforced composite or hybrid materials should be considered as substances or mixtures and not articles under REACH.

The polymer fibres or filaments, knitted or not, are used as a reinforcing ingredient in a mixture, before its final curing or drying process which leads to the production of an article (with a special shape) and provide distinct physical and mechanical properties to the composite or hybrid material, the final article is made of, in combination with other raw materials (e.g. wet cement for objects articles made of reinforced concrete; uncured or partially cured thermosetting mixture in certain polymeric reinforced articles).

This conclusion is coherent with the cases where inorganic fibres, which are substances under REACH, are used for similar applications.

Nevertheless, should fibre-like microplastics be considered as articles rather than substances or mixtures the wording of the restriction can be amended in due course to ensure that these types of articles are within the scope of the restriction.

2.1.2. RAC Rapporteurs comments

RAC considers that increasing the lower size limit to 100nm may lead to regrettable substitution to particles with smaller size, potentially compromising the effectiveness of the proposed restriction. The omission of polymer nanoparticles <100 nm from the scope of the restriction could potentially allow the continued use of nano-scale polymer particles consistent with the microplastic concern, or promote innovation to smaller particle sizes to circumvent the restriction.

Taking into account hazard and analytical practical issues RAC considers that the lower limit established for the purposes of a restriction should be the smallest size which can be measured today and, assuming analytical progress, the future. In this case, a lower limit is not appropriate and RAC has concluded that no lower limit should be set for particles and fibres in the microplastics definition (more details on RAC analysis can be found in the opinion document).

RAC rapporteurs are of the opinion that water soluble polymers should not be considered to fulfil the microplastics definition.

For the other issues, RAC rapporteurs agree with the comments made by the Dossier Submitter. The RAC analysis could be found in the opinion document.

2.1.3. SEAC Rapporteurs comments

SEAC rapporteurs agree with the comments made by the Dossier Submitter. For most general issues SEAC's analysis can be found in the opinion document.

SEAC rapporteurs wish to state the following in regards to the lower size limit of the microplastics definition: "*SEAC [Rapporteurs] notes [note] that a definition should delineate a group of substances with similar concern/hazard and therefore should not take*

into account considerations regarding enforceability and practicality. Difficulties in relation to determining the size of submicron particles, should be dealt with through adequate targeting of the restriction rather than modifying the underlying definition of a microplastic."

2.2. Scope of the proposed restriction

2.2.1. Dossier Submitter response to comments

Multiple comments on the scope of the proposed restriction were submitted by sector associations, companies and NGOs. These included for example comments #2043, #2044, #2056, #2058, #2069, #2073, #2074, #2082, #2102, #2106, #2115, #2117, #2118, #2119, #2126, #2131, #2139, #2152, #2153, #2163, #2182, #2187, #2188, #2192, #2193, #2194, #2199, #2204, #2209, #2221, #2230, #2237, #2254, #2365, #2380, #2382, #2412, #2432, #2435, #2447, #2448, #2467, #2476, #2503, #2506, #2515, #2516, #2539, #2541, #2542, #2543, #2544, #2547, #2556, #2557, #2575, #2590, #2609, #2623, #2725, #2631, #2645, #2646, #2647, #2651, #2670, #2690, #2691, #2693, #2696, #2704, #2719, #2726, #2728, #2738. Some of the comments have been handled as confidential as per the respondent's request.

Most of the comments submitted referred to the breadth of the restriction scope and to the derogation set in paragraph 4a for 'uses at industrial sites'.

With regard to the breadth scope, on one hand some respondents welcomed the scope of the restriction proposal whilst other respondents indicated that they would favour a restriction based on a definite list of polymers. Those respondents argue that the scope of the restriction would be easier to understand, and to apply, if a list of polymers/substances would be specified rather than a microplastic definition.

The Dossier Submitter acknowledges that the scope of the restriction proposal is indeed broad, nevertheless it is targeted to the microplastics concern in the environment and is consistent with the mandate from the Commission requesting the restriction proposal. The option to list polymers or substances was discarded by the Dossier Submitter during the preparation of the Annex XV report as it was considered to have limited risk reduction potential and could lead to regrettable substitution.

Finally, to clarify the scope of the proposal and more specifically the derogation under paragraph 4a, the definition of 'industrial site' has been further explained in section F of the Annex to the Background Document and in the Q&A on 'restriction proposal on intentionally added microplastics'. The obligations associated to derogation 4a, i.e. the reporting requirements and the 'instructions for use and disposal' are further detailed in sections 2.16 and 2.17 of this RCOM.

2.2.2. RAC Rapporteurs comments

RAC rapporteurs agree with the Dossier Submitter regarding the scope of the restriction and the proposed modifications made during opinion development (e.g. 'industrial sites', instructions for use and disposal, reporting). For more specific information please refer to the RAC opinion.

2.2.3. SEAC Rapporteurs comments

SEAC rapporteurs agree with the Dossier Submitter. SEAC agrees in general with the scope of the restriction as proposed by the Dossier Submitter including the modifications and refinements made during opinion development (e.g. 'industrial sites', instructions for use and disposal, reporting). SEAC agrees with the wide coverage of the restriction since it is needed to cover the identified risks. For more specific information please refer to the SEAC opinion.

2.3. Hazard and risk

2.3.1. Dossier Submitter response to comments

Multiple comments were submitted by sector associations and companies. These included for example comments #2021, #2026, #2042, #2056, #2073, #2074, #2075, #2085, #2091, #2093, #2105, #2106, #2119, #2160, #2168, #2182, #2193, #2205, #2212, #2242, #2243, #2254, #2358, #2383, #2445, #2467, #2493, #2495, #2508, #2521, #2532, #2550, #2558, #2595, #2609, #2637, #2645, #2651, #2678, #2679, #2680, #2689, #2692, #2723, #2725. Some of these comments have been handled as confidential as per the respondent's request.

The Dossier Submitter has grouped the comments received into two broad categories:

2.3.1.1. Assessing the hazard and risks of intentionally-added microplastics.

Some comments argue that the Annex XV report does not demonstrate any hazard or risk, or that release and persistency in the environment cannot be a proxy for risk. The Dossier Submitter considers that evidence on the hazard and risk of microplastics have been described in section 1.4 of the Annex XV report and are supported by a comprehensive and extensive literature review of the potential ecotoxicological effect of microplastics as well as the releases estimates from multiple sources.

The Dossier Submitter recognises that although there are uncertainties in the understanding of the hazard of microplastics, a number of adverse effect are associated to their intrinsic properties. With regard to the risk assessment approach, the Dossier Submitter considers that the case-by-case approach described in the Annex XV report is relevant to address the microplastics concern.

2.3.1.2. Impact of the proposed restriction on plastic pollution.

The Dossier Submitter notes that on one hand, some comments argue that the microplastic pollution is negligible when compared to the plastic in general. On the other hand, some other comments welcome the proposed restriction that *"would be a significant step forwards in addressing the issue of microplastic pollution, transferring responsibility from downstream treatment processes to upstream sources of pollution".*

No update of the Annex XV report content has been made based on the comment received.

2.3.2. RAC Rapporteurs comments

2.3.2.1. Assessing hazard and risks of microplastics

RAC rapporteurs agrees with the Dossier Submitter that evidence on the hazard and risk of microplastics have been extensively described in section 1.4 of the Annex XV report. RAC detailed discussion on the issue can be found in the opinion document.

Despite the uncertainties in the scientific literature, most of the studies have documented ecotoxic effects of MPs at different level (cellular/tissue, individual, population) in a variety of aquatic and terrestrial organisms. In addition, according to a report published in January 2019 by SAPEA (Science Advice for Policy by European Academies), the precautionary principle should be applied to MPs due to the combination of different factors, not limited to their persistence. Also, many studies underscore that contamination will likely continue to increase into the foreseeable future making the exposure of organisms largely unavoidable.

With regard to risk assessment approach, RAC agrees with the Dossier Submitter that microplastics should be considered as non-threshold substances (PBT-like). However, PBT assessment under REACH, specifically the concept of bioaccumulation as detailed in Annex XIII of REACH, cannot be applied to particulates like microplastics. Therefore, the case-by-case approach is the only method that can be applied.

2.3.2.2. Impact of the proposed restriction on plastic pollution

RAC rapporteurs note that the environmental releases of secondary microplastics from plastic articles are larger than those of intentionally added microplastics. However, the estimated releases of intentionally added microplastics to the environment range between 36 000-42 400 tonnes per year. Taking into account the stock effect associated with microplastics, these amounts cannot be considered negligible, and pose a relevant hazard for the environment. Accordingly, a reduction of releases from intentionally added microplastics, estimated of about 500 000 tonnes over 20 year period, is considered significant.

Due to their lower size, intentionally added microplastics are much more bioavailable to living organisms compared to bulk plastics and therefore they are expected to cause more severe effects than an equivalent quantity of bulk plastic.

RAC detailed discussion on the issue can be found in the opinion document.

2.3.3. SEAC Rapporteurs comments

As these issues are within RAC's remit, SEAC does not have any comments.

2.4. Derogation for (bio)degradable polymers

Additional information on the proposed derogation for ‘polymers that are (bio)degradable’, as set out in paragraph 3(b) of the proposed conditions of the restriction, was requested in specific information request 1 of the consultation.

2.4.1. Dossier Submitter response to comments

Around 80 comments were received on the proposed approach for establishing if a polymer can be considered as (bio)degradable as detailed in Section 2.2.1.6 of the Annex XV report (Appendix X). For example, comments #2008, #2014, #2035, #2041, #2080, #2093, #2098, #2115, #2120, #2125, #2126, #2129, #2135, #2149, #2153, #2158, #2160, #2180, #2186, #2201, #2236, #2238, #2239, #2278, #2343, #2361, #2377, #2383, #2388, #2389, #2390, #2399, #2400, #2406, #2408, #2422, #2430, #2433, #2437, #2442, #2492, #2497, #2501, #2507, #2548, #2551, #2554, #2559, #2562, #2565, #2568, #2576, #2578, #2581, #2582, #2599, #2600, #2606, #2609, #2612, #2613, #2623, #2637, #2641, #2642, #2652, #2660, #2674, #2680, #2682, #2685, #2693, #2699, #2707, #2708, #2712, #2727, #2732 and #2743

These comments provided feedback on the proposed approach, test methods and pass/fail criteria. The majority of the comments supported setting the criteria for (bio)degradability. However, some modifications to the criteria were suggested, including the permitted test methods and on the choice of appropriate test material.

The Dossier Submitter has grouped comments into the following categories: (i) general comments on the proposed criteria, (ii) proposed test methods and related thresholds (iii) test and reference material and (iv) transitional period(s).

Several respondents have provided information regarding the (bio)degradation properties of the substances or mixtures which they place on markets and on the applicability of proposed derogation. The Dossier Submitter (or ECHA) does not endorse any assessment by a respondent of whether an individual substance or mixtures are (bio)degradable according to the criteria included in the proposed restriction or whether or not specific derogations can be applied for these individual substances/materials in their specific uses.

2.4.1.1. General comments on the proposed criteria

For example, comments #2080, #2139 #2160, #2161,#2167, #2215 #2236, #2241, #2399, #2408, #2430, #2437, #2442, #2600, #2609, #2613, #2623, #2624, #2648, #2652, #2660, #2682, and #2707.

The Dossier Submitter notes that even if the large majority of the comments expressed their general support for setting the criteria for (bio)degradability, there were also a diverging opinion expressed in some comments that a complete ban on microplastics should be pursued regardless of their biodegradation potential. Similarly, the proposed criteria for demonstrating (bio)degradation where seen as stringent by some respondents but not stringent enough by others. There was general agreement on the range of the proposed test methods although some respondents proposed modifications. There was also request to clarify the basis for the proposed criteria for (bio)degradability. Comments on the test methods are addressed in Section 2.4.1.2.

The proposed testing approach was supported in general, but a need for further clarity on the testing strategy was frequently requested. Respondents noted that the proposed criteria were not based on “real” environmental conditions or required data for all environmental compartments. Several respondents proposed that a weight of evidence

(WoE) approach should be incorporated into the assessment framework. Abiotic degradation (hydrolysis, photo-degradation, oxidative degradation) and anaerobic degradation were also proposed by some respondents as additional, or alternative, assessment endpoints.

The scarcity of information on the biodegradation of microplastics was raised, as well as an acknowledgement that characterisation of the biodegradation of microplastics is an emerging field of research. Regardless, it was seen as important by some respondents to avoid short-term changes in any adopted criteria for biodegradability and permitted methodologies to allow industry to gain experience in their performance and requirements.

In terms of the requirement for laboratory accreditation / quality assurance, many respondents requested that GLP certification should be included as an alternative to ISO 17025 accreditation as they have similar requirements and GLP is already accepted under other REACH processes as well as for biodegradation testing under the EU Detergents Regulation.

After considering these comments, the Dossier Submitter has updated the Background Document as follows:

- Additional text further outlining the rationale for the proposed criteria for (bio)degradability has been added to Section 2.2.1.6.

- The term ‘tiered testing strategy’ was removed and the text in Table 22 has been clarified to better indicate that if one or more of the pass criteria for the methods included in groups 1-4 are met then the test material can be considered to be (bio)degradable. If the pass criteria are not achieved in test from groups 1 to 4 then tests from group five may still be performed to demonstrate (bio)degradability.

- Laboratory accreditation requirements were revised to allow either ISO 17025 or GLP.

To provide clear and enforceable criteria for the derogation, the Dossier Submitter has declined to include a weight-of-evidence approach or any non-standardised testing method in the criteria.

2.4.1.2. Test methods and related thresholds

For example, comments #2047, #2093, #2139, #2160, #2161, #2164 #2167, #2215, #2236, #2241, #2383, #2388, #2389, #2399, #2400, #2406, #2408, #2422, #2437, #2442, #2443, #2492, #2497, #2582, #2582, #2596, #2600, #2612, #2613, #2624, #2660, #2681, #2682, #2690, #2693, #2729.

Screening tests (groups 1-4)

The test methods and pass/fail criteria listed in groups 1 to 4 were generally considered by respondents to be sufficient to demonstrate the intrinsic property of biodegradation.

Many of the comments reflected the fact that, as proposed, the methods described in groups 1 to 4 would allow a polymer to be considered as (bio)degradable as long as it would pass the listed criteria in at least one of the methods proposed in groups 1 to 4. Respondents noted the conservative nature of the screening level tests (included in groups 1 to 3) and that incomplete biodegradation of some natural polymers such as seeds, waxes and leaves is frequently observed in these test systems. Respondents therefore proposed several modifications to the test conditions in screening methods (groups 1 to 3) to account for their inherent conservatism, including an extension of the test durations, lowering the required level of degradation to achieve a pass result or removing the requirement for the observation of the lag-phase of (bio)degradation to be observed.

Some respondents proposed to remove certain test(s) that they did not consider to be applicable for assessing polymer particles whilst others suggested to include additional test methods.

For the methods listed in group 4 (ISO test methods) it was proposed to change the proposed wording in Appendix X from “and” to “or” to clarify that, as intended by the Dossier Submitter, passing one test from among the permitted test methods would be sufficient to derogate a polymer from the proposed restriction.

After considering these comments, the Dossier Submitter has updated the Background Document as follows:

- OECD TG 302B was removed from the lists of permitted test methods (as it requires the measurement of dissolved organic carbon, which is incompatible with solid polymer particles as test material).

- OECD TG 302C pass/fail criteria were modified by removing the requirement for a lag phase of three days.

- The text associated with the group 4 (ISO) test methods was modified from ‘and’ to ‘or’ to indicate that passing one test from among the permitted test methods would be sufficient to demonstrate the biodegradability of a polymer for the purposes of this restriction.

Further modification of the duration and conditions of the test methods in groups 1 to 3 was not made. This was to ensure consistency with other REACH processes and acknowledges that the ISO methods, specifically developed for assessing the biodegradation of polymers, in group 4 can be used where incomplete biodegradation of polymers is observed in the tests in groups 1 to 3.

Higher tier assessment (simulation study) methods (group 5)

The general view of respondents was that the test methods for higher tier assessment included in group 5 (OECD TGs 307, 308 and 309), were technically challenging to perform and difficult to interpret.

Respondents proposed that these methods were either removed from the assessment framework or considered as optional. Respondents suggested that modifications to the conditions of the permitted test methods in group five should be allowed due to specific properties of microplastics. The Dossier Submitter notes that tests in group 5 are intended to be optional if biodegradability can be demonstrated by using the test methods and pass criteria included in any of the tests included in groups 1 to 4. Group 5 tests may be used to demonstrate (bio)degradability if positive results are not obtained using the test methods and criteria included in groups 1 to 4. The proposal already explicitly acknowledges that there is limited experience in interpreting the degradation half-life of microplastics in simulation tests by stating that results should be interpreted with caution.

Some respondents considered that the term “higher tier”, in relation to the group 5 test methods, was not appropriate as it refers to (semi-)field studies. The Dossier Submitter has replaced the term “higher tier” in the Background Document.

When considering the proposed pass/fail criteria for use in simulation studies (vP criteria from Annex XIII), responses varied between considering the pass level to be overly stringent (too short) to not sufficiently ambitious (too long). Some comments proposed that the “P” criteria set in REACH Regulation Annex XIII should be used instead of the vP criteria proposed by the Dossier Submitter. The Dossier Submitter considers that current pass level is appropriate as derogation 3(b) is underpinned solely on the basis of polymer persistency and not a combination of persistence, bioaccumulation and toxicity and thus did not change the proposed pass level for group five test methods.

Relevant test conditions and environmental compartments

The screening tests in groups 1 to 3 were considered by the majority of respondents to be conservative (i.e. difficult to pass) and, therefore, that a positive result would indicate that (bio)degradation would occur in the environment, irrespective of considerations around specific environmental compartments; they are ‘compartment independent’.

Achieving the pass criteria in a screening level test in groups 1 to 3 were interpreted, in line with the view of the Dosser Submitter, to be predictive of rapid biodegradation potential in a simulation test or the environment, noting that existing regulatory schemes in almost every jurisdiction (EU REACH, US, Canada, Japan, China, etc.) rely on screening tests to predict the biodegradation that would be observed in simulation studies and in the environment. Therefore, a pass in any standard screening test would address the potential for extreme persistency in the environment or “microplastic concern” that is intended to be addressed by the proposed restriction.

Although the various ISO test methods included in group 4 correspond, intuitively, to specific environmental media (e.g. water, soil, sediment), respondents did not consider them to be equivalent to simulation methods but rather as similar to the screening tests included in groups 1 to 3. This was because the test substance concentration in ISO test methods are many orders of magnitude greater than those specified in simulation tests.

The Dossier Submitter agrees that the ISO methods in group 4 should be considered as compartment independent screening tests and, therefore, that a positive test result (pass) in one test in group 4 would be sufficient to meet the criteria for derogation from the proposed restriction.

Respondents highlighted that when biodegradation is tested it is important to consider the influence of environmental conditions and compartments. Different respondents expressed a variety of opinions on the best means to account for this variability when assessing the biodegradation of microplastics ranging from suggesting that testing should be performed using multiple methods indicative of all environmental compartments (with pass criteria achieved in all tests) to requiring that only the most relevant environmental compartment was assessed and pass criteria achieved. It was noted that the pass/fail criteria proposed for the simulation tests in group 5 (60 days for water versus 180 for soil and sediment) account for the expected differences in the degradation rate between different environmental compartments.

The Dossier Submitter has reviewed and taken into consideration the comments received. The Dossier Submitter has clarified in the Background Document that soil the most relevant test compartment for microplastics that are deliberately applied to soil or foliage and that tests indicative of this compartment must be used from groups 4 or 5 (where these are required i.e. when positive (pass) results are not obtained using the conservative screening test methods included in groups 1 to 3).

However, mandatory testing of all environmental compartments when group 4 of 5 test methods were applied was not introduced as a requirement by the Dossier Submitter. Such a requirement was considered to be unnecessary to demonstrate that a polymer was sufficiently (bio)degradable to be derogated from the proposed restriction.

Suggestions to include additional test methods

Some respondents suggested that additional test methods or approaches should be added to the permitted tests methods listed in Appendix X. The following methods and approaches were proposed:

- ISO 22404:2019 Plastics - Determination of the aerobic biodegradation of non-floating materials exposed to marine sediment - Method by analysis of evolved carbon dioxide with pass/fail criteria mineralisation of 90% in 2 years (absolute or relative to the reference material, cellulose);

- Draft ISO/CD 23977- 1/-2 Plastics -- Determination of the aerobic biodegradation of plastic materials exposed to seawater --Part 1: Method by analysis of evolved carbon dioxide/ Part 2: Method by measuring the oxygen demand in closed respirometer;

- Simulation tests to assess the biodegradability of chemicals discharged in waste water and sewage sludge simulation (OECD TG 314B, OECD TG 314C and OECD TG 303A);

- Marine BODIS (modified ISO/TC 147/SC 5 N141);
- Methods for compostable plastics (EN 13432);
- Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:2010) in combination with Biological evaluation of medical devices -- Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9: 2009);
- Accelerated biodegradability methods to reduce study duration (e.g. accelerated biodegradation test in soil at 37 °C[2]);
- Further higher tier tests (disintegration and field tests);
- Additional tier for modified natural polymers;
- Modelling tools, QSAR.

The suggestion to include (bio)degradation tests simulating sewage treatment plant or composting process were not considered to be appropriate methods to assess the potential for (bio)degradation of microplastics in the environment. This was on the basis that they assess the degradation potential under highly artificial conditions (e.g. wastewater treatment or industrial composing) and not under conditions representative of the natural environment. Such tests are not permitted to be used for PBT/vPvB assessment under REACH for the same reason. Similarly, the test method for the evaluation of the degradation of medical devices was not considered to be appropriate. The Dossier Submitter notes that articles, such as many medical devices, are not within the scope of the proposed restriction.

In terms of chemical modified natural polymers, the Dossier Submitter notes that these substances can already be tested using the methods proposed in Appendix X. No further modifications to Appendix X are considered necessary by the Dossier Submitter to accommodate these types of polymers within the context of a restriction on intentionally-added microplastics. The Dossier Submitter considers that chemically modified natural polymers should have a half-life in the environment <vP criteria, irrespective of the half-life of the unmodified natural polymer.

In terms of QSAR or modelling approaches, the Dossier Submitter notes that there are currently no validated tools that could be used to predict the (bio)degradation potential of polymers in the environment. On this basis they have not been included in Appendix X by the Dossier Submitter.

As a general principle, the Dossier Submitter considers that only European or internationally standardised methods (e.g. EN, ISO or OECD methods) should be included in Appendix X, which would preclude the inclusion of some of the methods

[2] Šerá J., Serbruyns L., De Wilde B., Koutný M. 2020. Accelerated biodegradation testing of slowly degradable polyesters in soil. Polymer Degradation and Stability, 171.

proposed, including the novel accelerated test methods, by default, at least for the time being.

Therefore, despite the numerous suggestion for modification received in the consultation, Appendix X of the Background Document has only been updated by the Dossier Submitter to include the recently published ISO 22404 (2019) method in group 4 of the permitted test methods.

Nevertheless, the Dossier Submitter considers, as stated already in the restriction proposal, that scientific progress is foreseen regarding the methods for assessing biodegradation of microplastics. Currently permitted test methods, with modifications based on the received comments, are considered by the Dossier Submitter to serve as a good basis to predict the biodegradation behaviour of microplastics. When further experience on the applicability and performance of methods is available in the future (potentially on the basis of testing performed for the purposes of demonstrating compliance with this restriction) the list of permitted methods could be revisited and revised, where appropriate.

2.4.1.3. Test and reference material

For example, comments #2080, #2093, #2215, #2236, #2437, #2442, #2443, #2497, #2600, #2609, #2690, #2693, #2707, #2729

Several comments addressed the test material description presented in Appendix X (Table 22 of the Background Document), including the selection of reference material and the complexity of assessing the biodegradability of microplastics containing multiple polymeric components (hereafter termed ‘blends’). Specific comments were provided on testing polymers used for encapsulation.

The Dossier Submitter has reviewed and taken into consideration the comments received. Appendix X has been updated in order to increase both the clarity and flexibility permitted when selecting test material for biodegradation testing.

In the updated Background Document it is stated that the test material should be comparable, in terms of composition, form, size and surface area, to the particles as produced or disposed/released to the environment. Furthermore, polymers used for encapsulates may be tested taking into account the thickness of the coating in the form placed on the market, as isolated coating or placed on inert material.

Comments comprised a diversity of opinions on the relevance of testing only the polymeric component versus testing all the constituents separately. The Dossier Submitter notes that criteria as presented in the Background Document already state that microplastic shall not contain additives that meet the criteria for PBT/vPvB set in Annex XIII under REACH Regulation No 1907/2006.

In addition to the criteria set for the additives, the proposed criteria take into account both the biodegradability of the embedded polymeric component and the physical form of the microplastic both having an effect on the observed biodegradation (as

biodegradation of plastics is acknowledged to be a surface-area limited reaction). Some of the comments received raised a concern that non-biodegradable polymers could be present in microplastics that pass the criteria if the microplastic particle(s) consists of more than one polymeric component. The Dossier Submitter agrees that testing the biodegradability of a blend of polymeric components is challenging. Therefore, the Background Document was updated to introduce a specific scenario for testing microplastics consisting of polymer blends to ensure that all polymeric material is demonstrated to be biodegradable.

A proposal for the use of alternative reference materials, such as natural polymers and lignin, were introduced in some of the comments. The Dossier Submitter notes that reference materials, where applicable, are dependent on the standard test guidelines and due to the lack of knowledge of more appropriate reference materials within these test guidelines, no changes were introduced. However, according to the test guidelines the form and size of the reference material may be tailored to correspond the test material.

2.4.1.4. Transitional period(s)

For example, comments #2047, #2164, #2167, #2201, #2236, #2389, #2577, #2588, #2624, #2647

Some comments included proposals to either shorten and extend the proposed transition periods for sectors where the development of biodegradable alternatives to microplastics is the most likely response to the proposed restriction i.e. cosmetics, encapsulation of fragrances, biocides or plant protection products.

The transitional periods recommended for the different sectors affected by the proposed restriction are dependent on various factors, not limited to the time required to develop biodegradable polymers. Respondents are directed to the response to comments relevant to specific sectors.

A respondent stated that it will take at least 5-6 years to reach ISO 17025 compliance and that flexibility should be allowed for development of new methods. As described, GLP certification was included as an alternative to ISO 17025 accreditation, addressing the concern raised by the respondent. The Dossier Submitter notes that ISO17025 or GLP quality assurance requirements are already required for biodegradation testing performed for to demonstrate compliance with the EU Detergents Regulation. As such, their necessity within this proposed is not considered to be disproportionate.

2.4.2. RAC Rapporteurs comments

RAC rapporteurs share the comments of the Dossier Submitter on what should be tested and the reference material. Nevertheless, different views are reported in the opinion document, especially on the relevance of the ISO tests in comparison with the OECD tests and their meaning regarding biodegradation occurring in the different environmental compartment. This is this different point of view that leads RAC to recommend a revised testing approach.

2.4.3. SEAC Rapporteurs comments

As these issues are within RAC's remit, SEAC does not have any comments.

2.5. Derogations 5a, 5b and 5c

2.5.1. Dossier Submitter response to comments

Several comments were submitted on the proposed derogations 5a, 5b and 5c. For example, comments #2073, #2087, #2108, #2110, #2118, #2121, #2127, #2172, #2179, #2182, #2220, #2205, #2221, #2382, #2406, #2434, #2459, #2491, #2505, #2510, #2515, #2520, #2527, #2544, #2548, #2574, #2609, #2613, #2614, #2675, #2680, #2695, #2700, #2713, #2714, #2734.

The Dossier Submitter notes that there was no strong disagreement with the proposal, but rather a request for further clarifications of what these derogations would mean in practice. Where relevant, information has been added and further developed in the Background Document (section 2.1.2), and in the Q&A to improve the clarity of the requirements of derogations 5a, 5b and 5c. The Background Document and the Q&A provide some concrete examples where Derogation 5a, 5b or 5c could be applicable. It clarifies for example that 'swellable polymers' could benefit from derogation 5b (cf. section B.1.3.9.4 of the Annex to the Background Document) if the swelling is 'permanent', and the properties of the polymer at the point of use such that it would no longer fulfil the microplastic definition.

Based on the comments received, the Dossier Submitter also further clarified in the Background Document (cf. section 2.2.1.2 of the Background Document) why the derogations 5a, 5b and 5c are intended to work together with the 'instructions for use and disposal' requirement (paragraph 7) and the reporting requirement (paragraph 8).

Finally, the Dossier Submitter took into account the comments received on the initial wording of the derogation 5a, and in particular the fact that (i) the treatment of solid waste is determined by the relevant EU, national and even local legislation, and that (ii) the hazardous waste incineration capacity might be limited in different Member States. Therefore, to avoid issues with some consumer articles and difficulties with describing microplastic waste as 'hazardous,' the Dossier Submitter revised the wording of this derogation for 'Substances, mixtures or articles where microplastics are contained by technical means to prevent releases to the environment during end use'. The reference to the 'incineration or disposal as hazardous waste' is removed from the restriction proposal and the Background Document.

The term end use was introduced to clarify that these derogations are intended when microplastics are present in substances/mixtures used by consumers and professionals. Uses of intentionally-added microplastics at industrial sites are already derogated under paragraph 4a.

2.5.2. RAC Rapporteurs comments

RAC agrees with the Dossier Submitter also regarding the modifications and clarifications

made as a consequence of the comments received.

2.5.3. SEAC Rapporteurs comments

SEAC agrees with the responses provided by the Dossier Submitter and also the changes and clarifications that were made as a consequence of the comments received during the Consultation.

2.6. Plant protection and fertilising products (incl. coated seeds)

2.6.1. Dossier Submitter response to comments

Comments were submitted by large sector organisations (the European Crop Protection Association, Euroseeds, formerly known as the European Seed Association, and Fertilizers Europe) as well as individual companies regarding the use of microplastics in the agricultural and horticultural sectors. These included, for example, comments #2008, #2013, #2028, #2041, #2047, #2082, #2100, #2113, #2116, #2144, #2150, #2157, #2164, #2168, #2171, #2182, #2222, #2224, #2227, #2371, #2400, #2431, #2475, #2488, #2602, #2611, and #2701. Some of these comments have been handled as confidential as per the respondent's request.

Some of the industry associations updated the information that had been previously submitted to the Dossier Submitter during the preparation of the proposal. Updates were based on new surveys or interviews undertaken following the publication of the Annex XV report. The most important changes made to the Background Document in response to these submissions can be summarised as follows:

- Tonnages: Based on a survey of members of Fertilizers Europe, industry provided updated and more specific tonnage information. Moreover, they informed that 95% of controlled release fertilisers (CRFs) sold in the EU will be subject to requirements set in the EU fertilising product regulation (EC) No 2019/1009. Based on this information, the Dossier Submitter recalculated the emissions expected from the use of both CE marked and non-CE marked fertilisers as well as from the use of fertiliser additives.

- Reformulation costs: the European Crop Protection Association (ECPA) provided information about reformulation costs based on the results of a survey to which 25% of its members responded. The Dossier Submitter took those cost estimates into account when revising the economic impact assessment presented in Annex D.4 to the Background Document.

- Transitional period: several stakeholder organisations provided comments during the consultation indicating that a transitional period longer than five years after entry into force was needed in order to achieve the substitution of microplastics with biodegradable polymers. ECPA, supported by Euroseeds (formerly ESA), provided a detailed justification for a longer transitional period for capsule suspension plant protection products, arguing that these would have to go through a lengthy re-approval process required by the EU plant protection

products regulation (EC) No 1107/2009 before they could be placed on the market. Considering ECPA's detailed explanations , and after confirming with DG Santé, the Dossier Submitter revised its proposal for the transition period for capsule suspension plant protection products from five years to eight years after entry into force. Annex D.4. to the Background Document provides further details.

- Definition: ECPA also raised some concerns with regard to the regulatory definition of microplastics proposed in the Annex XV report. Respondents are referred to Section 2.1 of this document for the Dossier Submitter's response to these comments.

2.6.2. RAC Rapporteurs comments

RAC rapporteurs agree with the comments made by the Dossier Submitter. They noted the information provided during the consultation and, where relevant, has taken it into account for its conclusions. The in-depth analysis can be found in the opinion document. In particular RAC rapporteurs considered the additional information and noted that the recalculated emissions reflect the application of the EU plant protection products regulation (EC) No 1107/2009.

RAC rapporteurs agrees with the Dossier Submitter that the transition period for capsule suspension plant protection products from five years to eight years after entry into force is more adequate.

2.6.3. SEAC Rapporteurs comments

SEAC rapporteurs generally agree with the comments made by the Dossier Submitter. SEAC rapporteurs have thoroughly analysed the information provided during the consultation and, where relevant, have taken it into account for their conclusions. SEAC rapporteurs' in-depth analysis can be found in the opinion document. SEAC rapporteurs agree with the Dossier Submitter that an eight year transitional period is justified by the time required for authorisation under EU plant protection products regulation.

2.7. Cosmetic products

2.7.1. Dossier Submitter response to comments

During the consultation on the submitted dossier, 61 comments were submitted concerning the proposed restriction on cosmetic products. As many of the submissions raised multiple topics laid out over several thousand pages, it is not possible to address each individual comment separately. Therefore, the following section attempts to summarise the main comments raised specifically related to the socio-economic impact of the proposed restriction on the cosmetics sector and resulting proportionality of the proposed restriction measures presented in Sections D.5.4 and D.5.5 in the Annex to the Background Document.

For comments from the cosmetics industry submitted on the topics of scope, definitions,

derogations under paragraph 5 of the proposed restriction wording, and impacts on the proposed labelling and reporting requirements, please see the relevant sections.

The following main themes can be identified in the submitted comments:

2.7.1.1. Socio-economic impacts of the proposed restriction are large

Many submissions expressed concerns that the impacts from the proposed restriction on the cosmetics industry are substantial. A few consultation submissions presented their assessment of the socio-economic impacts of the proposed restriction (comments #2220, #2361, confidential submissions), resulting in a cost-effectiveness for a restriction on rinse-off products in excess of €1 000 per kg of emitted microplastics per year, based on a 5-year timeframe of analysis, assuming that all costs associated with the restriction would occur annually within this period: reformulation, material, unemployment effects, profit losses, and performance loss. For leave-on, stakeholders reported values in excess of €10 000 kg/year.

The Dossier Submitter has recognised that the proposed restriction would have substantial impacts on the cosmetics industry. The Dossier Submitter noted the higher impact estimates submitted by industry and investigated the sources of the variations and their impact on the overall conclusions on the proportionality of the proposed restriction.

a) Saved or accelerated baseline reformulations:

The stakeholders do not take into account any coordination with baseline reformulations similar to the approach agreed by SEAC in the D4/5 opinion (ECHA 2016b) and recently reflected in the SEAC D4/5/6 opinion. As this is an approach agreed by SEAC, the Dossier Submitter is not proposing changes at this stage.

b) Higher assumed costs per reformulation:

The Dossier Submitter used the same cost per reformulation already employed in the D4/5 restriction proposal (CPI adjusted to 2017 values) which based their estimates on an RTI study (RTI 2002), i.e., €365 000 per major reformulation for rinse-off products and 1.5 times higher for leave-on products recognising their greater complexity due to the presence of more than one microplastic ingredient. Recognising that SMEs have limited resources, and in line with the RTI study, lower values were used for 50% of the estimated reformulations. The Dossier Submitter also discusses that the value of €365 000 per reformulation is nearly 2.5 times higher than the average cost of reformulating microbeads (as reported by industry survey) and 5.5 times higher than the estimated average R&D investment based on data on R&D investments by the cosmetics industry. (See section on Costs per reformulation in D.5.4.3 in the Annex to the Background Document for details.)

Several submissions mentioned that costs per reformulation would be higher than €800 000 per product (comments#2220, #2361, #2375, confidential submissions), at the same time other confidential submissions from large EEA-based cosmetics companies

placed the costs per reformulation even lower than the costs assumed by the Dossier Submitter for major reformulations by SMEs.

While the Dossier Submitter agrees that some reformulations would employ substantial resources, it concludes not to use larger values for major reformulations as an average cost per reformulation for the industry because of:

- the nature of other available information: To estimate the total reformulation costs incremental to the proposed restriction, the Dossier Submitter applies the discussed costs per reformulation to the incremental number of reformulations estimated on the basis of information from the CosmEthics database. The Dossier Submitter assumed that each product with unique barcode is a separate formulation. Therefore, a product whose barcode has changed overtime would be counted as a unique product more than once. In addition, same brand products that have very similar composition (e.g., different colour make-up) have unique barcodes and therefore, counted as unique required reformulations. It is likely that these reformulations would be undertaken as one reformulation case and not 20 with a total cost of 20*€550 000 as the analysis assumes.
- learning-by-doing: It is expected that over time, with increased experience in substitution of microplastics, the average cost per reformulation would decline. Furthermore, the industry has communicated that they do not replace individual ingredients (polymers) but mixtures in each impacted formulation, referring to core technologies used in several formulations. It is highly likely that once the core technology is reformulated for one of the formulations, there could be financial and other savings to adjust the formula of the remaining. Furthermore, the reformulation of core technologies may to a certain extent be centralised with suppliers of microplastic ingredients, allowing for a faster diffusion throughout the industry and savings on a per product reformulation basis.
- potential for double counting: the Dossier Submitter applies 1.5 times higher costs per reformulation (on what is already a significantly overestimated number of reformulations, see the discussion in section D.5.5.6 in the Annex to the Background Document) for leave-on cosmetics in comparison to rinse-off cosmetics and these are higher than the effective costs per reformulation used in the D4/5/6 dossier in recognition of the higher complexity to reformulate mixtures containing more than one microplastic ingredient. The approach of some stakeholders to reflect the complexity of the reformulations of all microplastics is to assume scaled-up cost per reformulation, while at the same time, scaling up the number of reformulations required on the basis of the number of microplastic ingredients contained in the mixture requiring substitution (e.g., given 10 mixtures containing four microplastic ingredients, stakeholders have assumed that the restriction would induce 20 incremental reformulations with total costs of 20 times their assumed cost per reformulation). This stakeholder approach is increasing the costs per reformulation and the number of reformulations at the same time and, thereby, reflecting twice the same issue: the complexity of the reformulation. The Dossier Submitter concludes that this approach produces estimates in the extreme case and leads to double counting. Nevertheless, the Dossier Submitter presents a detailed sensitivity analysis testing the effects of

higher costs per reformulation in section D.5.5.6 in the Annex to the Background Document.

c) Tonnage estimates: Submission #2220 suggests that as the majority of polymers are liquid (assumed fraction of 50% for simplicity) and that according to results of their survey, 19% of formulations contain film-forming polymers which are proposed to be derogated (paragraph 5b of proposed restriction), the estimated tonnages by the Dossier Submitter should be reduced by 40.5%. As explained in section D.5.1 in the Annex to the Background Document, in recognition that many of the uses of the polymers assumed to fall in scope of the High scenario may not meet the microplastic definition, the Dossier Submitter accounted for this crudely by reducing the tonnage of the High scenario by around 50%. As the objective of the Dossier Submitter was to investigate proportionality against an upper bound of potential impacts of the proposed restriction, such adjustment was not made on the estimated number of reformulations due to lack of information (such information was requested under Specific Question 6 – see below). The Dossier Submitter accepts the stakeholder's approach as another approach to address the issue of lack of information on polymers impacted by the proposed restriction, it disagrees that "these calculations should not be used to reduce the number of reformulation for the Central scenarios, which are only based on the number of alternative products present on the market." (comment #2220). If fewer polymers or fewer polymer uses (about 40% as estimated by the stakeholder) would be impacted by the restriction, the estimated number of formulations on the market containing microplastic ingredients would be lower than currently estimated on the basis of the High scenario by the Dossier Submitter. As a direct consequence, the estimated number of reformulations induced by the proposed restriction would also be lower. Furthermore, if fewer polymers/polymer uses are in the scope of the restriction, the average number of microplastic ingredients that would need to be substituted would also decline, thereby reducing the complexity of the reformulation and the expected average cost per reformulation.

d) Incremental net costs to society: Some submissions have attributed costs to the restriction which would also incur under the baseline (e.g. patent costs), or are sunk costs in economic terms: patent costs or manufacturing equipment for the microplastic technologies. Others have argued that supplier impacts should be added to the already estimated impacts by the Dossier Submitter. It is expected that demand for cosmetics (e.g. mascara) will continue after the entry into effect of the restriction and this demand would be supplied by microplastic-free products, thereby increasing the demand for microplastic-free ingredients and providing income for their suppliers. Therefore, if those suppliers are within the EEA – which is likely as the EEA has been a regulatory leader in the substitution of microplastic ingredients – the effect on microplastic product/ingredient suppliers may be at least partially compensated by gains of microplastic-free product suppliers. Hence, the net effect of the proposed restriction in the EEA would not be equivalent to the negative impacts of suppliers of microplastic products but would have to account for the sectoral opportunity gains that arise from the restriction of intentionally-added microplastics. When assuming similar profit margins and continued steady demand for cosmetics, the net effect on EEA society may not even be negative in the long run. Furthermore, some respondents have assumed that profit

losses will take place over the entire study period or the remainder of the study period after the transitional period. While these losses may materialise for individual companies, it is unlikely that those impacts would be net effects to society for an extended period of time. Once a critical mass of microplastic-free products is available on the market, assuming similar profit margins and similar demand for cosmetic products, the profit losses of microplastic-containing products would be compensated by gains made from microplastic-free products. The Dossier Submitter assumes that this would take place at the latest nine years after the entry into effect of the proposed restriction (or three full reformulation cycles for a typical cosmetic ingredient) for leave-on cosmetics as the share of microplastic-containing formulations in some cases is more than 70%.

e) Other relevant impacts are not quantified: The Dossier Submitter analysed the submitted information and reflected the costs of such impacts (if and where credible) in the analysis. Please see sections on Patent costs and Distributional and wider economic effects for Leave-on cosmetics in D.5.5.4 and D.5.5.5 in the Annex to the Background Document.

f) Differences in terms of expected effective date and duration of impacts: For example, profit losses in some submissions are assumed to begin from the entry into force of the restriction even though microplastic-containing products can be placed on the market until the end of the transitional period, respectively, four and six years under the existing proposal and thus, such profit losses cannot be directly attributable to the proposed restriction.

2.7.1.2. Longer transitional period for rinse-off cosmetics

Several stakeholders requested a longer transition period for rinse-off cosmetic products, e.g., comments #2068, #2107, #2137, #2210, #2215, #2220, #2266, #2375, #2547, #2678, #2726, confidential submissions). Most of these submissions recommended that the transitional period is extended to 8 to 10 years or longer, while others did not specify a period. The submissions in most cases did not include a quantitative or qualitative justification for the need for a longer review period. A notable exception is submission #2220 that resubmitted partially modified information from ECHA CfE 2018 and a critical review of the Dossier Submitter's analysis (See point A above).

The reasons brought up in support of the requests for a longer transitional period include:

- Lack of alternatives and longer period required to reformulate
- Insufficient time for stability testing and the technical time for a shelf-life test (between 30 and 36 months) is to be added to the transitional period
- Significant pressure on industry, in particular SMEs.
- At the same time some submissions (e.g., comments #2024, #2075, #2112, #2155, #2161, #2168, #2180, #2201, #2372, #2575, #2690, confidential submissions) raised the opposite concerns, e.g.:
- The transitional periods for cosmetics are too long and emissions to the environment need to be addressed sooner

- Alternatives are available and some submitters provided reports that they do not use microplastics or are able to transition to microplastic-free alternatives within the transitional period

The Dossier Submitter took the following information into account in the recommendation of the 4-year transitional period for rinse-off cosmetic products:

- The length of activities required for a typical reformulation: 2.5 to 4.5 years according to https://www.cosmeticsinfo.org/product-reformulation, for the following activities: 12-18 month for raw material research and development, 6-12 months product testing and qualification, 6-12 months safety and regulatory requirements, 6-12 months manufacturing and marketing, post-market surveillance and evaluation. The Dossier Submitter notes several submissions that have provided alternative/longer timelines for the reformulation process spanning similar activities.
- Information that there are non-polymeric ingredients on the EEA market, biodegradable alternatives are emerging, and that there are a large number of formulations that do not contain any of the 500+ polymers tracked for the purpose of the High Scenario (on average about 70% of the formulations in the CosmEthics database, ranging from 42% to 97% for different rinse-off categories). (See section D.5.4.2 in the Annex to the Background Document.)
- Information from ECHA CfE 2018, partially modified for the purpose of (#2220), which stated that it will take on average five years to transition to alternatives (assumed an average for rinse-off and leave-on cosmetics) and that “using alternatives should be possible in a couple of years, when opacifiers that behave like microplastics might be replaced.”
- Emissions to the environment from rinse-off cosmetics and their overall contribution of emissions of intentionally added microplastics;
- Other stakeholders’ readiness to comply with the restriction in addition to industry whose readiness is dependent on their ability to transition to alternatives (e.g. enforcement authorities to put in place the necessary protocols to monitor the compliance with the restriction).
- Cost-effectiveness, non-monetised impacts of the restriction, practicality and monitorabilty of the proposed restriction.
- With respect to the last point, the Dossier Submitter notes that industry representatives have calculated a lower cost-effectiveness of the restriction (more than €1 000 per kg of emitted microplastics per year). The Dossier Submitter maintains that there are no strong cost-effectiveness justifications for a longer transitional period as even if the negative impacts of the restriction are 100 times higher than the estimated by the Dossier Submitter i.e. even higher than estimated by industry as the cost-effectiveness continues to be comparable to already adopted restrictions on substances of environmental concern.

There may however be arguments for a longer transitional period with respect to the practicality of the restriction, in particular its manageability for SMEs if all rinse-off and leave-on categories are in the scope of the proposed restriction. Please see the discussion below on impacts on SMEs. As RAC concluded that due to the persistent

nature of microplastics, all emissions to the environment need to be minimised and as each additional year of transitional arrangements would lead to an annual increase of the stock of microplastics in the environment, the Dossier Submitter concludes that strong justifications are needed to support a longer transitional period.

As stated above, the Dossier Submitter considered 6-12 months stability testing in the setting of the review period. This is fully consistent with Cosmetics Europe recommendation that “Accelerated tests, developed because of the relatively short development cycle for cosmetic products, enable the prediction of stability. A commonly accepted practice is to support the forecasts obtained from accelerated stability testing by carrying out periodic post-launch monitoring of retained samples stored at ambient temperatures. The resultant information can also be useful in further improving the product and in refining the methodology used for accelerated stability testing.” The Dossier Submitter hence concludes that, while there may be an argument to extend the transitional period by an additional two years to reflect the total time needed for stability testing, none of the stakeholders requesting such extension provided sufficient justification, including information on the required tests, their duration, whether this considers the possibility for accelerated testing, and why accelerated testing is not appropriate for microplastics when it is recommended for other ingredients.

2.7.1.3. Derogation for leave-on products

Several submissions expressed concerns with the proportionality of the proposed restriction on leave-on products, industry’s capacity to be able to handle so many reformulations, the lack of alternatives, and that six years is insufficient to reformulate. E.g., comments #2085, #2093, #2107, #2137, #2155, #2210, #2220, #2358, #2361, #2375, #2547, #2586, #2588, #2635, #2678, #2738, confidential submissions. Other submissions argued for longer transitional periods: in excess of 12 years, while yet others discussed how a few leave-on cosmetic product groups could be reformulated within the transitional period but others would require more than 12 years. Some respondents argue that the transitional periods proposed by the Dossier Submitter are already too long, e.g. #2075, #2121, #2201, #2372, #2575. While the majority of the submissions provided brief qualitative statements for a derogation, other submissions such as #2220, #2361 and confidential submissions, provided detailed quantitative and qualitative justifications.

The Dossier Submitter recognised in its analysis that the leave-on cosmetics sector has one of the lowest contributions to the emissions of intentionally added microplastic to the environment, while it would have to face the highest cost per kg of emissions reduced. The Dossier Submitter also highlighted that some groups of leave-on cosmetics (make-up, lip and nail leave-on products) could bear a larger cost than other product groups while they contribute less emissions to the environment than some of the other sectors in the scope of the proposed restriction. See section D.5.5.7 in the Annex to the Background Document for details and the Dossier Submitter’s discussion on the proportionality of an alternative action on leave-on cosmetics. At the time of dossier submission, these conclusions were associated with considerable uncertainty related to which polymer uses are impacted by the proposed restriction. This uncertainty to a large degree remains despite attempts by the Dossier Submitter to gather additional

information via the consultation (See section on response to Specific Question 6.).

Using the assumptions made by stakeholders (e.g. comment #2361, confidential submissions, also see Section 2.7.1.1 above) for sensitivity purposes shows low overall proportionality for the leave-on cosmetics and the cost-effectiveness falls within the so-called “grey zone” where action on environmental pollutants of between €1 000 and €50 000 per kg of emission avoided may or may not be approved by regulators (Oosterhuis et al., 2017). The disadvantage of the introduction of instructions for use for such products is that it would likely not eliminate emissions from these products, although it would lead to a decline in emissions sooner (from 2024 if similar to other proposed instructions for use requirements) and allow for a subsequent action if emissions do not decline should the restriction be reviewed after five years (as proposed).

As presented in the section D.5.5.7 in the Annex to the Background Document, the Dossier Submitter concludes that a ban on the remaining leave-on categories (excluding make-up, lip and nail products) has a cost-effectiveness comparable to the cost-effectiveness of the recently adopted restriction on D4/5 in wash-off cosmetic products. These categories of other leave-on cosmetics account for less than 40% of the total restriction costs for the proposed ban on the placing on the market of leave-on products and more than 70% of the leave-on emissions to the environment.

2.7.1.4. The Dossier Submitter has assumed that there are alternatives

Several stakeholders expressed concerns that in their analysis the Dossier Submitter has assumed that there are alternatives for all uses of microplastics. (E.g., comments #2168, #2172, #2220, #2361, confidential submissions). While many of the submissions did not provide supporting information, comment #2220 referred to a survey of their membership which showed that for 85.5% of the formulations there are no readily available alternatives. At the same time, several stakeholders spoke of the availability of alternatives, e.g., comments #2024, #2075, #2372, #2375, #2575, confidential submissions).

For all sectors in the scope of the proposed restriction, where there are known alternatives, such as for rinse-off cosmetics with exfoliating or cleansing functions, the Dossier Submitter has not proposed a transitional period. Instead, the proposed ban on the placing on the market is to enter into effect from the entry into force of the proposed restriction.

For uses for which the Dossier Submitter has recognised that it will take time to identify and transition to alternatives e.g. other rinse-off and leave-on cosmetics, the Dossier Submitter has proposed a transitional period. The length of the transition period was selected on the basis of an evaluation of several factors: please see point B above.

At the same time, the Dossier Submitter cannot ignore information demonstrating that there are:

- Non-polymeric cosmetic ingredients for all microplastic functions: a review

(Bertling et al., 2018) of the CosIng database showed that the only two functions where polymers represent more than 80% of all registered ingredients are film-forming (derogated from paragraph 1 of the proposed restriction) and skin conditioning;

- Polymer- or microplastic-free formulations are available on the market in all categories of cosmetic product categories: this is demonstrated by several certification programmes for cosmetic products as well as databases that track cosmetic ingredients. Such databases reveal that for the majority of cosmetic product categories, those containing polymers are less than 50%. The categories where polymers represent more than two-thirds of the formulations are primarily those products that are expected to be primarily disposed of in household waste, i.e., nail, lip and make-up products (See Table 49 and Table 53.).
- Polymer uses that do not meet the microplastic definition in the proposed restriction e.g., soluble/liquid polymers, natural polymers, biodegradable polymers, or polymers with film forming function, are not excluded from the results above. Therefore, i) the reported percentages above likely overstate the share of microplastic-containing products and ii) these polymer uses may also be potential substitutes for the microplastic ingredients.

2.7.1.5. Impacts on SMEs are underestimated

Several submissions expressed concerns that the impacts of the proposed restriction would be greater than estimated as the resources required to undertake concurrently a large number of reformulations within the transitional period may be particularly burdensome for SMEs. E.g., comments #2107, #2168, #2172, #2180, #2210, #2220, #2358, #2515, #2547, #2635, #2678.

Based on information provided from stakeholders, it can be concluded that the impact on SMEs would depend on their role in the supply chain:

- SMEs currently manufacturing microplastic-free cosmetics: These would include manufacturers of natural or organic cosmetics, representing about 5.9% of Cosmetics Europe membership (Cosmetics Europe survey, Feb 2019, comment #2220) but also other manufacturers whose products do not meet the microplastic definition in the proposed restriction (about 60% of the polymer uses in leave-on cosmetics, comment #2361). These manufacturers are expected to directly benefit from the restriction as they already have on the market formulations meeting the proposed requirements, hence they would not require resources to reformulate and would be able to respond quicker to the increased demand for alternative products.
- SMEs that manufacture products on behalf of clients: Many large cosmetics companies outsource the production of certain products to SMEs which then produce the products using microplastic ingredients. For example, in Italy, 126 out of 135 Italian contract manufacturers or 93% are SMEs (comments #2169, #2220, #2515). Contract manufacturers generally have a selection of basic formulas that customers can choose from, adding or subtracting ingredients to create a custom item, or they will make a client's formula or develop something original. If SMEs focus on manufacturing of microplastic-containing products

based on client formulas, it is expected that reformulation activities – the largest impact expected from the proposed restriction – would not be conducted by them. Individual impacts may be expected on selected contract manufacturers which are unable to secure contracts for microplastic-free alternatives. However, assuming continued demand for cosmetics in the EEA and no substantial changes in the manufacturing equipment or the business model for the manufacture of microplastic-free cosmetics, no overall net effect is expected from the restriction for this supply chain segment because manufacturing of microplastic-free alternatives would scale up and by the end of the transitional period take over manufacturing capacity from microplastic-containing products. Increased material costs are expected to be passed on to the contracting party. Those are taken into account by the Dossier Submitter under material costs. (See section D.5.5.4 in the Annex to the Background Document).

- SME suppliers of microplastic containing ingredients: In addition to contract manufacturers, these SMEs represent another large group of companies engaged in business-to-business (B2B) activities. According to a cosmetics industry expert, 94% of SMEs are in a B2B relationship with larger companies (SEAC meeting minutes, June 2019). These SMEs are expected to have to invest substantial resources in the reformulation of their ingredients. Taking into account information about the turnover and typical investment in R&D of Italian SMEs (comment #2515), it can be concluded that these companies may experience substantial difficulties finding the capacity and resources to reformulate several microplastic ingredients within the transitional period. It is expected that these difficulties could be experienced primarily for leave-on cosmetics, considering the diversity of functions that can be performed by microplastics, the substantially larger number of reformulations estimated to be needed to comply with the restriction and overall higher complexity of the reformulation process for leave-on cosmetics.
- SME manufacturing proprietary cosmetics products containing microplastics: These SMEs are likely to experience similar difficulties to SME suppliers with the proposed restriction on leave-on cosmetics if they have several products requiring reformulation.

The exact net impact on SMEs is uncertain, as one of the main factors influencing the SME's ability to comply with the proposed restriction – the number of reformulations required – is highly uncertain and difficult to predict even by sector organisations (see section D.5.5.6 in the Annex to the Background Document). The Dossier Submitter considers it unlikely that the net effect of the proposed restriction on SMEs would be negative from the proposed restriction on rinse-off products, considering the large number of microplastic-free reformulations already available on the market and primarily one main function – opacifying - that requires reformulation of microplastic containing products. In the event all leave-on cosmetics are restricted with a transitional period of six years, it can be concluded from comments submitted during the consultation that only some of the SMEs currently marketing proprietary microplastic-containing products may experience difficulties garnering resources to reformulate by the end of the transitional period.

2.7.1.6. INCI codes are not an adequate way to define microplastics and references to INCI names should be removed

Several stakeholders expressed concerns that polymers listed in Table 44, Table 105, and others in Section D.5 in the Annex to the Background Document cannot be considered microplastics (e.g. comments #2108, #2110, #2172, #2352, #2418, #2510, confidential submissions). As quoted by some of these respondents, the section on "state" in chapter D.5.1 of the Annex to the Background Document discusses that the building blocks of microplastics - polymers - come in many forms with the same polymer being used as a liquid in one product and a solid in another and that identifiers such as the INCI name do not provide information on the physical state of the polymer in the cosmetic formulations. This is because the state (phase) depends not only on the monomers that make up the polymer or copolymer, but also on properties like chain length, degree of crosslinking and molecular weight, or the ratio of different monomers in copolymer materials. Whether the polymer use is within the scope of the restriction proposal also depends on the function of the polymer (e.g. film forming is derogated from paragraph 1 of the proposal), the nature of the mixture (in particular as it relates to the solubility of the polymer due to interaction with the mixture ingredients), and whether the polymer meets the biodegradability conditions outlined in Appendix X.

All this suggests that whether a specific polymer use falls in the scope of the proposed restriction has to be determined on a level of an individual formulation. As such information is not available to the Dossier Submitter for more than 400 000 formulations on the EU market, some assumptions needed to be made in terms of the polymer uses that would fall in the scope of the proposed restriction. Therefore, for the purpose of the Low Scenario, all uses of the 19 polymers identified by Cosmetics Europe (see Table 44) during the ECHA CfE 2018 were assumed to be falling in the scope of the proposed restriction and in the High Scenario in excess of 500 polymers were included (Table 105). Therefore, at the time of publication of the dossier for the purpose of the consultation on the restriction proposal, and in addition to the information presented in the section on "state", a footnote was included with Table 105 stating that "Not all uses of these polymers may meet the proposed microplastics definition in Table 3 of the report…". Such similar text was included with the remaining tables in section D.5.5 of the Annex. The list of polymers in the Low and High scenario are purely an analytical aid and do not intend to imply a different scope of the proposed restriction. The restriction scope is as defined in Table 3 of the Annex XV restriction report.

2.7.1.7. Responses to Specific Question 6 in the Consultation of the submitted dossier

Because of difficulties to identify microplastics on the basis of INCI information, specific information was requested during the consultation from manufacturers and formulators of cosmetic products on the share of their formulations that contain ingredients meeting the microplastic definition. Several stakeholders provided information (comments #2161, #2256, #2259, #2278, #2727) and a number of other submissions provided confidential or partial answers on this topic. The information provided was by-and-large not sufficiently robust to narrow down the list of polymers in order to query the CosmEthics database and revised the current socio-economic impact assessment.

Instead, the Dossier Submitter used the information provided to further identify which polymers may be most likely impacted by the scope on the basis of their physico-chemical properties (i.e. excluding liquid or soluble polymers) to refine the approach which led to a rough reduction of the microplastic tonnages in the High scenario by about 50% on average (this reduction was not applied to the number of reformulations however).

This additional analysis focused on the polymers present in leave-on products, primarily because as the uncertainty in the proportionality assumptions for leave-on products was greater but also because of the nature of the information provided. On that basis, the Dossier Submitter estimated that approximately 60% of polymer uses could fall in the scope of the proposed restriction. As further polymers may have film-forming properties – 19% by estimates from Cosmetics Europe survey – the resulting estimate of polymers falling in scope is 45%: which is close to the assumption provided by industry that only 40% of polymer uses would fall in scope. Therefore, the Dossier Submitter chose to revise the estimated tonnages of microplastics used in leave-on cosmetics using the 40% assumption provided by industry (comments #2220, #2361).

To summarise, the Dossier Submitter estimated the tonnages of microplastics used in leave-on cosmetics on the basis of the estimated number of formulations on the EEA market containing polymers, scaled up by the ratio of tonnes microplastics per formulation (based on information provided by Cosmetics Europe, ECHA CfE 2018) and multiplied by 40%. Such a reduction was not applied to the estimated number of reformulations required to comply with the proposed restriction. This is because the number of required reformations is estimated on the basis of the share of polymer-containing formulations on the market. These estimates cannot be revised not knowing which particular formulations fall outside the scope of the proposed restriction.

The Dossier Submitter concludes that this approach results in a significant overestimation of the number of required reformations to comply with the proposed restriction and therefore, overestimate the total restriction costs of the proposed ban on the placing on the market of leave-on products (see detailed response on this topic above).

Therefore, the results presented in the revised analysis for leave-on products confirm earlier results: a restriction on leave-on cosmetics has similar proportionality to previously adopted restrictions addressing environmental pollutants. However, many of the uncertainties identified in the original analysis in the submitted dossier are also present in this revised analysis. The main uncertainty in the analysis relates to the fact that while an attempt was made to exclude liquid or less relevant uses of polymers in the estimation of the tonnages used and emitted from leave-on cosmetics, the analysis still does not exclude irrelevant formulations from the estimation of the reformulation costs – the cost category that accounts for more than two-thirds of the total restriction costs. As a consequence, the total costs estimated are likely an overestimate the actual costs imposed on the cosmetic sector by the restriction proposal. Please see section D.5.5.6 in the Annex to the Background Document for further discussion on the uncertainties in the assessment.

2.7.2. RAC Rapporteurs comments

RAC rapporteurs agrees with the comments made by the Dossier Submitter and notes that the releases have been evaluated taking into account the new information derived from the consultation. In-depth analysis can be found in the opinion document.

2.7.3. SEAC Rapporteurs comments

SEAC rapporteurs generally agree with the comments made by the Dossier Submitter. SEAC rapporteurs have thoroughly analysed the information provided during the consultation as well as the updated assessment by the Dossier Submitter addressing the comments received. Where relevant, SEAC rapporteurs have taken this information into account for their conclusions (please see in-depth analysis in the opinion document).

2.8. Detergents and household products

2.8.1. Dossier Submitter response to comments

Several comments were submitted regarding the detergents and maintenance sector from industry associations, companies and non-governmental organisations. These included, for example, comments #2010, #2026, #2160, #2167, #2182, #2236, #2239, #2240, #2241, #2335, #2351, #2382, #2386, #2421, #2497, #2547, #2577, #2596, #2609, #2648, #2678 and #2679. Some of these comments have been handled as confidential as per the respondent's request.

Some of the industry associations submitted updated data based on surveys and interviews undertaken following the publication of the Annex XV report. The data is summarised as follows:

- Tonnages: Based on the definition of microplastics in the Annex XV report, industry was able to provide updated and more specific tonnage information. This data allowed the Dossier Submitter to narrow down significantly the wide tonnage ranges initially reported in the Annex XV report.

- Number of affected formulations: For fragrance encapsulates, industry argues that the number of affected reformulations would be greater than assumed in the Annex XV report. The Dossier Submitter has taken this into account in the updated Background Document. For other product categories, industry respondents argue that the reformulations required because of the ban is lower than estimated in the Annex XV report, but that more reformulations would be undertaken to avoid the labelling and reporting requirements. The Dossier Submitter has considered only the reformulations required due to the ban in the main analysis but has included the other reformulations in a sensitivity analysis.

- Costs of reformulation/R&D: The cost of reformulation is claimed by industry respondents to the consultation to be greater than assumed in the Annex XV report. The Dossier Submitter has used the higher cost claimed by industry respondents as the upper value in the analysis. The R&D costs for the

development of alternatives to the current polymeric fragrance encapsulates have been updated in the Background Document.

- Transition period: Industry respondents argued that the 5-year transition period proposed in the Annex XV report for all detergents and maintenance product groups would be too short (resulting in products being withdrawn from the market).

    - For fragrance encapsulates, industry intends to develop alternatives that would be out of the scope of the restriction (e.g. biodegradable encapsulates) and provided evidence that previous comparable innovation cycles have taken approximately 10 years from initiation until implementation. In response, the Dossier Submitter has undertaken an additional analysis of impacts for an 8-year transition period (which would mean the restriction would come into effect in approximately 10 years from now).

    - For other product categories, the Dossier Submitter did not consider that the available information indicated that a longer transition period would be warranted. However, as an upper cost it has considered the potential profit losses in case not all reformulations are successful.

The detergents and maintenance industry also provided comments on other topics, including the microplastics definition, the instructions for use and reporting requirements and the derogation for biodegradable polymers. The Dossier Submitter's answers on those topics are provided under the relevant headings.

2.8.2. RAC Rapporteurs comments

RAC rapporteurs agree with the comments made by the Dossier Submitter. In the Opinion RAC addressed the discussion on the updated tonnage ranges and additional information provided during the consultation. In-depth analysis can be found in the opinion document.

2.8.3. SEAC Rapporteurs comments

SEAC rapporteurs generally agree with the comments made by the Dossier Submitter. SEAC rapporteurs have thoroughly analysed the information provided during the consultation as well as the updated assessment by the Dossier Submitter addressing the comments received. Where relevant, SEAC rapporteurs have taken this information into account for their conclusions (please see in-depth analysis in the opinion document). With regard to fragrance encapsulates, more specific information on the availability of alternatives and on the substitution process would be appreciated during the consultation on SEAC's draft opinion.

2.9. *In vitro* diagnostic devices and medical devices

2.9.1. Dossier Submitter response to comments

Several comments were received from sector associations, supply chain actors and competent authorities from the *in vitro* diagnostic devices and medical devices sectors, respectively: for example comments #2056, #2087, #2098, #2115, #2126, #2127, #2158, #2162, #2205, #2219, #2267, #2412, #2432, #2434, #2447, #2491, #2505, #2550, #2595, #2700, #2714. Some of these comments have been handled as confidential as per the respondent's request.

The Dossier Submitter notes general support from the *in vitro* diagnostic devices (IVD) and medical devices (MD) sectors for the Annex XV restriction proposal, and the willingness from those sectors to act to reduce the presence of microplastics in the environment.

The Dossier Submitter has grouped comments into the following main categories and has responded to them accordingly: (i) information on use, (ii) releases and risk assessment (iii) socio-economic impact of the proposed restriction (iv) wording of the conditions of the restriction. Where relevant, information has been added and further developed in the Background Document and its annex (Sections D.7 and D.8) to improve the clarity of the proposal and further elaborate the justification for the restriction options proposed.

Comments have also been made on the definition of microplastics (including solubility), the reporting and instructions for use and disposal requirements. Please refer to the other sections in this document for the responses from the Dossier Submitter on these topics. With regard to the reporting and instructions for use and disposal requirements, we note that there was no strong disagreement with the proposal from the IVD and medical devices actors, but rather a request for further clarifications of what these requirements would mean in practice for the different actors in the supply chain.

2.9.1.1. Information on use

The Dossier Submitter has received information on uses that were not covered by the initial description of the sector in the Annex XV proposal. The initial use description and impact analysis was indeed essentially focussing on medical human health applications: medical devices (covered by Regulation (EU) 2017/745) and *in vitro* diagnostic medical devices (covered by Regulation (EU) 2017/746).

With regard to *in vitro* diagnostics, new uses have been reported in veterinary, pest control and research and development applications. It was also clarified that those uses were not covered by the IVDR regulation.

For Medical Devices, respondents have highlighted the presence of microplastics in various type of (substance-based) medical devices, and medical devices for health-care professionals and consumers e.g. dental in-fill, toothpaste, skin disease treatment (eczema, dryness…), vaginal gels, sunscreens, etc.

The Dossier Submitter has therefore reviewed and assessed the information provided in

this consultation, and has updated the Background Document accordingly. More specifically, the annex to the Background Document contains now two separate annexes (D.7 and D.8) with two different impact analysis of the proposed restriction: one dedicated to *in vitro* diagnosis devices (medical and other applications), and one dedicated to the Medical Devices. The proposed wording of the conditions of the restriction has also been revised accordingly in order to address the different concerns raised by IVD and Medical Devices: a derogation accompanied with instructions for use and reporting requirements is proposed for IVDs, while a restriction from placing on the market with a transition period similar to the one proposed for leave-on cosmetics is proposed for the (substance-based)-MD.

2.9.1.2. Releases and risk assessments

The comments received confirmed the release estimates reported in the Annex XV report by the Dossier Submitter for *in vitro* diagnostic devices. Re. medical devices, the Dossier Submitter would like to clarify that, as specific information on these uses were not available, the initial release estimates in the Annex XV proposal did not include releases from (substance-based) medical devices. It is therefore not correct to assume and state that the releases from (substance-based) medical devices are negligible. Releases have been confirmed, but no tonnage information was provided during the consultation on the uses/releases from (substance-based) MD and the Dossier Submitter has not made any attempt to estimate them. As the uses, and formulation reported can be similar to cosmetics products (e.g. tooth paste, creams…), the Dossier Submitter is proposing the same restriction option and transitional period as for leave-on cosmetic products.

2.9.1.3. Socio-economic impact of the proposed restriction

Requests for a ‘full’ derogation or longer transitional (implementation) period have been made by respondents. In both cases, the Dossier Submitter reviewed the evidence presented, both confidential and non-confidential responses. The information primarily comprised impacts for society (e.g. patients, healthcare systems), costs for laboratories, clinics, hospitals (for IVD application only) to implement the initially proposed restriction option (containment and incineration), information on the difficulties of reformulation, particularly for IVD applications, as well as the potential timelines for mandatory regulatory approvals processes prior to placing reformulated products on the market. This information was analysed and reported in two new sections in the Annex to the Background Document (Sections D.7 for IVDs and section D.8 for MDs).

The Dossier Submitter has considered all the information available when proposing the transitional period for this restriction and reflected that in revisions to the Background Document. The originally proposed transitional period of 2 years for MD and MD IVD, and 0 years for other IVD applications (veterinary, research and development, pest control, etc) have been revised based on the comments received. Details are presented in section D.7 and D.8 of the Annex to the background document

2.9.1.4. Wording of the conditions of the restriction

Several comments have indicated that the initial derogation wording (and impact

analysis) was only referring to IVD used for medical application (as only the reference to the MD-IVDR (EU) 2017/746), and would automatically exclude from any derogation all the other uses of IVDs (e.g. for veterinary, R&D, pest control). The Dossier Submitter has therefore updated the wording of the restriction proposal by referring to IVDs application in general instead of MD-IVD covered by Regulation (EU) 2017/746.

2.9.2. RAC Rapporteurs comments

RAC agrees with the Dossier Submitter that the IVD and the MD should be treated separately in the restriction proposal.

In the opinion RAC addressed the discussion on the updated tonnage ranges and additional information provided during the consultation.

RAC rapporteurs note that there are not information on the releases of medical devices and agrees with the Dossier Submitter that it is not correct to assume that the releases from medical devices are negligible.

2.9.3. SEAC Rapporteurs comments

SEAC rapporteurs generally agree with the comments made by the Dossier Submitter. SEAC rapporteurs have thoroughly analysed the information provided during the consultation as well as the updated assessment by the Dossier Submitter addressing the comments received. Where relevant, SEAC rapporteurs have taken this information into account for their conclusions (please see in-depth analysis in the opinion document).

With regard to (substance-based) MD, further information on the impact of the proposed restriction would be appreciated.

2.10. Medicinal products for human and veterinary health

2.10.1. Dossier Submitter response to comments

Several comments were received from sector associations, supply chain actors and competent authorities from the human and veterinary medicinal products sectors: for example comments #2098, #2153, #2158, #2163, #2171, #2194, #2219, #2237, #2263, #2267, #2415, #2482, #2514, #2550, #2595, #2675, #2688, #2689, #2732. Some of these comments have been handled as confidential as per the respondent's request.

Overall, the sector confirmed the information indicated in the Annex XV restriction proposal on the use and benefits of microplastics in medicinal formulations both for the patients and the society, as well as the information on (non-)availability of alternatives. In general, respondents welcomed the proposed derogation for medicinal products but were nevertheless arguing for either a longer transitional period, or a 'full' derogation where no instructions for use and disposal, nor reporting requirements would be requested. Based on the analysis of the information received, the Dossier Submitter is now proposing a longer transitional period for both the instructions and reporting requirements.

The Dossier Submitter has grouped comments into the following main categories and has responded to them accordingly: (i) Instructions for use and disposal, (ii) Polymers in scope (iii) Affected formulations. Where relevant, information has been added in the Background Document and its annex (Section D.9). Additional comments were also made on the microplastics definition (e.g. on the need for a solubility criteria, the lack of analytical methods to detect microplastics, swellable polymers), on the reporting requirement. Please refer to the relevant sections in this document for the responses from the Dossier Submitter. When relevant, the comments have been reflected in the background document section D.9. In order to improve the clarity of the proposal, some specific questions on the pharmaceutical applications have also been added in the Q&A on 'restriction proposal on intentionally added microplastics'.

2.10.1.1. Instructions for use and disposal

Several respondents indicated that the 'instructions for proper disposal' are already included in the package leaflet (PL) of medicines, and that therefore no additional requirements under REACH would be needed. The Dossier Submitter does not argue against the fact that a majority of pharmaceutical companies already include 'instructions for proper disposal' in their PL. This has also been confirmed by EMA (European Medicines Agency). Nevertheless, the Dossier Submitter notes that this inclusion is not compulsory (from a legal point of view). Indeed, Title V of Directive 2001/83 for human medicines, and Title V of Directive 2001/82 for veterinary medicines, lay down the obligations in term of labelling, outer-packaging and package leaflet.

In particular, Articles 54(j) in both Directives mention the obligation to include 'where appropriate' instructions for the disposal of (unused) medicines 'on the outer packaging' of the medicinal products for both human and veterinary medicines. The Package Leaflet (PL) (as well as the SmPc) is also approved as part of the marketing authorisation of each medicine. According to Article 59 in both Directives, the PL 'shall be drawn in accordance with the SmPC' (which includes instructions for disposal based on the EMA QRD standard phrases), and shall contain the minimum information listed in Article 59 (i.e. legally binding information). The minimum legally binding set of information to be specified on the PL does not include the 'instructions for disposal'. So the Dossier Submitter considers that even if the inclusion in the PL of instructions for disposal (e.g. using sentences such as 'Any unused product or waste material should be disposed of in accordance with local requirements' or 'Any unused medicines should be returned to the pharmacy, or disposed according to the local Regulation. Unused medicines should not be flushed down the toilet nor placed in liquid waste disposal systems.'), seems to be a common practice in the sector, there is no legal obligations at the moment to do so.

The Dossier Submitter considers therefore that the presence of microplastics is an appropriate situation to trigger the disposal instruction to be compulsory. Therefore, the restriction proposal aims to reinforce the existing medicinal product regulations with the obligation to indicate on the package leaflet (PL) of the medicines, sufficient instructions (as per the QRD template) for the patients to dispose properly the unused medicines in case they contain microplastics.

Some respondents argued as well that an instruction for use and disposal, and a

reporting requirements are not needed as the medicines containing microplastics are ingested and could swell and would therefore not be a concern for the environment. The Dossier Submitter has therefore clarified both in Annex D.9 and in the Q&A its position with regard to swellable polymers, and that the purpose of paragraph 7 and 8 requirements is to influence how the products are used but also disposed of in a way that minimises the negative impacts on the environment. For pharmaceuticals, this could for example instruct users not to dispose of the unused products down the drain (via the toilets or sink). The paragraph 8 reporting requirement will also help to understand the scale of microplastics uses and to assess whether there is a need for further regulatory action on the derogated uses in the future.

Last but not least, the Dossier Submitter has taken into account the comments received on the potential negative effect on the patients' adherence to their treatment in case the presence of microplastics would be clearly indicated on medicinal products packaging. This proposal has therefore been removed from the background document and the restriction proposal, and is also now clarified in the Q&A.

2.10.1.2. Polymers in scope - degradability and water solubility after ingestion

Re. degradability, on one hand some respondents argued that it is unknown which proportion of microplastics from the medicinal formulations is released unchanged in the environment (i.e. not degraded, not soluble). On the other hand, other respondents confirmed that polymers are broadly used in pharmaceutical applications because of their (in)solubility, and non degradability properties which allow to achieve a good safety profile (non bio-degradation), and phys-chem stability throughout the transition time (non soluble in water) in order to have reliable performance of the medicine formulation.

Some comments were also received, asking for water soluble polymers used as excipients in medicinal formulation to not be considered as microplastics. The Dossier Submitter has now clarified that polymers that would fulfil certain solubility criteria would not be considered as microplastics (cf. relevant section in this document).

In addition, during the consultation, respondents also indicated that some polymers used in medicinal formulations were swellable and should therefore benefit from a derogation. Others mentioned that 'swellability' was not permanent and could vary/revert depending on the pH, temperature, or salinity conditions. The response from the Dossier Submitter regarding the issue of swellable polymers is available in the section on Microplastic definition in this document.

Overall, the Dossier submitter has made effort to include in the scope of the impact analysis only polymers that would fulfil the microplastics definition, and has tried to not include any polymer that could benefit from the biodegradation or solubility derogations set in paragraph 3b and 3c of the restriction proposal.

2.10.1.3. Affected formulations

Some comments informed about the presence of polymers not only in controlled released formulations, but also in instant release (IR) formulations. The Dossier

Submitter has taken note of this information in the Annex to the Background Document. Nevertheless, considering that polymers used in IR formulation (e.g. for film-forming, binding, taste masking or 'disintegrant' function) aim by definition at quickly dissolving (when in contact with water or in slightly acidic conditions) in order for the API in the core to be released quickly/immediately ; the Dossier Submitter has initially assumed (in the Annex XV proposal) that IR formulations would not contain polymers that would fall under the scope of this restriction (because they would be water soluble or would be degradable). Based on the information submitted, it appears that microplastics could also be present in IR formulations, nevertheless it remains unclear to what extent. This potential use, and the associated uncertainties have therefore been reported in the Annex to the Background Document in section D.9.1.2 and D.9.7.

2.10.2. RAC Rapporteurs comments

RAC noted the DS response. In the Opinion RAC addressed the discussion on the additional information provided during the consultation.

2.10.3. SEAC Rapporteurs comments

SEAC rapporteurs generally agree with the comments made by the Dossier Submitter. SEAC rapporteurs have thoroughly analysed the information provided during the consultation and, where relevant, have taken it into account for their conclusions. SEAC rapporteurs' in-depth analysis on 'instructions for use and disposal' as well as reporting can be found in the opinion document.

2.11. Food additives

2.11.1. Dossier Submitter response to comments

Several comments were received from sector associations, and supply chain actors from the food supplement, medical food and pharmaceutical sectors on food additives potentially fulfilling the definition of microplastics, for example comments # 2103, #2234, #2267, #2501, #2514, #2516, #2550, #2599, #2642, #2675, #2691, #2708, #2712, #2713, #2728, #2732. Some of these comments have been handled as confidential as per the respondent's request.

In the initial Annex XV restriction proposal, the Dossier Submitter tested the following restriction option: 'A ban with no transitional period'. In responses to the consultation on the Annex XV proposal, industry associations and stakeholders provided additional useful information on food additives potentially fulfilling the microplastic definition, and on the practical impacts of such a restriction. Where relevant, information has been added and further developed in the Background Document and its annex (Section D.10). The Dossier Submitter has been able to carry out a more detailed qualitative impact assessment, which is available in section D.10 of the Annex to the Background Document, and has elaborated a restriction proposal which is similar to the one proposed for medicinal products: derogation accompanied by an instructions for use and disposal, and a reporting requirement.

The Dossier Submitter has grouped the comments into the following main categories and has responded to them accordingly: (i) Information on use and existing regulatory framework, (ii) Releases and risk assessment (iii) Polymers in scope, (iii) Request for derogations.

Comments have also been made on the definition of microplastics (including solubility, degradability), the reporting and instructions for use requirements. Please refer to other sections in this document for the responses from the Dossier Submitter on these topics.

2.11.1.1. Information on use and existing regulatory framework

The Dossier Submitter has received additional information on uses and authorised food additives (E number) potentially fulfilling (or not) the microplastic definition. Information was also provided on the water solubility of authorised food additives listed in the initial Annex XV proposal. The Dossier Submitter has therefore reviewed and updated the list of authorised food additives potentially fulfilling the microplastic definition in the Background Document (cf. section D.10.2). For example E1208 has been removed from the table in section D.10.2. It should be noted that the information on E numbers fulfilling the microplastic definition was not always consistent among the respondents. The Dossier Submitter has therefore performed some substance ID checks, and some literature reviews to confirm or not the information received from the respondents.

Stakeholders confirmed the use of food additives fulfilling the microplastic definition in two main types of application: food supplements and medical food. They also confirmed that the substances authorised as food additives are used as excipients in medicinal products formulations.

In their comments, the respondents have also indicated that food additives were already authorised and assessed under the Food additives Regulation, and should therefore not be restricted under REACH. While the Dossier Submitter recognises that authorised Food additives are assessed in order to not pose a risk for human health safety, the current Regulation does not specifically foresee an environmental risk assessment to be performed prior placing on the market a food additive. The risk to the environment can therefore be assessed under REACH, and a restriction might apply.

2.11.1.2. Releases and risk assessments

Similar to medicinal products, respondents argued that a restriction, or even an requirement for instruction for use and disposal or reporting are not needed as the food supplements or medical food containing microplastics are ingested and some of them could swell and would therefore not be a concern for the environment.

The Dossier Submitter has therefore clarified both in Annex D.9 and in the Q&A its position with regard to swellable polymers, and that the purpose of paragraph 7 and 8 requirements is to influence how the products are used but also disposed of in a way that minimises the negative impacts on the environment. The paragraph 8 reporting requirement will also help to understand the scale of microplastics uses and to assess whether there is a need for further regulatory action on the derogated uses in the future.

2.11.1.3. Polymers in scope - degradability and water solubility after ingestion

Please refer to the response provided under the section on Medicinal products.

2.11.1.4. Request for derogations

Requests for a full derogation, longer transitional (implementation) period, or derogation similar to the one proposed for medicinal products have been made by the respondents. In all cases, the Dossier Submitter reviewed the evidence presented, both in confidential and non-confidential responses. The information primarily comprised impacts and benefits for the society (e.g. consumers, healthcare systems), information on the difficulties of reformulation, the similarity with medicinal product formulation, and the lack of harmonisation of food supplement or medical food qualification at the EU level. This information was analysed and reported in the Annex to the Background Document (Sections D10). As a conclusion, the Dossier Submitter is proposing a derogation similar to the one applied to medicinal products. This is to avoid a double regulation on the food additives, and a potential market distortion.

2.11.2. RAC Rapporteurs comments

RAC agrees with the DS response and conclusions. In the Opinion RAC addressed the discussion on the updated tonnage ranges and additional information provided during the consultation.

2.11.3. SEAC Rapporteurs comments

SEAC rapporteurs generally agree with the comments made by the Dossier Submitter. SEAC rapporteurs have thoroughly analysed the information provided during the consultation and, where relevant, have taken it into account for their conclusions. SEAC rapporteurs' in-depth analysis on 'instructions for use and disposal' as well as reporting can be found in the opinion document.

2.12. Ink-printing, paint and coatings and construction products

2.12.1. Dossier Submitter response to comments

Several comments were received from companies and associations regarding paints and coatings (for example comments #2039, #2040, #2044, #2058, #2065, #2066, #2073, #2092, #2095, #2102, #2117, #2118, #2148, #2152, #2154, #2188, #2216, #2265, #2271, #2356, #2476, #2508, #2511, #2536, #2541, #2542, #2658, #2698) and the printing inks sector (#2027, #2039, #2058, #2077, #2095, #2235, #2305, #2433, #2467, #2476, #2536), with some overlaps between these comments. The construction sector also provided comments (#2221, #2271, #2345, #2499, #2503, #2521, #2557, #2695).

Where these comments provided new information on e.g. tonnage, concentrations or descriptions of use, these were incorporated into the Background Document. Most of the comments related to these products referred to the instructions for use and the reporting requirement. These comments and the general responses to them are outlined further

under the relevant sections for those topics.

2.12.2. RAC Rapporteurs comments

RAC rapporteurs agree with the Dossier Submitter. In the Opinion RAC addressed the discussion on the updated tonnage ranges and additional information provided during the consultation.

2.12.3. SEAC Rapporteurs comments

SEAC rapporteurs generally agree with the comments made by the Dossier Submitter. SEAC rapporteurs have thoroughly analysed the information provided during the consultation and, where relevant, have taken it into account for their conclusions. SEAC rapporteurs' in-depth analysis on 'instructions for use and disposal' as well as reporting can be found in the opinion document.

2.13. Oil and Gas sector

2.13.1. Dossier Submitter response to comments

Few comments were received from oil and gas exploration and production companies and sector associations. For example, comments #2132, #2151, #2166, #2182, #2339, #2536, #2561, and #2661.

Most of the comments submitted referred to the instructions for use and the reporting requirement. These comments and the general responses to them are outlined further under the relevant sections for those topics.

The Dossier Submitter notes also a general support from this sector for the proposed derogation for the use of microplastics at industrial sites.

2.13.2. RAC Rapporteurs comments

RAC rapporteurs have thoroughly analysed the information provided during the consultation and, where relevant, have taken it into account for their conclusions.

2.13.3. SEAC Rapporteurs comments

SEAC rapporteurs generally agree with the comments made by the Dossier Submitter. SEAC rapporteurs have thoroughly analysed the information provided during the consultation and, where relevant, have taken it into account for their conclusions. SEAC rapporteurs' in-depth analysis on 'instructions for use and disposal' as well as reporting can be found in the opinion document.

2.14. Polymeric infill material for synthetic sports pitches

2.14.1. Dossier Submitter response to comments

Numerous comments were received from competent authorities, NGOs, sport associations, sports clubs, suppliers of infill material, sector associations and citizens. For

example comments #2021, #2042, #2043, #2045, #2046, #2048, #2051, #2053, #2054, #2059, #2076, #2079, #2088, #2101, #2104, #2112, #2119, #2122, #2123, #2131, #2139, #2140, #2142, #2143, #2146, #2147, #2156, #2161, #2165, #2181, #2190, #2197, #2202, #2208, #2223, #2225, #2233, #2249, #2264, #2272, #2348, #2354, #2357, #2359, #2362, #2363, #2364, #2367, #2369, #2373, #2374, #2378, #2388, #2392, #2436, #2438, #2439, #2440, #2445, #2446, #2450, #2451, #2452, #2453, #2454, #2455, #2456, #2457, #2458, #2459, #2460, #2461, #2462, #2463, #2464, #2465, #2466, #2468, #2472, #2478, #2479, #2480, #2493, #2498, #2500, #2509, #2518, #2520, #2522, #2523, #2524, #2525, #2526, #2527, #2530, #2532, #2533, #2535, #2546, #2567, #2572, #2573, #2580, #2591, #2593, #2594, #2598, #2608, #2610, #2621, #2633, #2634, #2639, #2650, #2671, #2676, #2687, #2692, #2694, #2706, #2723, and #2743.

A large amount of information on various aspects of the use of polymeric infill material for replenishing synthetic sports pitches was reported during the consultation. The Dossier Submitter has assessed this information in a new section (D.13) of the Annex to the Background Document and has updated various parts of the Background Document accordingly. Specifically, the following points have been analysed:

- Uses and functions
- Baseline situation
- Emissions
- Risk management measures
- Alternatives
- Proposed regulatory actions

Stakeholders will be invited to provide additional detailed use information, and socio-economic impact assessment of the proposed restriction during the SEAC draft opinion consultation.

2.14.2. RAC Rapporteurs comments

In the opinion document RAC addressed the issue in-depth, based on the information provided during the consultation, and the updated background document.

2.14.3. SEAC Rapporteurs comments

SEAC has analysed and taken into consideration the information received during the Consultation on the Annex XV restriction dossier. SEAC has also analysed the assessment performed by the Dossier Submitter.

SEAC refers to the opinion document for more information. Input from stakeholders is very much appreciated during the consultation on SEAC's draft opinion.

2.15. Additional (newly reported) uses

2.15.1. Dossier Submitter response to comments

A limited number of additional uses microplastics were reported in the consultation, and are now mentioned in the section D.14 of the Background Document annex:

- Bulk IER (Ion exchange resins) used for water domestic treatment (water softening) (for example #2118, #2714)
- Microplastics used as toys or for Do It Yourself (DIY) (for example comment #2544, #2710)
- Microplastics used as packing material for the transportation of sheet glass (for example comment #2590)

Stakeholders will be invited to provide additional detailed use information, and socio-economic impact assessment of the proposed restriction during the SEAC draft opinion consultation.

2.15.2. RAC Rapporteurs comments

In the opinion RAC addressed the discussion on the additional information provided during the consultation.

2.15.3. SEAC Rapporteurs comments

In the opinion SEAC addressed the discussion on the additional information provided during the consultation.

2.16. Paragraph 7 - 'instruction for use and disposal' requirements for derogated uses (also referred to as 'labelling' requirements)

2.16.1. Dossier Submitter response to comments

Numerous comments were received: for example, comments #2027, #2040, #2044, #2056, #2065, #2073, #2077, #2087, #2092, #2106, #2108, #2117, #2127, #2128, #2132, #2151, #2152, #2153, #2155, #2163, #2168, #2179, #2182, #2188, #2193, #2194, #2195, #2203, #2205, #2215, #2235, #2237, #2240, #2241, #2263, #2265, #2267, #2271, #2335, #2339, #2345, #2382, #2415, #2448, #2467, #2476, #2510, #2515, #2543, #2550, #2556, #2558, #2566, #2590, #2595, #2609, #2613, #2630, #2631, #2661, #2688, #2646, #2661, #2695, #2697, #2698, #2734, #2737. Comments were from a range of different sectors. Some of these comments have been handled as confidential as per the respondent's request.

Many of the comments requested clarification of the proposal conditions or appeared to have misunderstood the proposal. Clarifications and answers to common misunderstandings were previously addressed in the Q&A document published in July 2019. Where relevant, information from the Q&A documents has been added to the

relevant sections of the Background Document (Section 2.2.1.4) to improve the clarity of the proposal and further elaborate the justification.

The most important changes made to the Background Document in response to these submissions can be summarised as follows:

- The term 'labelling' has been replaced throughout the Background Document with the term 'instructions for use and disposal' (IFUD). This revision was to clarify that product labels did not necessarily need to contain the required information on conditions of use. The revision acknowledges that safety data sheets or product leaflets (for example) may be more appropriate in certain instances than product labels.

- The use of pictrograms has been explicitly allowed in the paragraph 7 text.

- Section 2.2.1.4 and the conditions of the restriction have been modified to require that certain additional (non-confidential) information, relevant to the paragraph 8 reporting requirement, is passed down the supply chain under certain conditions (placing on the market for industrial use). This is to facilitate the implementation of the reporting requirement by downstream users. These requirements build on existing supplier obligations under REACH Article 32(c).

- Section 2.2.1.4 has been revised to clarify the underlying justification and obligations introduced by paragraph 7; addressing common misunderstandings apparent from multiple consultation responses.

- Clarified that the paragraph 7 obligations would not apply to (bio)degradable or soluble polymers (where demonstrated according to paragraphs 3(b) or 3(c), respectively).

- The transitional period for implementing the paragraph 7 requirements has been revised from 18 months to 24 months after entry into force, and has been phased such that paragraph 7 obligations enter into effect 12 months prior to the paragraph 8 reporting obligations to allow sufficient time for information to pass through supply chains.

- Additional information on the effectiveness of labelling has been added to Section 2.2.1.4.

- An additional section (Section 2.5.4) on the costs of the instructions for use and disposal requirement has been added to the Background Document.

2.16.2. RAC Rapporteurs comments

In the opinion document RAC addressed the issue in-depth, based on the information provided during the consultation, and the updated background document.

2.16.3. SEAC Rapporteurs comments

SEAC rapporteurs' in-depth analysis on 'instructions for use and disposal' as well as reporting can be found in the opinion document.

2.17. Paragraph 8 - Reporting requirements for derogated uses

2.17.1. Dossier Submitter response to comments

Comments referring to the proposal, detailed in paragraph 8 of the conditions of the restriction, which requires suppliers of substances/mixtures containing microplastics to report certain information to the Agency were received: for example, #2027, #2039, #2040, #2044, #2056, #2062, #2065, #2066, #2073, #2074, #2077, #2087, #2092, #2102, #2106, #2117, #2127, #2128, #2132, #2148, #2151, #2152, #2154, #2155, #2163, #2168, #2179, #2188, #2193, #2194, #2195, #2203, #2204, #2205, #2215, #2216, #2235, #2237, #2263, #2265, #2267, #2271, #2305, #2335, #2345, #2356, #2371, #2415, #2448, #2467, #2476, #2487, #2499, #2503, #2506, #2508, #2510, #2515, #2521, #2541, #2542, #2543, #2544, #2547, #2550, #2556, #2557, #2558, #2566, #2571, #2579, #2588, #2590, #2606, #2609, #2630, #2631, #2645, #2646, #2658, #2661, #2662, #2688, #2689, #2693, #2695, #2696, #2697, #2698, #2727, #2734 and #2737.

Comments were from a range of different sectors. Some of these comments have been handled as confidential as per the respondent’s request.

The most important changes made to the Background Document in response to these submissions can be summarised as follows:

- The specific information to be reported has been carefully re-evaluated in response to the comments submitted in the consultation. The information requested has been revised by the Dossier Submitter to maximise the availability of useful data to both companies and the Agency, whilst minimising administrative burden. Details of the revisions to the proposal are provided in Section 2.2.1.5 of the Background Document.

- The transitional period for implementing the paragraph 7 requirements has been revised from 12 months to 36 months after entry into force, and has been phased such that paragraph 7 obligations enter into effect 12 months prior to the paragraph 8 reporting obligations to allow sufficient time for information to pass through supply chains.

- An additional section (Section 2.5.5) on the costs of the reporting requirement has been added to the Background Document.

2.17.2. RAC Rapporteurs comments

In the opinion document RAC addressed the issue in-depth, based on the information provided during the consultation, and the updated background document.

2.17.3. SEAC Rapporteurs comments

SEAC rapporteurs' in-depth analysis on 'instructions for use and disposal' as well as reporting can be found in the opinion document.

2.18. Implementation and enforcement, including availability of analytical methods

2.18.1. Dossier Submitter response to comments

The restriction targets the **intentional** use of microplastics. Therefore, it is reasonable to assume that formulators of mixtures will know whether or not they are using microplastics in their products. Acknowledging analytical difficulties in detecting and quantifying microplastics on complex final products, the Dossier Submitter has specified ‘instructions for use and disposal requirements’ in paragraph 7 of the proposal which are intended to ensure that there is sufficient information in the supply chain to enable formulators to assess whether or not the starting materials they use are or contain microplastics. Enforcement can then be made on the basis of document checks rather than analytical means.

During the consultation, many respondents have brought up the issue of not having suitable analytical method to measure microplastics in [complex] products. This statement deserves some discussion since it is true that the complexity and type of product that contains microplastics influences the strategy and limitations to identify and quantify the microplastics that might or might not be present in the substance that placed on the market. This might cause real problems in case of enforcement/monitoring activities on certain products available on the market. To confirm the presence and identity of the microplastics might not always straight forward especially if the product is complex and contain many ‘similar’ objects (e.g. oil droplets, other solid particles etc.) that are comparable to the Microplastics particles. Nevertheless, raw materials are much easier to characterise than complex final products and the Dossier Submitter considers that document-based enforcement will be as important as analytical based enforcement as part of the implementation of the restriction.

The Dossier Submitter’s intention is that the restriction tackles microplastics that are intentionally added to products and therefore it is know whether they are present in the substance or not. The Dossier Submitter acknowledges the current limitation in the analytical techniques that are capable of identify microplastic particles, morphology and particle size distribution below the micrometre range. However at the same time the Dossier Submitter is aware of many R&D activities that discuss in detail which analytical techniques from nanomaterials analysis might be adapted to overcome the problem of measuring below micrometre range.

Further explanation on the presence of microplastic in products and the analytical limitation to detect them is provided in section 2.6.1 of the Background Document.

2.18.2. RAC Rapporteurs comments

RAC rapporteurs agree with the DS analysis and recognises that currently there are technical limits in the analytical techniques for the detection and identification of microplastics. However, in the same time, RAC notes that novel analytical technologies will be available as a consequence of the R&D activities already ongoing or expected in the next future.

2.18.3. SEAC Rapporteurs comments

SEAC rapporteurs agree with the comments made by the Dossier Submitter. SEAC rapporteurs agree with Forum that sufficient guidance should be provided to both industry and national inspectors in order to maximise implementability and enforceability of the proposed restriction. SEAC acknowledges current technological barriers in identifying microplastics and advises (time-limited) changes to the targeting of the restriction.