EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) …/…

of XXX

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles

(Text with EEA relevance)

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amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[1], and in particular Article 68(1) thereof,

Whereas:

(1) The ubiquitous presence of tiny fragments of synthetic or chemically-modified natural polymers, which are insoluble in water, degrade very slowly and can easily be ingested by living organisms, raises concerns about their general impact on the environment and, potentially, on human health. Those polymers are widespread in the environment and have also been found in drinking water and food. They accumulate in the environment and contribute to the microplastic pollution.

(2) A big part of the microplastic pollution forms unintentionally, for example as a result of the breakdown of larger pieces of plastic waste, or the wear and tear of tyres and road paint, or the washing of synthetic clothes. However, tiny fragments of synthetic or chemically-modified natural polymers are also manufactured to be used as such or added to products.

(3) The Council, in the conclusions of 20 June 2016 on the EU action plan for the circular economy[2] and of 24 March 2017 on international ocean governance[3], called upon the Commission to propose measures to reduce the discharge of macro- and micro-sized plastic debris in the marine environment, including a proposal for a ban on polymers in cosmetics, personal care products and detergents.

(4) In a bid to tackle plastic pollution, in January 2018 the Commission adopted a plastics strategy[4] which aimed, among other things, to reduce all sources contributing to the

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1 OJ L 396, 30.12.2006, p 1.

2 https://data.consilium.europa.eu/doc/document/ST-10518-2016-INIT/en/pdf /

3 https://www.consilium.europa.eu/media/24073/st_7348_2017_rev_1_en.pdf

4 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A European Strategy for Plastics in a Circular Economy (COM/2018/028 final).

microplastic pollution. This commitment was renewed with the publication of the European Green Deal[5] in December 2019, the new Circular Economy Action Plan[6] in March 2020 and the Zero Pollution Action Plan[7] in May 2021. The latter, in particular, includes reducing by 30% the amount of microplastics released into the environment among its 2030 targets.

(5) In September 2018, the European Parliament called[8] on the Commission to introduce a ban on microplastics in cosmetics, personal care products, detergents and cleaning products by 2020.

(6) The potential impacts of microplastic pollution on the environment and possibly human health have raised concerns in various parts of the world. Several Member States have adopted or proposed dedicated measures. However, a patchwork of national restrictions potentially hampers the functioning of the internal market and therefore requires harmonisation at Union level.

(7) On 9 November 2017, the Commission asked[9] the European Chemicals Agency ('the Agency') pursuant to Article 69(1) of Regulation (EC) No 1907/2006 to prepare a dossier with a view to a possible restriction of synthetic, water-insoluble polymers of 5 mm or less ('synthetic polymer microparticles') that are present in products to confer a sought-after characteristic ('intentionally-present'), in order to address the risk that those microparticles may pose to the aquatic environment ('the Annex XV dossier').

(8) On 29 January 2019, the Agency published the Annex XV dossier[10] where it concludes that the intentional use of synthetic polymer microparticles, resulting in releases to the environment, poses a risk to the environment that is not adequately controlled and needs to be addressed on a Union-wide basis. The Agency estimated that, currently, more than 42 000 tonnes of intentionally-present microplastics are eventually released into the environment every year[11]. The Annex XV dossier proposed a differentiated risk management approach to address the risk from such synthetic polymer microparticles that is not adequately controlled. A complete ban on the placing on the market was proposed for sectors and applications where the releases were considered unavoidable. Instructions for use and disposal were proposed to minimise avoidable

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5 Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions: The European Green Deal (COM/2019/640 final).

6 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A new Circular Economy Action Plan for a cleaner and more competitive Europe (COM/2020/98 final).

7 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil' (COM/2021/400 final).

8 European Parliament resolution of 13 September 2018 on a European strategy for plastics in a circular economy (P8_TA(2018)0352).

9 Commission request of 9 November 2017 asking the European Chemicals Agency to prepare a restriction proposal conforming to the requirements of Annex XVII to REACH. https://echa.europa.eu/documents/10162/5c8be037-3f81-266a-d71b-1a67ec01cbf9

10 Annex XV restriction report. https://echa.europa.eu/documents/10162/05bd96e3-b969-0a7c-c6d0-441182893720; Annex to the Annex XV restriction report. https://echa.europa.eu/documents/10162/db081bde-ea3e-ab53-3135-8aaffe66d0cb.https://echa.europa.eu/documents/10162/6ef877d5-94b7-a8f8-1c49-8c07c894fff7

11 ECHA (2020). Background Document to the Opinion on the Annex XV report proposing restrictions on intentionally added microplastics. https://echa.europa.eu/documents/10162/b56c6c7e-02fb-68a4-da69-0bcbd504212b

releases. A reporting requirement to obtain information on releases from uses excluded from the ban on the placing on the market was also suggested.

(9) More specifically, the Annex XV dossier proposed a prohibition of the placing on the market of any solid polymer contained in microparticles or microparticles which have a solid polymer surface coating, as a substance on their own or in a mixture in a concentration equal to or greater than 0,01 % by weight. This is estimated to result in a cumulative emission reduction of approximately 500 000 tonnes of microplastics over the 20-year period following the introduction of the prohibition. That corresponds to a reduction of 70 % of the quantified emissions. The concentration limit of 0,01 % corresponds to the lowest concentration reported where synthetic polymer microparticles could still have an influence on the function of a product.

(10) Due to large variability in the composition, properties and dimensions of synthetic polymer microparticles, the Annex XV dossier did not address specific polymers or any additives or other substances that the polymers may contain, but analysed a group of polymers sharing the same intrinsic properties with regard to size, dimension ratio, solid state, synthetic origin and extreme persistence in the environment.

(11) The Annex XV dossier proposed to exclude degradable or water-soluble polymers and natural polymers that have not been chemically modified, as they do not possess the same long-term persistence and, therefore, do not contribute to the identified risk.

(12) The Annex XV dossier proposed a framework of standardised test methods and pass criteria to identify degradability for the purpose of restriction. The test methods were designed to measure biotic degradation, although it cannot be excluded that some abiotic degradation takes place during the test and contributes to the test results. The test methods were grouped according to their test design and rationale. Groups 1 to 3 include relatively rapid but stringent screening tests. Groups 4 and 5 include screening and simulation studies which are increasingly more sophisticated, technically demanding and lengthy, but use testing conditions that are more environmentally relevant. The Annex XV dossier proposed that meeting the pass criteria in any of the permitted test methods in groups 1 to 5 is sufficient to demonstrate degradability for the purpose of restriction.

(13) Water-soluble solid polymers lose their solid state after their release to the environment, and therefore do not contribute to the identified concern. The Annex XV dossier therefore proposed internationally-accepted methods to test solubility and to exclude those water-soluble polymers from the scope of the restriction.

(14) The Annex XV dossier furthermore proposed a 5 mm diameter in any dimension as an upper size limit for the synthetic polymer microparticles addressed. This value is widely used in the scientific community and in legal acts in some Member States. Such limit is also consistent with the upper limit of micro-litter (including microplastics) specified in the Annex to Commission Decision (EU) 2017/848[12] and used for the implementation of Directive 2008/56/EC of the European Parliament and of the Council[13]. Finally, according to Annex XV dossier, particles below that size are more likely to be ingested by biota than larger items.

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[12] Commission Decision (EU) 2017/848 of 17 May 2017 laying down criteria and methodological standards on good environmental status of marine waters and specifications and standardised methods for monitoring and assessment, and repealing Decision 2010/477/EU (OJ L 125, 18.5.2017, p. 43).

[13] Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19).

(15) Certain fibre-like synthetic polymer particles have a length exceeding 5 mm but lower than 15 mm, for example the particles used for the reinforcement of adhesives and concrete. As those fibre-like particles are very persistent and contribute to the identified risk, the Annex XV dossier considered that they should be included in the scope of the restriction.

(16) To avoid regrettable substitution, i.e. the replacement of synthetic polymer microparticles with even smaller persistent polymer particles that may pose an equal or even larger risk to the environment, the Annex XV dossier initially included particles below the microscale in the scope of the restriction. To be consistent with the lower size limit already recommended by Commission Recommendation C/2022/3689[14], a lower size limit of 1 nm for particles and 3 nm for fibre-like particles was proposed. However, comments received during the consultation on the Annex XV dossier pointed out significant practical concerns, including regarding enforcement. To ensure enforceability, the Annex XV dossier was adjusted and the lower size limit for the synthetic polymer microparticles increased from 1 nm to 0,1 μm for particles and from 3 nm to 0,3 μm for fibre-like particles.

(17) Particles containing or coated by a synthetic or chemically-modified natural polymer that is solid and insoluble in water come in a variety of sizes. When added to a product, only some of those particles meet the size limits laid down in the Annex XV dossier and contribute to the identified concern. The Annex XV dossier therefore proposed that a polymer should be considered within the scope of restriction if, among other things, at least 1 % by weight of the particles containing or coated by that polymer meet those size limits.

(18) The Annex XV dossier proposed to exclude several uses or sectors from the prohibition of the placing on the market. It was proposed to exclude synthetic polymer microparticles for use at industrial sites because it is easier to control emissions from such uses than, for example, emissions from consumer or professional uses. To avoid overregulation regarding certain uses and sectors, it was proposed to exclude medicinal products within the scope of Directive 2001/83/EC of the European Parliament and of the Council[15] and veterinary medicinal products within the scope of Regulation (EU) 2019/6 of the European Parliament and of the Council[16], EU fertilising products within the scope of Regulation (EU) 2019/1009 of the European Parliament and of the Council[17], and food additives within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council[18]. In the view of the Agency, potential releases from in-vitro diagnostic devices can be minimised by setting conditions of use and disposal while ensuring continued socio-economic benefits of use of such devices. Moreover, derogations from the ban on the placing on the market are proposed where the risk from releases is expected to be minimised

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14 Commission Recommendation C/2022/3689 of 10 June 2022 on the definition of nanomaterial (OJ C 229, 14.6.2022, p. 1).

15 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

16 Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

17 Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1).

18 Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

because synthetic polymer microparticles are contained by technical means, permanently lose their particle form or are permanently enclosed in a solid matrix during end use.

(19) The Annex XV dossier assessed several restriction options for granular infill for use on synthetic sports surfaces and suggested either a ban on the placing on the market with a transitional period of 6 years, without exemptions, or a ban on the placing on the market with a transitional period of 3 years, with an exemption from that ban in case of use of specific risk management measures ensuring that annual releases of synthetic polymer microparticles from a synthetic sports pitch do not exceed 7 g/m^2.

(20) Regarding the prohibition of the placing on the market, for sectors or products identified during the restrictions process, specific transitional periods were proposed to allow sufficient time for concerned stakeholders to comply with the restriction and transition to suitable alternatives, for example, degradable polymers. Such transitional periods are also necessary for the Member States to prepare for the enforcement of the restriction. Finally, they minimise costs to society, without causing unnecessary delay in emission reduction. No transitional periods were proposed for other uses and products not individually identified during the restriction process.

(21) Concerning the ban on the placing on the market of 'microbeads', i.e. synthetic polymer microparticles for use as an abrasive, i.e. namely to exfoliate, polish or clean, mainly used in rinse-off cosmetic products or detergents, no transitional period was proposed, as industry was expected to have voluntarily phased out their use by 2020. For 'rinse-off' and 'leave-on' cosmetic products without microbeads, the Annex XV dossier proposed a 4-year and a 6-year transitional period.

(22) For synthetic polymer microparticles encapsulating fragrances, the Annex XV dossier considered that transitional periods of 5 or 8 years may both be appropriate in terms of their economic costs and their economic benefits. For detergents, waxes, polishes and air care products, a transitional period of 5 years was considered appropriate to give industry sufficient time to reformulate their products and substitute synthetic polymer microparticles.

(23) For controlled-release fertilisers, a transitional period of 5 years was considered justified to allow manufacturers to reformulate their products so that they achieve appropriate degradability in the environment. For capsule suspension of plant protection products covered by Regulation (EC) No 1107/2009 of the European Parliament and of the Council[19] and biocidal products covered by Regulation (EU) 528/2012 of the European Parliament and of the Council[20], a transitional period of 8 years was considered necessary to give industry sufficient time to reformulate their products, obtain an authorisation and place them on the market, while maintaining the benefits of the encapsulation technology in the interim period. As regards other agricultural and horticultural uses a transitional phase of 5 years was considered appropriate.

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[19] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

[20] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

(24) For devices covered by Regulation (EU) 2017/745 of the European Parliament and of the Council[21], 6 years were considered necessary for reformulation and transition to suitable alternatives.

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

(26) Furthermore, the Annex XV dossier proposed annual reporting requirements to monitor the effectiveness of the requirement to provide instructions for use and disposal and improve the evidence base available for the risk management of the uses of synthetic polymer microparticles exempted from the prohibition of placing on the market.

(27) On 3 June 2020, the Agency's Committee for Risk Assessment (RAC) adopted an opinion[22] pursuant to Article 70 of Regulation (EC) No 1907/2006 with respect to the Annex XV dossier. In that opinion, RAC concurred with the Annex XV dossier's conclusions about the identified risks and that the proposed restriction is an appropriate Union-wide measure to reduce those risks.

(28) RAC considered that, from a risk perspective, it is more appropriate to set no lower size limit for polymer microparticles, i.e. include all fibre-like particles smaller than 15 mm (with regard to the longest dimension of the fibres) and all other particles smaller than 5 mm. RAC considered that the omission of synthetic polymer microparticles smaller than 0,1 µm from the scope of the restriction could either provide for the continued use of synthetic polymer microparticles or even promote a shift to smaller particle sizes to circumvent the restriction. This could compromise the effectiveness of the proposed restriction, since the toxicity of particles is expected to increase the smaller their size.

(29) Furthermore, RAC considered that the criteria for excluding degradable polymers from the restriction should be more stringent than those proposed by the Annex XV dossier. Specifically, RAC considered that where it is necessary to perform tests from groups 4 and 5 to justify an exclusion, those tests should be performed and passed in three relevant environmental compartments and not only in the most relevant compartment, as proposed in the Annex XV dossier.

(30) With regard to the placing on the market of infill material for use on synthetic sports surfaces, taking into account considerations of emissions reduction, practicality and enforceability, RAC expressed a clear preference for a ban on the placing on the market after a transitional period over an exception from the ban conditional on the implementation of risk management measures. The main reason for RAC's preference was that infill material for use on synthetic turf sport surfaces is the largest contributor in terms of use of microplastics in products as well as the largest source of environmental emissions of intentionally-present synthetic polymer microparticles at European level. RAC had also concerns regarding the effectiveness of the proposed risk management measures, in particular in relation to existing sport surfaces and smaller size particles. It also stated that it does not endorse the referred limit of 7

[21] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

[22] https://echa.europa.eu/documents/10162/b4d383cd-24fc-82e9-cccf-6d9f66ee9089

g/m^2/year as any sort of acceptable threshold, as this on its own still implies substantial releases to the environment on a continued basis.

(31) On 10 December 2020, the Agency's Committee for Socio-economic Analysis (SEAC) adopted an opinion pursuant to Article 71(1) of Regulation (EC) No 1907/2006, concluding that the proposed restriction is an appropriate Union-wide measure to address the identified risks taking into account its socio-economic benefits and costs.

(32) Taking into account RAC's opinion, SEAC proposed modifications to the restrictions proposed in Annex XV dossier and considered that the definition of synthetic polymer microparticles should contain a lower size limit of 1 nm. However, in order to ensure that it is possible to implement, enforce and monitor the proposed restriction, SEAC acknowledged that it would be at least temporarily necessary to set a lower size limit at 0,1 μm (100 nm) when analytical methods or accompanying documentation cannot confirm the concentration of synthetic polymer microparticles below that size and thus the compliance with the concentration limit of the restriction cannot be verified.

(33) In addition to the exclusion of natural, degradable, and soluble polymers from the definition of synthetic polymer microparticles, as proposed by the Annex XV dossier, SEAC suggested to exclude polymers that do not contain carbon in their chemical structure as, in its view, current tools to prove persistence are not suitable for such polymers. However SEAC considered that such exclusion would need to be confirmed by RAC.

(34) For the use in the encapsulation of fragrances SEAC could not conclude whether 5 or 8 years would be the most appropriate transitional period and recommended to review the need for a transitional period longer than 5 years after the introduction of the restriction and that such review should not lead to open-ended derogations.

(35) For make-up, lip and nail 'leave-on' cosmetic products, due to their low contribution to the overall emissions of microplastics, as well as the potentially large impact on the cosmetics industry of a ban of synthetic polymer microparticles in those products, SEAC considered two additional measures as appropriate alternatives to the ban on the placing on the market of those products after a 6-year transitional period, as proposed by the Annex XV dossier: either appropriate instructions for use and disposal or a transitional period longer than 6 years. However, the uncertainties related to the different impacts on industry and concerning releases did not allow SEAC to conclude whether any of those options would be more appropriate than a ban and a 6-year transitional period, as proposed in the Annex XV dossier.

(36) SEAC noted that the implementation of risk management measures to reduce releases from granular infill for use on synthetic sports surfaces is likely to entail significantly lower costs than substituting them with alternatives. However, risk management measures would not completely eliminate such releases, so they would be less effective than a ban in the long term. Against this background, SEAC concluded that a choice of one of the options could only be based on policy priorities.

(37) SEAC notes that information received during the consultation on the SEAC draft opinion indicates that certain actors in the supply chain of plastic pellets, flakes and powders ('plastic pellets') falling within the definition of synthetic polymer microparticles are likely to be able to start reporting on their use earlier than after 36 months as proposed in Annex XV dossier due to efforts made to implement voluntary industry initiatives, such as Operation Clean Sweep.

(38) The Forum for Exchange of Information on Enforcement ('the Forum') was consulted during the restrictions process in accordance with Article 77(4), point (h), of Regulation (EC) No 1907/2006 and its recommendations were taken into account.

(39) The Forum considered that the measurement of synthetic polymer microparticles smaller than 0,1 µm poses technical difficulties and noted that, currently, the lowest technically achievable limit is around 0,1 µm. The Forum further noted that enforcement authorities may rely on documentary evidence to demonstrate that the substance or the mixture does not contain particles below 5 mm in concentrations above the limits imposed by the restriction. However, in case of doubt, the documentary evidence can only be verified by a valid physical or analytical method, or both. The Forum thus recommended to include a lower size limit in the definition of synthetic polymer microparticles. In the event that no lower limit is recommended, the Forum suggested that a temporary solution for the implementation and enforcement of the restriction based on what is practicable and in line with the currently available analytical techniques is considered. In addition, the Forum recommended a review of the definition after the entry into force of the restriction to reflect the latest scientific and technological developments.

(40) On 23 February 2021, the Agency submitted the opinions of RAC and SEAC[23] to the Commission.

(41) On 22 April 2021, the Agency submitted a RAC supplementary opinion[24] to the Commission. In particular, the Commission had asked RAC to consider i) the restriction options for infill material for artificial sports surfaces, in view of the recently published European Committee for Standardization (CEN) technical report TR17519 Surfaces for sports areas - Synthetic turf sports facilities - Guidance on how to minimise infill dispersion into the environment; and ii) the exclusion of polymers without carbon atoms that was proposed by SEAC. RAC reiterated a clear preference for a ban on the placing on the market of infill material for use on synthetic turf sports surfaces. Concerning the derogation for polymers without carbon atoms in their structure, RAC stated that, due to the absence of relevant ecotoxicity data, it was not possible to conclude that such polymers in particle form would not pose the same risks as particles originating from polymers with carbon atoms in their structure.

(42) Taking into account the Annex XV dossier, the opinions of RAC and SEAC, the socio-economic impact and the availability of alternatives, the Commission considers that there is considerable microplastic pollution arising from the use of synthetic polymer microparticles on their own or intentionally present in products. That pollution poses an unacceptable risk to the environment, which needs to be addressed on a Union-wide basis. It has been demonstrated that microplastic pollution is extremely persistent, practically impossible to remove from the environment once emitted and that it accumulates progressively in the environment. It is therefore necessary to introduce a restriction on the placing on the market of synthetic polymer

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[23] Committee for Risk Assessment (RAC), Committee for Socio-economic Analysis (SEAC) Opinion on an Annex XV dossier proposing restrictions on intentionally-added microplastics of 10 December 2020. https://echa.europa.eu/documents/10162/a513b793-dd84-d83a-9c06-e7a11580f366

[24] Committee for Risk Assessment (RAC) Opinion related to the request by the Executive Director of ECHA under Art. 77(3)(c) of REACH to prepare a supplementary opinion on: CEN technical report 17519 on risk management measures for artificial pitches and the ESTC study on their effectiveness and the proposed derogation for polymers without carbon atoms in their structure. https://echa.europa.eu/documents/10162/17229/art77_3c_mpinfillandnewderogationforpolymers_opi_rac_en.pdf/b85be7e7-c0a8-649a-a0db-56e89e39b3d5?t=1619618145726

microparticles on their own, or intentionally present in mixtures, in order to reduce emissions without undue delay. Depending on the expected socio-economic impacts and the availability of alternatives, specific transitional periods and exceptions are proposed for selected product groups.

(43) Evidence of risk exists for many polymers within the scope of the restriction. Regarding other polymers, for which there are less data, conclusions about the risk posed by them can nevertheless be drawn based on objective criteria regarding the microparticles which contain those polymers or are coated by them. The Commission considers that groups of polymers that share relevant physical and chemical properties, particle size and persistence in the environment should be covered by this restriction. This allows for the objective identification of the substances that fall within the scope of this restriction.

(44) The Commission considers it appropriate to exclude natural, degradable and soluble polymers from the definition of synthetic polymer microparticles, as they do not contribute to the risk. Furthermore, the Commission considers justified to exclude from the scope of the restriction polymers without carbon atoms in their structure as there is no relevant ecotoxicity data on whether such polymers in particle form would pose the same risks as particles originating from polymers that have carbon atoms in their structure.

(45) The Commission considers that synthetic polymer microparticles below 0,1 μm pose an equivalent or potentially higher risk to the environment than particles between 0,1 μm and 5 mm. The definition of synthetic polymer microparticles should therefore cover polymers in or coating particles below 5 mm and fibre-like particles below 15 mm. However, the Commission agrees with the Forum and SEAC that the identification and quantification of particles below 0,1 μm currently pose analytical constraints because the particles are too small. To ensure legal certainty, in those cases where existing analytical methods or accompanying documentation are not able to determine the concentration of synthetic polymer microparticles in the product, the lower size limit of those microparticles for the purpose of enforcing the restriction should therefore be set at 0,1 μm.

(46) The Commission agrees with RAC that only polymers which degrade in multiple environmental compartments should be excluded from the scope of the restriction. It is widely accepted that a positive result in any of the screening test methods in groups 1 to 3 predicts degradability in all environmental compartments. Consequently, the Commission considers that passing any of those test methods is sufficient to demonstrate degradability for the purpose of this restriction. On the other hand, it is uncertain whether a polymer passing a group 4 or 5 test in one environmental compartment would have a similar degradation behaviour in another compartment. Consequently, the Commission considers that, where group 4 or 5 test methods are used, a polymer needs to pass those tests in at least three environmental compartments to be excluded from the scope of the restriction.

(47) Synthetic polymer microparticles used in agricultural and horticultural products, for example to control the release of fertilisers or the water flow between such products and the soil, reduce the amount of active substances applied to soil and plants and limit the operator's exposure to such potentially toxic products as well as their environmental impact. It is necessary to facilitate the development of environmentally sustainable alternatives that would allow those beneficial applications to become 'microplastics-free' and remain on the market. SEAC considered that the measures

proposed for agricultural and horticultural products would be appropriate only if degradable alternatives with at least similar functionality would become available in the medium term. Finally, Regulation (EU) 2019/1009 already lays down the general principles to assess whether polymers in EU fertilising products are degradable. Against this background, the Commission considers justified to set specific conditions and pass criteria for testing the degradability of polymers in products for agricultural and horticultural applications, other than EU fertilising products, in order to ensure consistency with the testing conditions laid down in Regulation (EU) 2019/1009 and facilitate the development of alternatives.

(48) The Commission considers that the risk management measures proposed in the Annex XV dossier, as modified by RAC and SEAC, are relevant for addressing the risk identified. However, the Commission considers that the decision on which of those risk management measures is the most appropriate to address the risk identified taking into account their socio-economic impact, including the consideration of specific derogations or transitional periods, should be taken case-by-case in the various applications.

(49) It is not necessary to explicitly exclude food, feed, sewage sludge and compost from the scope as suggested in the Annex XV dossier and the opinions of RAC and SEAC, given that the synthetic polymer microparticles in these products are not intentionally present and therefore do not fall within the scope of this Regulation.

(50) For encapsulation of fragrances, the Commission considers that 6 years is the most appropriate transitional period as it will provide industry with sufficient time to reformulate all products where no alternatives are currently available.

(51) The reformulation costs expected for make-up, lip and nail 'leave-on' cosmetic products in response to the proposed restriction are higher than for other 'leave-on' cosmetic products. Taking also into account the comparatively lower contribution of make-up, lip and nail 'leave-on' cosmetic products to the overall emissions, the Commission considers that a transitional period of 12 years for the ban on placing on the market of such products is justified in order to ensure sufficient time to develop suitable alternatives and limit the costs for industry. However, in order to encourage the substitution of synthetic polymer microparticles in make-up, lip and nail 'leave-on' cosmetic products before the end of the transitional period, any make-up, lip and nail 'leave-on' cosmetic product still containing synthetic polymer microparticles after … [*OP: insert the date = 8 years from the entry into force of this Regulation*] should have a label informing consumers of this fact.

(52) As regards the risk management measure requiring to supply instructions for use and disposal, the Commission considers that the latest technological developments in electronic labelling and widespread use of mobile electronic devices should be taken into account. The restriction should therefore allow for digital access to instructions for use and disposal in electronic format as an additional method of providing information.

(53) Directive 2001/83/EC and Regulation (EU) 2019/6 require instructions for use and disposal of medicinal products for human and veterinary use, respectively, to be included on the packaging or in the package leaflet of the medicinal product. The Commission therefore does not consider that it is needed to introduce additional obligations for instructions for use and disposal of medicinal products for human or veterinary use.

(54) As regards the reporting requirements proposed in the Annex XV dossier, as modified by RAC and SEAC, the Commission finds that they will contribute to monitoring the effectiveness of the instructions for use and disposal and will improve the evidence base for the risk management of the uses exempted from the prohibition of placing on the market.

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

(56) To avoid double reporting, when there is more than one actor in the supply chain placing on the market the same product containing synthetic polymer microparticles, only the first actor within that supply chain should provide the required information to the Agency.

(57) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(58) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula von der Leyen