COMMISSION REGULATION (EU) 2023/2055

of 25 September 2023

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 microplastic pollution.

(2) A big part of 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 its 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 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.

([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) 28 final).
([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).

(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 risks from such synthetic polymer microparticles that are 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 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 quantified emissions that would otherwise occur. The concentration limit of 0,01 % corresponds to the lowest concentration level 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 a 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

([8]) European Parliament resolution of 13 September 2018 on a European strategy for plastics in a circular economy (P8 TA(2018) 352).

([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.

([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

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 be sufficient to demonstrate degradability for the purpose of the restriction.

(13) Water-soluble solid polymers lose their solid state after their release into 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 for 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.

(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 on 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 over-regulation 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

([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).

([14]) Commission Recommendation of 10 June 2022 on the definition of nanomaterial (C(2022) 3689) (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).

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 socioeconomic benefits of use of such devices. Moreover, derogations from the ban on placing on the market are proposed where the risk from releases is expected to be minimised because synthetic polymer microparticles are contained by technical means, such as those in chromatography columns, water filtering cartridges or printer toners, or permanently lose their particle form because, for example, they swell or form a film, like in diapers, nail polish or paint, or are permanently enclosed in a solid matrix during end use, such as fibres added to concrete or pellets used as feedstock for moulded articles.

(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 plant protection products covered by Regulation (EC) No 1107/2009 of the European Parliament and of the Council ([19]) and seeds treated with those products, and biocidal products covered by Regulation (EU) No 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, such as seeds coated with colorants or lubricants or other products which are not or do not contain plant protection products, a transitional period of 5 years was considered appropriate.

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

([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).

([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).

([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).

(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-reduction 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 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 Socioeconomic 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 socioeconomic benefits and costs.

(32) Taking into account RAC's opinion, SEAC proposed modifications to the restrictions proposed in the 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.

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

(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 excluding 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 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 certain 'leave-on' cosmetic products, that is make-up products, lip products and nail 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 noted 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.

([23]) Committee for Risk Assessment (RAC), Committee for Socioeconomic 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

(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 socioeconomic 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. In order to reduce emissions without undue delay, it is therefore necessary to introduce a restriction on the placing on the market of synthetic polymer microparticles on their own, or intentionally present in mixtures to confer a sought-after characteristic, for example colour, texture, bulk, water absorption, fluidity or heat resistance. Depending on the expected socioeconomic 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 in all dimensions pose an equivalent or potentially higher risk to the environment than particles between 0,1 μm and 5 mm in all dimensions. The definition of synthetic polymer microparticles should therefore cover polymers in or coating particles below 5 mm in all dimensions and fibre-like particles below 15 mm in length. However, the Commission agrees with the Forum and SEAC that the identification and quantification of particles below 0,1 μm in any dimension, or 0,3 μm in length, as the case may be, currently pose analytical constraints because the particles are too small. To ensure legal certainty, in those cases where available analytical methods or the documentation accompanying the product do not permit 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 be set at 0,1 μm in any dimension or 0,3 μm in length, as the case may be. This limit should no longer apply as soon as new or improved methods become available permitting the identification and quantification of synthetic polymer microparticles measuring less than 0,1 μm in any dimension or 0,3 μm in length, as the case may be.

([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

(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 three environmental compartments to be excluded from the scope of the restriction.

(47) To take into account any scientific developments concerning polymer degradation and solubility, including new test methods specifically developed to assess the degradability or solubility of synthetic polymer microparticles, it may be necessary to review the standardised test methods and pass criteria to demonstrate degradability or solubility.

(48) Synthetic polymer microparticles used in agricultural and horticultural products, for example to control the release of fertilisers or plant protection products, or the water flow between fertilisers 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, such as fertilising products which are not CE marked when made available on the market, in order to ensure consistency with the testing conditions laid down in Regulation (EU) 2019/1009 and facilitate the development of alternatives.

(49) 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 socioeconomic impact, including the consideration of specific derogations or transitional periods, should be taken case-by-case in the various applications.

(50) It is not necessary to explicitly exclude 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. On the other hand, food and feed within the scope of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([25]) should be excluded from the scope to prevent double-regulation.

(51) 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.

(52) The reformulation costs expected for make-up products, lip products and nail 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 products, lip products and nail 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 products, lip products and nail products before the end of the transitional period, any make-up product, lip product and nail product placed on the market still containing synthetic polymer microparticles should bear a statement informing consumers of this fact starting

([25]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

from 17 October 2031. To avoid unnecessary burden for suppliers and product recalls, suppliers should not be required to provide the above-mentioned statement on the products which have already been placed on the market before 17 October 2031 for a certain additional period.

(53) For granular infill for use on synthetic sports surfaces, the Commission considers that increasing the transitional period for the ban on placing on the market to 8 years is justified in order to ensure that a larger number of existing synthetic sport surfaces using this product can reach their natural end-of-life before they need to be replaced.

(54) As regards the risk management measure requiring the supplying of instructions for use and disposal, it is justified to set a transitional period longer than 24 months for suppliers of in vitro diagnostic devices containing synthetic polymer microparticles to allow for the information on the appropriate disposal of such microparticles to be passed down the supply chain and, in case of change to the product leaflet or packaging, for sufficient time to obtain the necessary regulatory approvals, where needed. Furthermore, 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.

(55) 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.

(56) 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. The Commission further considers that including a reference to the applicable derogations in the information to be reported to the Agency is needed in order to facilitate enforcement without imposing additional burden on industry. In addition, manufacturers and industrial downstream users should be required to estimate and report their own emissions. Furthermore, in order to ensure that all emissions along the supply chain are monitored and reported without adding undue burden on end users, suppliers of products containing synthetic polymer microparticles that place those products on the market for the first time to professional users and the general public are to also estimate, in addition to their own emissions, the downstream emissions from the moment the product is placed on the market to the moment it is disposed of after end use and report the total emissions to the Agency. To ensure the optimal use of the reported information and facilitate enforcement, such information should be made available to the Member States.

(57) 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 a 24-month transitional period for reporting requirements for this sector justified.

(58) 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.

(59) In order to facilitate the enforcement of this restriction, manufacturers, importers and industrial downstream users of products containing synthetic polymer microparticles should provide to competent authorities, upon their request, specific information enabling the unequivocal identification of the polymers in the scope of this restriction contained in their products and the function of those polymers in the product. Furthermore, manufacturers, importers and industrial downstream users claiming that certain polymers in their products are excluded from the designation of synthetic polymer microparticles on grounds of degradability or solubility should provide information proving those properties to competent authorities upon their request. Industrial downstream users that do not have the required information should request it from their suppliers first. To protect the confidentiality of commercial information, suppliers that do not wish to share the requested information with industrial downstream users should be allowed to provide it directly to the competent authority requesting it.

(60) To prevent unnecessary product recalls and reduce waste, it is necessary to provide that synthetic polymers microparticles, on their own or in mixtures, that have been placed on the market before 17 October 2023 may continue to be placed on the market. That rule is not needed for uses of synthetic polymers microparticles subject to transitional periods.

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

(62) 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, 25 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annex XVII to Regulation (EC) No 1907/2006 is amended as follows:

(1) the following entry is added:

‘78.	Synthetic polymer microparticles: polymers that are solid and which fulfil both of the following conditions: (a) are contained in particles and constitute at least 1 % by weight of those particles; or build a continuous surface coating on particles; (b) at least 1 % by weight of the particles referred to in point (a) fulfil either of the following conditions: (i) all dimensions of the particles are equal to or less than 5 mm; (ii) the length of the particles is equal to or less than 15 mm and their length to diameter ratio is greater than 3. The following polymers are excluded from this designation: (a) polymers that are the result of a polymerisation process that has taken place in nature, independently of the process through which they have been extracted, which are not chemically modified substances; (b) polymers that are degradable as proved in accordance with Appendix 15; (c) polymers that have a solubility greater than 2 g/L as proved in accordance with Appendix 16; (d) polymers that do not contain carbon atoms in their chemical structure.	1. Shall not be placed on the market as substances on their own or, where the synthetic polymer microparticles are present to confer a sought-after characteristic, in mixtures in a concentration equal to or greater than 0,01 % by weight. 2. For the purposes of this entry, the following definitions apply: (a) “particle” means a minute piece of matter, other than single molecules, with defined physical boundaries; (b) “solid” means a substance or mixture other than a liquid or gas; (c) “gas” means a substance or mixture which at 50 °C has a vapour pressure greater than 300 kPa (absolute), or is completely gaseous at 20 °C at a standard pressure of 101,3 kPa; (d) “liquid” means a substance or mixture that meets any of the following conditions: (i) the substance or mixture at 50 °C has a vapour pressure of not more than 300 kPa, is not completely gaseous at 20 °C and at a standard pressure of 101,3 kPa, and has a melting point or initial melting point of 20 °C or less at a standard pressure of 101,3 kPa; (ii) the substance or mixture fulfils the criteria in the American Society for Testing and Materials (ASTM) D 4359-90 Standard Test Method for Determining Whether a Material Is a Liquid or a Solid; (iii) the substance or mixture passes the fluidity test (penetrometer test) described in chapter 2.3.4 of Part 2 of Annex A to the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) concluded at Geneva on 30 September 1957; (e) “make-up product” means any substance or mixture intended to be placed in contact with specific external parts of the human body, namely the epidermis, eye brows and eye lashes, with a view to, exclusively or mainly, changing their appearance; 3. Where the concentration of synthetic polymer microparticles covered by this entry cannot be determined by available analytical methods or accompanying documentation, in order to verify the compliance with the concentration limit referred to in paragraph 1, only the particles of at least the following size shall be taken into account: (a) 0,1 μm for any dimension, for particles where all dimensions are equal to or smaller than 5 mm; (b) 0,3 μm in length, for particles that have a length that is equal to or smaller than 15 mm and a length to diameter ratio greater than 3.

	4. Paragraph 1 shall not apply to the placing on the market of: (a) synthetic polymer microparticles, as substances on their own or in mixtures, for use at industrial sites; (b) medicinal products within the scope of Directive 2001/83/EC and veterinary medicinal products within the scope of Regulation (EU) 2019/6 of the European Parliament and of the Council (*); (c) EU fertilising products within the scope of Regulation (EU) 2019/1009 of the European Parliament and of the Council (**); (d) food additives within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council (***); (e) in vitro diagnostic devices, including devices within the scope of Regulation (EU) 2017/746 of the European Parliament and of the Council (****); (f) food within the meaning of Article 2 of Regulation (EC) No 178/2002, not covered by point (d) of this paragraph, and feed as defined in Article 3(4) of that Regulation. 5. Paragraph 1 shall not apply to the placing on the market of the following synthetic polymer microparticles, as substances on their own or in mixtures: (a) synthetic polymer microparticles which are contained by technical means so that releases to the environment are prevented when used in accordance with the instructions for use during the intended end use; (b) synthetic polymer microparticles the physical properties of which are permanently modified during intended end use in such a way that the polymer no longer falls within the scope of this entry; (c) synthetic polymer microparticles which are permanently incorporated into a solid matrix during intended end use. 6. Paragraph 1 shall apply as follows regarding the following uses: (a) from 17 October 2029 to synthetic polymer microparticles for use in the encapsulation of fragrances; (b) from 17 October 2027 for “rinse-off products” as defined in point (1)(a) of the Preamble to Annexes II to VI to Regulation (EC) No 1223/2009 unless such products are covered by point (a) of this paragraph or contain synthetic polymer microparticles for use as an abrasive, i.e. namely to exfoliate, polish or clean (“microbeads”); (c) from 17 October 2035 for lip products as defined in point (1)(e) of the Preamble to Annexes II to VI to Regulation (EC) No 1223/2009, nail products as defined in point (1)(g) of the Preamble to Annexes II to VI to that Regulation, and make-up products within the scope of that Regulation, unless such products are covered by points (a) or (b) of this paragraph or contain microbeads;

	(d) from 17 October 2029 for leave-on products, as defined in point (1)(b) of the Preamble to Annexes II to VI to Regulation (EC) No 1223/2009, unless such products are covered by points (a) or (c) of this paragraph; (e) from 17 October 2028 for detergents, as defined in Article 2(1) of Regulation (EC) No 648/2004, waxes, polishes and air care products, unless those products are covered by point (a) of this paragraph or contain microbeads; (f) from 17 October 2029 for "devices", within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council (*****), unless those devices contain microbeads; (g) from 17 October 2028 for "fertilising products", as defined in Article 2, point (1), of Regulation (EU) 2019/1009, which do not fall within the scope of that Regulation; (h) from 17 October 2031 for plant protection products within the meaning of Article 2(1) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council (******) and seeds treated with those products, and biocidal products as defined in Article 3(1), point (a), of Regulation (EU) No 528/2012 of the European Parliament and of the Council (*******); (i) from 17 October 2028 for products for agricultural and horticultural uses not covered by points (g) or (h); (j) from 17 October 2031 for granular infill for use on synthetic sports surfaces. 7. From 17 October 2025 suppliers of synthetic polymer microparticles referred to in paragraph 4, point (a), shall provide the following information: (a) instructions for use and disposal explaining to industrial downstream users how to prevent releases of synthetic polymer microparticles to the environment; (b) the following statement: "The synthetic polymer microparticles supplied is subject to conditions laid down by entry 78 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council"; (c) the information on quantity or, as applicable, concentration of synthetic polymer microparticles in the substance or mixture; (d) generic information on the identity of the polymers contained in the substance or mixture that enables manufacturers, industrial downstream users and other suppliers to comply with their obligations laid down in paragraphs 11 and 12. 8. From 17 October 2026 suppliers of products containing synthetic polymer microparticles referred to in paragraph 4, point (e), and from 17 October 2025 suppliers of products containing synthetic polymer microparticles referred to in paragraph 4, point (d), and paragraph 5, shall provide instructions for use and disposal explaining to professional users and the general public how to prevent releases of synthetic polymer microparticles to the environment.

	9. From 17 October 2031 until 16 October 2035 suppliers of products referred to in paragraph 6, point (c), containing synthetic polymer microparticles shall provide the following statement: "This product contains microplastics." However, products placed on the market before 17 October 2031 are not required to bear that statement until 17 December 2031. 10. The information referred to in paragraphs 7, 8 and 9 shall be provided in the form of clearly visible, legible and indelible text or, where appropriate regarding the information in paragraphs 7 and 8, in the form of pictograms. The text or pictograms shall be placed on the label, the packaging, or the package leaflet of the products containing synthetic polymer microparticles or, regarding the information in paragraph 7, on the safety data sheet. In addition to the text or pictograms, suppliers may provide a digital tool that gives access to an electronic version of that information. Where instructions for use and disposal are provided in accordance with paragraphs 7, 8 and 9 in the form of a text, they shall be in the official languages of the Member States where the substance or mixture is placed on the market, unless the Member States concerned provide otherwise. 11. Starting from 2026 manufacturers and industrial downstream users of synthetic polymer microparticles in the form of pellets, flakes, and powders used as feedstock in plastic manufacturing at industrial sites, and, starting from 2027, other manufacturers of synthetic polymer microparticles and other industrial downstream users using synthetic polymer microparticles at industrial sites shall submit the following information to the Agency by 31 May of each year: (a) a description of the uses of synthetic polymer microparticles in the previous calendar year; (b) for each use of synthetic polymer microparticles, generic information on the identity of the polymers used; (c) for each use of synthetic polymer microparticles, an estimate of the quantity of synthetic polymer microparticles released to the environment in the previous calendar year, which shall include also the quantity of synthetic polymer microparticles released to the environment during transportation. (d) for each use of synthetic polymer microparticles, a reference to the derogation laid down in paragraph 4, point (a). 12. From 2027, suppliers of products containing synthetic polymer microparticles referred to in paragraphs 4, points (b), (d) and (e), and paragraph 5, placed on the market for the first time to professional users and the general public, shall submit the following information to the Agency by 31 May of each year: (a) a description of the end uses for which the synthetic polymer microparticles were placed on the market in the previous calendar year;

	(b) for each end use for which the synthetic polymer microparticles were placed on the market, generic information on the identity of the polymers placed on the market in the previous calendar year; (c) for each end use for which the synthetic polymer microparticles were placed on the market, an estimate of the quantity of synthetic polymer microparticles released to the environment in the previous calendar year, which shall include also the quantity of synthetic polymer microparticles released to the environment during transportation. (d) for each use of synthetic polymer microparticles, a reference to the applicable derogation or derogations laid down in paragraph 4, point (b), (d) or (e), or 5 point (a), (b) or (c). 13. The Agency shall make the information submitted under paragraphs 11 and 12 available to the Member States. 14. Manufacturers, importers and industrial downstream users of products containing synthetic polymer microparticles shall provide specific information on the identity of polymers covered by this entry contained in those products and the function of those polymers in the products to competent authorities upon their request. The specific information on the polymer identity shall be sufficient to unequivocally identify polymers and shall at least include the information laid down in points 2.1 to 2.2.3 and points 2.3.5, 2.3.6 and 2.3.7 of Annex VI, where applicable. If the information is not available to industrial downstream users, they shall request it from their supplier within 7 days from the receipt of the request from the competent authorities and shall inform the authorities of the request made without delay. Having received the request referred to in the second subparagraph, the suppliers shall provide the requested information within 30 days to the industrial downstream user or directly to the competent authority requesting it. Where the supplier provides the information to the industrial downstream user, the industrial downstream user shall forward that information to the competent authorities without delay. Where the supplier provides the information directly to the authority, it shall without delay inform the industrial downstream user concerned to that effect. 15. Manufacturers, importers and industrial downstream users of products containing polymers claimed to be excluded from the designation of synthetic polymer microparticles on grounds of degradability or solubility shall provide, without delay, information proving that those polymers are degradable in accordance with Appendix 15 or soluble in accordance with Appendix 16, as applicable, to competent authorities upon their request.

	16. Paragraph 1 shall not apply to placing on the market of synthetic polymers microparticles, on their own or in mixtures, placed on the market before 17 October 2023. However, the first subparagraph shall not apply to the placing on the market of synthetic polymers microparticles for uses listed in paragraph 6.

(*) 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).

(**) 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).

(***) 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).

(****) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

(*****) 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).

(******) 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).

(*******) 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).'

(2) the following Appendices 15 and 16 are added:

'Appendix 15

Entry 78 – Rules on proving degradability

This appendix lays down the rules for proving degradability of polymers for the purposes of entry 78, namely the permitted test methods and the pass criteria for those methods. 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 tests shall be conducted by laboratories complying with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency or accredited to ISO 17025.

1. **Test methods**

The permitted test methods are organised into five groups, on the basis of their design and underlying rationale. Meeting the pass criteria in any of the permitted test methods in groups 1 to 3 is sufficient to demonstrate that the polymer or polymers contained in the tested material and subject to the test are degradable and are therefore excluded from the scope of entry 78. Where group 4 or group 5 tests are used to demonstrate degradability of polymers for uses other than agricultural and horticultural uses, the pass criteria shall be met in three environmental compartments chosen as follows:

Compartment 1: fresh, estuarine or marine water;

Compartment 2:

(a) fresh, estuarine or marine sediment; or

(b) fresh, estuarine or marine water/sediment interface

Compartment 3: soil.

1.1. *Group 1. Screening test methods and pass criteria to demonstrate ready biodegradation*

1.1.1. Permitted test methods in group 1:

T1. "Ready Biodegradability" (OECD TG 301 B, C, D, F)

T2. "Ready Biodegradability – CO_2 in sealed vessels (Headspace Test)" (OECD TG 310).

1.1.2. Pass criteria: 60 % mineralisation measured, over 28 days, as evolved CO_2 or consumed O_2. The 10-day window requirement mentioned in the T1 and T2 test guidelines does not need to be fulfilled.

1.2. *Group 2. Modified and enhanced screening test methods and pass criteria to demonstrate ready biodegradation*

1.2.1. Permitted test methods in group 2:

T1. "Ready Biodegradability" (OECD TG 301 B, C, D, F);

T2. "Ready Biodegradability – CO_2 in sealed vessels (Headspace Test)" (OECD TG 310);

T3. "Biodegradability in Seawater" (OECD TG 306).

1.2.2. For group 2 test methods, the test duration can be extended to up to 60 days and larger test vessels used.

1.2.3. Pass criteria: 60 % mineralisation measured, over 60 days, as consumed O_2 (allowed for T1 and T2 tests only) or evolved CO_2. The 10-day window requirement mentioned in the T1 and T2 test guidelines does not need to be fulfilled.

1.3. *Group 3. Screening test method and pass criteria to demonstrate inherent degradation*

1.3.1. Permitted test method in group 3:

T4. "Inherent Biodegradability: modified MITI Test (II)" (OECD 302C).

1.3.2. The pre-adaptation of the inoculum mentioned in the T4 test guideline shall not be allowed.

1.3.3. Pass criteria: ≥ 70 % mineralisation measured as consumed O_2 or evolved CO_2 within 14 days.

1.4. *Group 4. Screening test methods and pass criteria to demonstrate degradation relative to a reference material*

1.4.1. Permitted test methods in group 4:

T5. "Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium – Method by analysis of evolved carbon dioxide." (EN ISO 14852:2021);

T6. "Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium – Method by measuring the oxygen demand in a closed respirometer." (EN ISO 14851:2019);

T7. "Plastics – Determination of aerobic biodegradation of non-floating plastic materials in seawater/sediment interface – Method by analysis of evolved carbon dioxide" (EN ISO 19679:2020);

T8. "Plastics – Determination of aerobic biodegradation of non-floating plastic materials in seawater/sandy sediment interface – Method by measuring the oxygen demand in closed respirometer" (EN ISO 18830:2016);

T9. "Plastics – Determination of the ultimate aerobic biodegradability of plastic materials in soil by measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved" (EN ISO 17556:2019);

T10. "Plastics – Determination of the aerobic biodegradation of non-floating materials exposed to marine sediment – Method by analysis of evolved carbon dioxide" (ISO 22404:2019).

1.4.2. The specifications laid down in ISO 22403:2020 "Plastics – Assessment of the intrinsic biodegradability of materials exposed to marine inocula under mesophilic aerobic laboratory conditions – Test methods and requirements" shall be taken into account when applying T7 and T8.

1.4.3. For group 4 test methods, the pre-adaptation of the inoculum shall not be allowed. The result shall be reported as the maximum level of degradation determined from the plateau phase of the degradation curve, or as the highest value if the plateau has not been reached. The form, size and surface area of the reference material shall be comparable to that of the test material. The following materials may be used as reference materials:

— positive controls: biodegradable materials such as micro-crystalline cellulose powder, ashless cellulose filters or poly-β-hydroxybutyrate.

— negative controls: non-biodegradable polymers such as polyethylene or polystyrene.

1.4.4. Pass criteria: ultimate degradation of ≥ 90 % relative to the degradation of the reference material within:

— 6 months in aquatic tests, or,

— 24 months in soil, sediment or water/sediment interface tests.

1.5. *Group 5. Simulation test methods and pass criteria to demonstrate degradation under relevant environmental conditions*

1.5.1. Permitted test methods in group 5:

T11. "Aerobic and Anaerobic Transformation in Soil" (OECD TG 307);

T12. "Aerobic and Anaerobic Transformation in Aquatic Sediment Systems" (OECD TG 308);

T13. "Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test" (OECD TG 309)

1.5.2. The required test temperatures shall be 12 °C for fresh/estuarine water, fresh/estuarine water sediment and soil, and 9 °C for marine water and marine sediment because these are the average temperatures for those compartments in the Union.

1.5.3. Pass criteria:

— the degradation half-life in marine, fresh or estuarine water is less than 60 days;

— the degradation half-life in marine, fresh or estuarine sediment is less than 180 days;

— the degradation half-life in soil is less than 180 days.

2. **Specific requirements for demonstrating the degradability of polymers in products for agricultural and horticultural applications**

2.1. *Fertilising products containing polymers which are coating agents or increase the water retention capacity or the wettability of the product*

The degradability of polymers which are coating agents or increase the water retention capacity or the wettability in fertilising products, as defined in Article 2, point (1), of Regulation (EU) 2019/1009, which do not fall within the scope of that Regulation shall be demonstrated in accordance with the delegated acts referred to in Article 42(6) of that Regulation. In the case of absence of such delegated acts, such polymers shall not be placed on the market in fertilising products which do not fall within the scope of Regulation (EU) 2019/1009 after 17 October 2028.

2.2. *Agricultural and horticultural products other than fertilising products referred to in paragraph 2.1*

Where group 4 or group 5 test methods are used, the degradability of polymers in products for agricultural or horticultural applications other than fertilising products referred to in point 2.1 shall be demonstrated in at least two environmental compartments chosen as follows:

Compartment 1: fresh, estuarine or marine water;

Compartment 2: soil.

To be considered degradable for the scope of entry 78, a polymer in a product for agricultural or horticultural applications other than a fertilising product referred to in point 2.1 shall achieve 90 % degradation in:

(a) soil within 48 months after the end of that product functionality period; the functionality period is the time following the product application during which the product exerts its function.

(b) water within:

(i) 12 months plus the product functionality period, where group 4 test methods are used; or

(ii) 16 months plus the product functionality period, where group 5 test methods are used.

To this end, the pass criteria for group 4 and 5 test methods shall be modified to indicate the percentage of degradation (for group 4) or the half-life (for group 5) that needs to be observed at the end of the standard test duration in order to achieve the conditions laid down in the previous paragraph.

The modified pass criteria of group 4 and 5 test methods are set in Tables A and B, respectively.

Table A

Group 4 pass criteria for polymers in products for agricultural or horticultural applications, listed by duration of the functionality period (FP) and type of test

Test method	Criterion assessed	Pass criterion (FP = 0)	Pass criterion (1 month FP)	Pass criterion (2 month FP)	Pass criterion (3 month FP)	Pass criterion (6 month FP)	Pass criterion (9 month FP)
T9 (soil)	Target degradation after 24 months	≥ 68,4 %	≥ 67,6 %	≥ 66,9 %	≥ 66,2 %	≥ 64,1 %	≥ 62,1 %

T5 and T6 (surface water)	Target degradation after 6 months	≥ 68,4 %	≥ 65,4 %	≥ 62,7 %	≥ 60,2 %	≥ 53,6 %	≥ 48,2 %

Table B

Group 5 pass criteria for polymers in products for agricultural or horticultural applications, listed by duration of the functionality period (FP) and type of test

Test method	Criterion assessed	Pass criterion (FP = 0)	Pass criterion (1 month FP)	Pass criterion (2 month FP)	Pass criterion (3 month FP)	Pass criterion (6 month FP)	Pass criterion (9 month FP)
T11 (soil, 48 months + F-P)	Degradation half-life (DegT50)	DegT50 ≤ 440 days	DegT50 ≤ 449 days	DegT50 ≤ 458 days	DegT50 ≤ 467 days	DegT50 ≤ 495 days	DegT50 ≤ 522 days
T13 (surface water, 16 months + F-P)	Degradation half-life (DegT50)	DegT50 ≤ 147 days	DegT50 ≤ 156 days	DegT50 ≤ 165 days	DegT50 ≤ 174 days	DegT50 ≤ 202 days	DegT50 ≤ 229 days

For functionality periods not covered in Tables A or B, the pass criteria shall be calculated using the exponential decay formulas indicated below.

Group 4, T9 (soil):

The target degradation over 24 months (TD_{24m}) shall be calculated as follows:

$$TD_{24m} = 1 - \exp(-\lambda \times c \times 24)$$

Group 4, T5 and T6 (surface water)

The target degradation over 6 months (TD_{6m}) shall be calculated as follows:

$$TD_{6m} = 1 - \exp(-\lambda \times c \times 6)$$

Group 5, T11 (soil) and T13 (surface water):

The degradation half-life (DegT50) observed at the end of the group 5 test duration shall be calculated as follows:

$$DegT50 = \ln(2)/\lambda$$

where:

c is the average number of days per month, calculated as:

$c = 365{,}25/12$

λ is the degradation rate, calculated as:

for T9 and T11: $\lambda_{T9/T11} = \ln(0,1)/-t_{90,T9/T11}$

for T5 and T6: $\lambda_{T5/T6} = \ln(0,1)/-t_{90,T5/T6}$

for T13: $\lambda_{T13} = \ln(0,1)/-t_{90,T13}$

t_{90} is the time- to- 90 %-degradation, calculated as:

for T9 and T11: $t_{90,T9/T11} = c \times (48 + FP)$

for T5 and T6: $t_{90,T5/T6} = c \times (12 + FP)$

for T13: $t_{90,T13} = c \times (16 + FP)$

FP is the functionality period, expressed in months.

3. **Specific requirements for the test material to be used in degradation tests**

The test shall be performed on a test material consisting of a polymer or polymers contained in or building a continuous coating on particles ("polymer particles") comparable in terms of composition, form, size and surface area to the polymer particles present in the product or, if not technically feasible, to the polymer particles that are disposed of or released to the environment.

By way of derogation from the first paragraph, polymers used for encapsulation may be tested in any of the following forms:

— in the form placed on the market;

— in the form of isolated coating;

— in the form placed on the market where the organic core of the material is replaced by an inert material such as glass.

The test material shall be of comparable thickness to the solid polymer coating of the particle placed on the market. When the degradation is assessed in relation to a reference material, as referred to in point 1.4.3, the form, size and surface area of the reference material shall be comparable to that of the test material.

Where the test material contains more than one polymer and test methods from groups 1, 2 or 3 are used to prove degradation, the degradation of each of the polymers shall be demonstrated in either of the following ways:

— separately testing the degradation of the test material and of each polymer in the test material using the permitted test methods and pass criteria set out in this Appendix,

— testing the degradation of the test material using the permitted test methods and pass criteria set out in this Appendix and, during testing, demonstrating, by any appropriate means, that all polymers in the test material contribute to the degradation observed during testing and that each polymer meets the pass criteria in the relevant permitted test method set out in this Appendix.

Where the test material is composed of a single polymer but contains other non-polymeric organic substances in concentration higher than 10 % by weight of the test material, and test methods from groups 1, 2 or 3 are used to prove degradation, either of the following conditions shall apply:

— the degradation of the test material and of the polymer in the test material shall be tested separately using the permitted test methods and pass criteria set out in this Appendix;

— the degradation of the test material shall be tested using the permitted test methods and pass criteria set out in this Appendix and, during testing, it shall be demonstrated, by any appropriate means, that the polymer contributes to the degradation of the test material observed during testing and meets the pass criteria in the relevant permitted test method set out in this Appendix.

Appendix 16

Entry 78 – Rules on proving solubility

This appendix lays down the permitted test methods and the test conditions to prove that a polymer is soluble for the purposes of entry 78. The tests shall be conducted by laboratories complying with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency or accredited to ISO 17025.

Permitted test methods:

1. OECD Guideline 120
2. OECD Guideline 105

The test shall be performed on a test material consisting of a polymer or polymers contained in or building a continuous coating on particles ("polymer particles") comparable in terms of composition, form, size and surface area to the polymer particles present in the product or, if not technically feasible, to the polymer particles that are disposed of or released to the environment.

By way of derogation from the third paragraph, for polymer particles that have all dimensions greater than 0,25 mm or have a length to diameter ratio greater than 3 and are longer than 0,25 mm, the size of the polymer particles to be tested shall be reduced in accordance with OECD guideline 120, so that at least one dimension of the polymer particle or, for polymer particles that have a length to diameter ratio greater than 3 the length of the polymer particle, is between 0,125 mm and 0,25 mm. For polymer particles containing inorganic substances in addition to a polymer or polymers, such as polymer particles encapsulated with inorganic substances or polymer particles where a polymer is grafted onto an inorganic carrier, it shall be sufficient to demonstrate that the polymer meets the pass criterion. To this end, it is allowed to test the solubility of the polymer or the polymers prior to the formation of the polymer particles.

The conditions for the solubility test shall be the following:

— Temperature 20 °C

— pH 7

— Loading: 10 g/1 000 mL

— Test time: 24 h

Pass criterion: solubility > 2 g/L.'