The road to an effective EU restriction of intentionally-added microplastics

POSITION PAPER

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Contents

Executive summary

In 2019, upon request from the European Commission, the European Chemicals Agency (ECHA) submitted a proposal for restricting the use of intentionally added microplastic particles to consumer or professional products of any kind. This restriction has the potential to significantly reduce the quantity of microplastics emitted into the environment, with subsequent positive effects on ecosystems and human health. It may stand as a crucial precedent in the fight against microplastic pollution, and other toxic chemicals. Beyond environmental considerations, the restriction has the potential to level the playing field for the providers of microplastic-free products, and open a new market for alternative providers.

A truly ambitious EU restriction of intentionally-added microplastics is within reach, but critical concerns remain to be addressed. Too many derogations, some of them unsubstantiated, unclear wording or lengthy transitional periods risk jeopardising the overall effectiveness of the restriction. The review of the restriction by ECHA's Committees is nearly finished. Once completed, the European Commission and the Member States have the power to fix the remaining issues, identified or neglected by the Committees, in line with the REACH Regulation and the Green Deal commitments.

This position paper invites decision-makers to defend an ambitious restriction and recommends the actions that the Commission and the Member States must take to secure this outcome:

1. **Secure a broad scope restriction,** that includes lower-sized microplastics, biodegradable, liquid and soluble polymers.

2. **Reject the derogations proposed when they significantly undermine the goal of the restriction or when they are unjustified.** A derogation to the general ban should only be considered when it covers an essential use without suitable alternatives. It should be scientifically justified and as narrow as possible to minimise the emission of microplastics. **This is not the case for several derogations:** microplastics placed in sport pitches; "contained by technical means"; with "physical properties [that] are permanently modified during end use at industrial sites"; or those "permanently incorporated into a solid matrix during end use", as referred to in the restriction proposal.

3. **Reject unnecessary transitional periods, in particular for microplastics in cosmetics, detergents and agricultural uses,** unless they cover an essential use without alternatives. In those cases, the transition periods should be strictly limited to what is necessary for developing substitutes.

4. **Strengthen the reporting requirements, in particular for pellets,** to make sure they support parallel regulatory supply chain measures.

This paper also recommends the EU policy-makers to keep in mind, for future action, the uses not covered in the current proposal, but which are already of concern or might be of concern later on, including microplastics used at industrial sites, liquid and semi-solid polymers but also non-intentionally added microplastics (e.g. in food and feed).

Introduction

The microplastic ball is now in the court of the European Commission and the Member States

In 2018, the European Commission tasked the European Chemicals Agency (ECHA) to review the available science on intentionally used microplastics. ECHA had to determine if it supported an EU-wide restriction under the Regulation on the Registration, Evaluation and Authorisation of Chemicals (REACH). The scope of the request was broad as it concerned "synthetic water-insoluble polymers of 5mm or less in any dimension."[1]

ECHA gathered in an Annex XV Report[2] overwhelming evidence of the need for a restriction covering all sectors. Its proposal aims to prevent the stockpiling of 400,000 tonnes of microplastics into the environment over the next 20 years and is a definite step in the right direction.[3]

When preparing the dossier, ECHA had to select the nature and scope of the mandatory restrictions, as well as whether transition periods were needed, and, if so, how long they should be. Its proposal is one interpretation of what restrictions are proportionate, considering that all available science calls for the elimination of emissions of microplastic into the environment. The interpretation it selected failed to give full effect to the prevention and precautionary principles. ECHA indeed proposed to grant many unjustified or excessive derogations and transitional periods. It also decided to subject a main source of emissions, pellets, solely to weak labelling and reporting requirements.

As part of the restriction process under REACH, ECHA's Risk Assessment Committee (RAC) and Socio-economic Assessment Committee (SEAC) adopt opinions reviewing the restriction's proposal. SEAC submitted to public consultation its final draft opinion that focuses on the costs and benefits of the proposed restriction and the question of the availability of suitable alternatives.[4] This opinion is expected to be finalised in December. RAC already adopted its final opinion.

RAC largely supports the proposed restriction with key recommendations for improvement.[5] Notably, the committee confirmed that the release of microplastics into the environment contributes to long-term irreversible environmental pollution that is practically impossible to remove, hence justifying EU-wide action. At the same time, the RAC raised important doubts with regard to some of the derogations and asked for much-needed clarifications as further explained below. SEAC is finalising its opinion. As this paper might rely on preliminary conclusions of SEAC, we will mark them with an asterisk* where the proposal might still evolve before its publication.

Even though the process is still ongoing, worrying developments have already been crystallized by ECHA in its revised proposal.[6] ECHA has expanded the scope of some derogations and extended transition periods, following increased pressure from industry to water down the proposed measures, oftentimes based on insubstantial justifications.

As soon as SEAC publishes its final opinion, the next procedural step is the decision, by the European Commission, of the extent to which the final text will follow ECHA's proposal in light of the Committees' opinion. It is an opportunity for the European Commission – and then for the EU States when they vote on this proposal - to fulfil their original commitment to curb microplastic pollution. As confirmed by RAC, there is sufficient scientific evidence of the potential of microplastics to cause large-scale irreversible harm to the environment. The Commission and Member States therefore must now decide what activity, if any, can justify causing irreversible harm.

1. Annex XV Report, p.22
2. Annex XV Report: https://echa.europa.eu/documents/10162/05bd96e3-b969-0a7c-c6d0-441182893720
3. Annex XV Report, p.11
4. Draft SEAC Opinion, dated 11 June 2020: https://echa.europa.eu/documents/10162/5a730193-cb17-2972-b595-93084c4f39c8
5. RAC Opinion dated, 11 June 2020: https://echa.europa.eu/documents/10162/b4d383cd-24fc-82e9-cccf-6d9f66ee9089
6. ECHA's Background Document to the Opinion on the Annex XV report proposing restrictions on intentionally added microplastics: https://echa.europa.eu/documents/10162/2ddaab18-76d6-49a2-ec46-8350dabf5dc6

The EU institutions and Member States have some, but not full, discretion in the definition of what amounts to "acceptable pollution" – they have to respect EU primary law, secondary law and their EU and international political commitments. Under the European Treaties and legislation, when there is scientific evidence that not acting will or will probably lead to unacceptable consequences to human health or the environment, the EU institutions and States have a duty to prevent harm. That is why, in the context of a REACH restriction, due account must be taken of the complex scientific assessments provided by ECHA and its committees; yet the EU institutions enjoy a broad discretion in following that scientific advice.[7] If they were to disregard one of the scientific opinions, they "must provide specific reasons for its findings by comparison with those made in the ECHA opinion and its statement of reasons must explain why it is disregarding the latter".[8] As the Court of Justice has recently made clear,[9] Article 35 of the Charter of Fundamental Rights requires the EU institutions to comply with the precautionary principle when acting in areas such as chemicals regulation that have implications for human health. Article 37 of the Charter demands the same when it comes to environmental protection. So the EU institutions and Member States must adhere to the precautionary principle when assessing the relevance of each measure under the restriction's proposal, in the light of the opinions of RAC and SEAC but, most importantly, of the environmental protection objective.

HOW TO USE THIS POSITION PAPER?

With this position paper, **the coalition of NGOs** (as identified on page 50) **wish to alert the European Commission and the Member States to the crucial remaining concerns undermining ECHA's proposal, and help identifying a better way forward.**

The paper highlights first the essential elements from ECHA's proposal and scientific opinions that the Commission and Member States need to take due account of, or endorse, for this restriction to have any positive effect for the environment (Part I). The paper then identifies the most problematic proposals made which, if adopted, risk jeopardising the overall effectiveness of the restriction (Part II). Finally, the paper lists the issues that fall outside the scope of the evaluation carried out by ECHA but are clearly cause for serious concern and thus will need to be addressed in the near future (Part III). Specific recommendations on the amendments required to the restriction proposal can be found in the Annex to this paper.

The recommendations were drafted with the support of several experts, who are listed and can be contacted for each specific topic.

This paper will be updated after SEAC adopts its final opinion. Argumentation based on the draft SEAC Opinion and that is still not definitive will be marked with an asterisk (*) throughout the document.

7. Judgment of the General Court of 7 March 2019, *Kingdom of Sweden v European Commission*, T-837/16, para.64-69
8. Judgment of the General Court of 7 March 2019, *Kingdom of Sweden v European Commission*, T-837/16, para.69
9. Judgment of the Court of Justice (Grand Chamber) of 1 October 2019, *Blaise and others,* Case C-616/17, paras.41-42: "[W]hile Article 191(2) TFEU provides that the policy on the environment is to be based on, inter alia, the precautionary principle, that principle is also applicable in the context of other EU policies, in particular the policy on the protection of public health and where the EU institutions adopt, under the common agricultural policy or the policy on the internal market, measures for the protection of human health…. There is therefore an obligation on the EU legislature… to comply with the precautionary principle, in order to ensure, in particular, in accordance with Article 35 of the Charter of Fundamental Rights of the European Union and Article 9 and Article 168(1) TFEU, a high level of protection of human health."

Essential elements from the ECHA proposal that should be secured

1 The need to endorse the strong scientific evidence of unacceptable risk

On several occasions, industry stakeholders have claimed the restriction proposal lacks scientific justification that would allow for a valid assessment of microplastics' hazardous properties.[10] They further noted that incomplete scientific evidence, for example on the bioaccumulation properties and biodegradation of nanomaterials, makes it impossible to draw a threshold-based risk assessment. They have also questioned the applicability of the precautionary principle due to the absence of an unacceptable risk.[11]

The environmental and health hazards of microplastics: The arguments raised by industry stakeholders are not convincing considering the extensive literature that reported on the issues raised by microplastics over the last decade.[12] Globally, 2,249 species of plant, animal and microbe are known to interact with micro- and nano-plastics,[13] and a growing body of research demonstrates these interactions are widely detrimental to the health of these organisms.[14] Hazards are typically associated with the non-polymeric substances that leach from plastic, such as residual monomers, oligomers and additives.[15] Considering that microplastics are not only pervasive in the environment, but also in the fish and shellfish destined for human consumption,[16] there is broad consensus in the scientific community that a significant risk of harm to human health exists.[17]

10. See Presentation by Mayer Brown (October 2019); and industry responses to the public consultation on ECHA's restriction proposal (RCOM documents): https://echa.europa.eu/fr/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73

11. PlasticsEurope notably highlighted that: "Since a hazard or a risk posed by microplastics has not been identified in accordance with the rules of the REACH Regulation, the proposed measures cannot be considered appropriate and proportional to an objective that is legitimate under the REACH Regulation; The scientific evidence provided to substantiate the proposed restrictions does not meet the standards required on the application of the precautionary principles". See RCOM 2 , comment #2187 at: https://echa.europa.eu/fr/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73

12. See for example: European Commission, Scientific Advice Mechanism, *Environmental and health risks of microplastic pollution*, 2019. Kelly, A., et al., Microplastic contamination in east Antarctic sea ice, 2020, Marine Pollution Bulletin, 154, 111130, https://doi.org/10.1016/j.marpolbul.2020.111130. Mason, S. et al., Microplastic pollution is widely detected in US municipal wastewater treatment plant effluent, 2016, Environmental Pollution, 218, 1045-1054, https://doi.org/10.1016/j.envpol.2016.08.056. Piehl, S., et al.,Identification and quantification of macro-and microplastics on an agricultural farmland, 2018, Scientific reports, 8(1), 1-9, https://doi.org/10.1038/s41598-018-36172-y. Westerhoff, P., et al., Antimony leaching from polyethylene terephthalate (PET) plastic used for bottled drinking water, 2008, Water Research, 42(3), 551-556, https://doi.org/10.1016/j.watres.2007.07.048. Gasperi, J., et al., Microplastics in air: are we breathing it in?, 2018, Current Opinion in Environmental Science & Health, 1, 1-5, https://doi.org/10.1016/j.coesh.2017.10.002.

13. See: https://litterbase.awi.de/

14. McCormick, M., et al., Microplastic exposure interacts with habitat degradation to affect behaviour and survival of juvenile fish in the field, 2020, *Proc. R. Soc.* B.28720201947, https://doi.org/10.1098/rspb.2020.1947.
Stephanie L. Wright, et al., Microplastic ingestion decreases energy reserves in marine worms. Current Biology, 2013, 23 (23): R1031, https://doi.org/10.1016/j.cub.2013.10.068. Martins, A., Guilhermino, L., Transgenerational effects and recovery of microplastics exposure in model populations of the freshwater cladoceran Daphnia magna Straus, 2018, Science of the Total Environment 631-632, 421-428; Sussarellu, R., et al., Oyster reproduction is affected by exposure to polystyrene microplastics, 2016, Proceedings of the National Academy of Sciences, 113(9), 2430-2435, https://doi.org/10.1073/pnas.1519019113. Kashiwada S., Distribution of nanoparticles in the see-through medaka (Oryzias latipes), 2006, Environmental Health Perspectives 114(11): 1697-702, https://doi.org/10.1289/ehp.9209. Rochman, C. M., et al., Early warning signs of endocrine disruption in adult fish from the ingestion of polyethylene with and without sorbed chemical pollutants from the marine environment, 2014, Science of the Total Environment, 493, 656-661, https://doi.org/10.1016/j.scitotenv.2014.06.051. Seuront L., Microplastic leachates impair behavioural vigilance and predator avoidance in a temperate intertidal gastropod, 2018, Biology Letters 14: 20180453, https://doi.org/10.1098/rsbl.2018.0453. Pedà C., et al., Intestinal alterations in European sea bass Dicentrarchus labrax (Linnaeus, 1758) exposed to microplastics: Preliminary results, 2016, Environmental Pollution 212: 251-256, https://doi.org/10.1016/j.envpol.2016.01.083

15. See Organization for Economic Cooperation and Development (OECD), Considerations and Criteria for Sustainable Plastics from a Chemicals Perspective Background Paper 1 (Copenhagen, 29-31 May 2018), pp.16-17

16. Rochman, C. M., et al., Anthropogenic debris in seafood: Plastic debris and fibers from textiles in fish and bivalves sold for human consumption, 2015, Sci. Rep. 5:14340, https://doi.org/10.1038/srep14340

17. Smith, M., L. et al., Microplastics in seafood and the implications for human health, 2018, Current Environmental Health Reports, 5(3), pp.375-386, https://doi.org/10.1007/s40572-018-0206-z. Muncke, J., et al., Impacts of food contact chemicals on human health: a consensus statement, 2020, Environmental Health, 19(1), p.1-12

The detailed hazard assessment made by ECHA: As a support to its investigation of the hazards of microplastics, ECHA conducted an impressive review of that literature (over 900 articles), principally from an environmental perspective but also considering risks to human health.[18] Despite the fact that the extent of impact on humans is still understudied, what started out as an environmental issue is now a growing human health concern.[19]

ECHA found that microplastics occur pervasively in almost all marine and freshwater environments as well as in wastewater and sewage sludge, and terrestrial environments. This justifies that "they can truly be considered as globally pervasive pollutants."[20] Numerous hazards can be associated with microplastic particles, including obstruction or interference with the normal functioning of feeding, and eco-toxicity occurring from residual monomers and oligomers or via the presence of additives and sorbed contaminants. Extensive scientific evidence reviewed by ECHA has shown that microplastics also facilitate the bioaccumulation of environmental pollutants in animals and plants, including persistent organic pollutants.[21] These contaminants can be transferred along food chains.[22]

Both ECHA and RAC acknowledged that uncertainties remain on the risks linked to exposure to microplastics.[23] However ECHA's detailed hazard assessment points very clearly towards an unacceptable risk.[24] The "arguably permanent" and "extreme" persistence of microplastics in the environment, coupled with a predicted increase of their concentration in ecosystems over time, means any release could result in adverse effects that will be difficult to reverse in the future, including on health.[25] That is the reason why ECHA chose to consider microplastic emissions as a "proxy for risk,"[26] meaning any release can be assumed to result in a risk.

The correct identification of microplastic emissions as a proxy for risk: The relevant risk characterisation should be evaluated in terms of when safe thresholds will be exceeded, rather than if safe thresholds will be exceeded.[27] ECHA's position is consistent with recent restrictions where it has not been possible to derive a safe threshold, such as decaBDE, PFOA or lead in PVC or in gunshot.

The position of ECHA as the dossier submitter is also perfectly coherent with the precautionary approach that underpins the REACH Regulation.[28] Where there are real threats of serious and irreversible harm, a lack of certainty surrounding the issue should elicit policy responses that would accommodate for a worst-case scenario.[29] Professor De Sadeeler substantiates this by noting that "precaution is testament to a new relationship with science, where it is consulted less for the knowledge which it has to offer than for the doubts and concerns which it is in a position to raise."[30]

18. Annex XV Report, p 68: "there is some evidence that exposure to certain chemicals could cause infertility, genetic disruption, poisoning, reduced feeding and increased mortality in marine organisms and in humans if ingested in very large quantities"
19. Studies suggest that microplastic particles can cause lung and gut injury, oxidative stress, cell damage, inflammation, and impairment of energy allocation functions. Likewise, with up to 74% of everyday plastic products containing some form(s) of toxic compounds, humans are likely to accumulate contaminants, thus affecting reproduction, fecundity, and other somatic processes. See: Galloway, T. S., Micro-and nano-plastics and human health, 2015, Marine anthropogenic litter (pp. 343-366). Springer, Cham. Tyree, C., Morisson, D., Invisibles, The plastic inside us, 2017, https://orbmedia.org/stories/Invisibles_plastics/; J. Gasperi, J., et al., Microplastics in air: Are we breathing it in?, Curr. Opin. Environ. Sci. Heal. 1, 2018, https://doi.org/10.1016/j.coesh.2017.10.002
20. Annex XV Report, p.20
21. Gallo, F., et al., Marine litter plastics and microplastics and their toxic chemicals components: the need for urgent preventive measures, 2018, https://doi.org/10.1186/s12302-018-0139-z
22. Farrell P., Nelson K., Trophic level transfer of microplastic: Mytilus edulis (L.) to Carcinus maenas (L.), 2013, Environmental Pollution, 177:1-3, https://doi.org/10.1016/j.envpol.2013.01.046. Nelms S.E., et al.,. Investigating microplastic trophic transfer in marine top predators, 2018, Environmental Pollution 38 :999-1007, https://doi.org/10.1016/j.envpol.2018.02.016; Mattsson K., et al., Brain damage and behavioural disorders in fish induced by plastic nanoparticles delivered through the food chain, 2017, Scientific Reports, 7, https://doi.org/10.1038/s41598-017-10813-0.
23. Annex XV Report, p.67
24. RAC Opinion, dated 11 June 2020, p.71 ""there are uncertainties related to hazard, fate and exposure (...) however, such uncertainties are not in the view of RAC, solved by taking a polymer-specific approach and attempting multiple quantitative assessments"
25. RAC Opinion, dated 11 June 2020, p.46 : "although there are uncertainties [...], there is sufficient evidence to conclude that they constitute an intrinsic hazard because of their long term persistence in the environment in combination with their particulate form and potential to cause adverse effects"
26. ECHA considers that microplastics should be treated as non-threshold substances for the purposes of risk assessment, similar to PBT/vPvB substances under REACH. However, ECHA did not describe a PBT/vPvB assessment for microplastics arguing that "based on the currently available information, the criteria in Annex XIII may not be applicable to microplastics". Annex XV Report, p.69
27. Annex XV Report, p.2
28. See European Commission, Communication on the Precautionary Principle, 2000 and REACH Article 1, 3)
29. Rio Declaration on Environment and Development, 1992, Principle 15
30. de Sadeleer, N., The Principles of Prevention and Precaution in International Law : two Heads of the Same Coin ?, in M. Fitzmaurice, D. Ong & P. Merkouris (ed.), Research Handbook on International Environmental Law, Cheltenham, Edward Elgar, 2010, p.186

In several cases relating to chemicals, the Court of Justice of the EU had the opportunity to recall that even in instances where it is not possible to determine with certainty the existence of a risk, the precautionary principle will justify the adoption of restrictive measures if "the likelihood of real harm to public health persists should the risk materialise".[31] Any risk management measure has to be based on "the most reliable scientific data available"[32] or on "sufficiently reliable and cogent information" that is currently available.[33] It is clear from the Annex XV report that ECHA conducted a thorough analysis of the available scientific information on microplastics, showing the existence of reasonable grounds for concern, in particular the irreversibility of microplastic pollution.[34]

With regard to the hazards and related unacceptable risks of microplastics to the environment; considering the high level of evidence available on this, it may not even be necessary to call upon the precautionary principle to justify a restriction, since the prevention principle should apply instead.[35] For human health, the level of evidence is lower; therefore such cases may require the Commission to rely on the precautionary principle to act. However, as knowledge of the human health effects of microplastics progresses, regulatory measures will automatically become less precautionary and more preventive.

In any event, ignorance and uncertainty must be clearly distinguished. Knowledge gaps form an inherent part of any scientific or risk assessment[36] and should not serve as an excuse for regulatory inertia. Several case studies, e.g. asbestos, lead or mercury, show scientific uncertainty may serve as an early warning for future grave and irreversible harm, which preventive action can help to mitigate.[37] It is also widely acknowledged that precautionary policies tend to drive, rather than impede, innovation towards safer chemicals.[38]

Our recommendation

Endorse the scientific findings presented by ECHA, and confirmed by RAC, considering those as sufficient proof of the disastrous impact of microplastics on the environment that justifies adopting an ambitious restriction without delay.

Contact person

Tom Gammage, EIA
tomgammage@eia-international.org

Frédérique Mongondin, Seas At Risk
fmongodin@seas-at-risk.org

Gaëlle Haut , Surfrider Europe
ghaut@surfrider.eu

31. See Case C-192/01, *European Commission v Denmark*, para.52; Case C-343/09, *Afton*, para.171, Case E-3/00 *EFTA Surveillance Authority v Norway*, para.31; Case C-282/15, *Queisser Pharma*, para.55
32. Case C- 236/ 01 *Monsanto*, para.113; Case C- 192/ 01 *Commission v Denmark,* para.51; Case C- 616/ 17 *Blaise*, para.94
33. Case T- 13/ 99 *Pfizer*, para.145
34. RAC Opinion, dated 11 June 2020: "The uncertainties related to risk assessment of microplastics are described in the respective sections on hazards, fate, exposure and risks. (...). The non-threshold based approach to risk assessment (and the minimisation approach to risk management) was adopted in response to these uncertainties."
35. As opposed to the precautionary principle, the prevention principle is intended to "avert risks for which the cause-and-effect relationship is already known". See N. de Sadeleer, Environmental Principles: From Political Slogans to Legal Rules (Oxford: Oxford University Press 2002), pp.74-75
36. "in the end all risk reduction measures are precautionary to some degree" - See Arie Trouwborst, "Prevention, Precaution, Logic and Law, The relationship between the precautionary principle and the preventative principle in international law and associated questions", 2009, Erasmus Law Review, Volume 02 Issue 02, p.118
37. Gee, D., "More or less precaution?", Chapter 27 in EEA Report, Late lessons from early warnings: science, precaution, innovation, 2013
38. Center for International Environmental Law (CIEL), 2013. Driving innovation, how stronger laws help bring safer chemicals to market. See at: http://www.ciel.org/Publications/Innovation_Chemical_Feb2013.pdf. Center for Strategy and Evaluation Services (CESS), 2012, Interim Evaluation: Impact of the REACH regulation on the innovativeness of EU chemical industry: https://publications.europa.eu/en/publication-detail/-/publication/c862992b-9b32-4438-b188-72ce73981ed9/language-en/format-P

2 The need to endorse the broad scope of the restriction

ECHA's restriction proposal targets the intentional uses of microplastics defined as "solid-polymer-containing particles, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 100nm ≤ x ≤ 5mm, or (ii), for fibres, a length of 300nm ≤ x ≤ 15mm and a length to diameter ratio of >3". It thus covers any synthetic polymer that "has the potential to exist as a small (typically microscopic) solid particle in the environment, and which is resistant to (bio)degradation."[39] All the intentional uses of microplastic, whatever the sector concerned, are covered except if excluded in a specific derogation.

ECHA discarded the option to have a definite list of substances as it would not be consistent with the objective of risk reduction.[40] It should be noted that the lower size limit of microplastics is still under discussion at SEAC, after ECHA revised its initial proposal (1nm) and excluded nano-sized plastics (under 100nm).* RAC has nonetheless recommended not to include any lower limit.

For a few industry lobbies, this scope remains unacceptably broad. According to them, the substances subject to restriction are "neither identified nor identifiable", which implies all polymers may be concerned by the restriction.[41] Some lobbies have challenged the proportionality of the restriction, e.g. the cosmetic lobby which argues that microplastics are part of the core technology and are essential for competitiveness.[42]

However, a restriction covering all the microplastics, and all the intentional uses of microplastics by default (with limited and justified derogations), is proportionate to its objective as it is the only way to effectively eliminate and minimise their emission into the environment.

A broad restriction is the only way to effectively minimise emissions.[43] A restriction is effective only if it achieves its objective, i.e. the minimisation of microplastics being released into the environment, in a timely and proportionate manner considering the risks at stake. In the context of this restriction, the risks at stake are particularly high: an estimated 42,400 tonnes of microplastics are released to the environment every year, with variations ranging from 13,200 to 95,000 tonnes.[44] Recent studies show these numbers may be much lower than what is in reality released.[45] As highlighted previously, any further release is bound to contribute to an increasing and practically impossible to remove environmental stock, which ECHA says "would eventually result in exposures exceeding safe thresholds in the future."[46] Furthermore, it would be ineffective to consider different restrictions depending on the type or use of microplastics, given the widespread use of microplastics across sectors, the diversity of hazards associated with those particles and the need to prevent potentially new uses that could pose similar risks.

39. RAC Opinion, dated 11 June 2020, p.7
40. "RAC agrees that the microplastic definition should be inclusive enough to avoid regrettable substitution and that because of the diversity of different polymers, and the fact that they do not have to be registered under REACH, a sufficiently comprehensive list of polymers to achieve such an aim could not be made" - See the RAC Opinion, dated 11 June 2020, p.12
41. See the VCI contribution to public consultation, RCOM 2, comment #2105, also accessible at https://www.vci.de/langfassungen/langfassungen-pdf/2019-05-20-vci-position-restriction-microplastic-echa-annex-xv-proposal-003.pdf
42. RCOM Responses, p.28
43. See the ClientEarth contribution to public consultation in May 2019, RCOM 2, comment #2121, also accessible at: https://www.documents.clientearth.org/wp-content/uploads/library/2019-05-20-clientearths-contribution-to-the-public-consultation-on-echas-proposal-to-restrict-intentionally-added-microplastic-ce-en.pdf
44. RAC opinion, dated 11 June 2020, p.67
45. Pabortsava, K., Lampitt, R.S., High concentrations of plastic hidden beneath the surface of the Atlantic Ocean. Nat Commun 11, 4073 (published on 18 August 2020), https://doi.org/10.1038/s41467-020-17932-9
46. Annex XV Report, p.4

A broad scope restriction is proportionate to its objective, i.e. the protection of health and the environment.[47] According to a settled case-law, a risk-management measure is 'proportionate' if it does not go beyond what is appropriate and necessary for achieving the objectives legitimately pursued by the measure in question, and "where there is a choice between several appropriate measures, recourse must be had to the least restrictive and that the disadvantages caused must not be disproportionate to the aims pursued."[48] ECHA diligently undertook the proportionality analysis exercise, looking at the costs and benefits of the restriction per sector. It even estimated that the restriction would have the potential to avoid 85% - 95% of the emissions from its entry into effect.[49] While the restriction does create costs on the industries impacted, ECHA has recalled that no other measure would offer similar protection given the irreversibility of microplastic pollution. "In such situations, restricting an activity can be the optimal strategy even if the expected costs of regulation outweigh the direct benefits."[50]

So far, based on the draft opinion published in June 2020, SEAC has not opposed this conclusion and concurred that the irreversibility of microplastic emissions is a key argument in favour of the proportionality of the proposed restriction, together with the availability of alternatives. The draft opinion reads: "even if the impacts of emission reduction are uncertain, early action can still be worthwhile from a social welfare perspective."[51]

Our recommendation

The European Commission and Member States must endorse the approach proposed by ECHA to restrict microplastics across sectors and irrespective of the identity of the various polymers used.

Contact person

Elise Vitali, EEB
elise.vitali@eeb.org

Hélène Duguy, ClientEarth
hduguy@clientearth.org

47. European Commission, Communication "A European Strategy for Plastics in a Circular Economy", 2018, accessible at https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1516265440535&uri=COM:2018:28:FIN
48. See joined cases T-125/96 *Boehringer Ingelheim Vetmedica and C.H. Boehringer Sohn v. Council* and T-152/96 B*oehringer Ingelheim Vetmedica and C.H. Boehringer Sohn v. Commission*, para.73
49. Annex XV Report, p.123
50. Annex XV Report, p.125
51. SEAC Draft Opinion, dated 11 June 2020, p.63

3 The restriction is enforceable, even with no lower size limit

Industry has attacked the practical enforceability of the restriction due to remaining uncertainties and lack of available analytical methods, e.g. to define biodegradability or to monitor nanoplastics.[52] The Commission and Member States should reject these arguments for the following reasons.

First, these claims are contradicted by the conclusions of the Enforcement Forum, responsible for advising on monitoring and enhancing the enforcement of REACH-connected obligations. According to the Forum, a prerequisite for the general enforceability of the restriction is that definitions are clarified, derogations are explained and justified, and extensive guidance for industry and enforcement authorities is provided.[53] Members of the Forum were not opposed to the 'no lower size limit' option, provided that it was included in the text that the microplastics definition will be reviewed "in the light of experience and with scientific and technological developments."[54]

Second, the analytical methods, e.g. for detecting microplastics in products, do already exist or are likely to be developed in the foreseeable future for the vast majority of uses.[55]

Third, if harmonised methods, in particular for identifying biodegradables, remain to be agreed upon, it does not mean the overall restriction is not "implementable, enforceable and manageable" as rightly pointed out by ECHA.[56] RAC, SEAC and the Enforcement Forum also agreed to this conclusion, highlighting that the provision of sufficient guidance should help companies and national inspectors enforce the restriction while adequate methodologies are being developed.[57]

Fourth, clear regulatory incentives - such as a restriction - are expected to trigger the development of innovative technologies.[58] Companies have shown their ability and willingness to operate a sudden shift in production, when needed to meet emerging market demands and stay competitive.[59]

Our recommendation

1) **Evaluate the analytical methods that are needed and those already available to enforce the restriction;**
2) **When there is no available method yet, or when wording clarifications are required, mandate ECHA and the European Commission to provide detailed guidance to facilitate the enforcement of the restriction.**

Contact person

Hélène Duguy, ClientEarth
hduguy@clientearth.org

Dolores Romano, EEB
dolores.romano@eeb.org

52. See, for instance, previously mentioned comments from PlasticsEurope, VCI and Verband der deutschen Lack- und Druckfarbenindustrie e.V., see NCBI Table
53. This was emphasised by the Enforcement Forum - See SEAC Draft Opinion, dated 11 June 2020, p.72
54. RAC Opinion, dated 11 June 2020, p.16
55. Annex XV Report, p. 11; SEAC draft Opinion, dated 11 June 2020, p.65
56. SEAC Draft Opinion, dated 11 June 2020, p.71
57. RAC Opinion, dated 11 June 2020, p.88
58. See CIEL, "Driving Innovation - How stronger laws help bring safer chemicals to market" report (2013), which finds how, in response to stricter laws to protect people and the environment from phthalates, international patent filings have accelerated their transition to alternative chemicals and products. See at: https://www.ciel.org/Publications/Innovation_Chemical_Feb2013.pdf
59. According to McKinsey Global Survey of Executives (October 2020), in the context of the COVID 19 outbreak, "organizations that are successfully responding to the crisis have deployed more advanced technologies, digital products, and tech talent to speed up innovation". See at: https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/how-covid-19-has-pushed-companies-over-the-technology-tipping-point-and-transformed-business-forever

Problematic elements in ECHA's proposal to be addressed

1 Unacceptable derogations

As a preliminary remark, it is worth recalling that, by principle, derogations to a restriction under REACH must be strictly necessary and proportionate in light of the objective pursued. The Court has already sanctioned the European Commission in the past for granting unjustified exemptions to the restriction of hazardous chemicals.[60] The conditions for granting derogations to a restriction under REACH should also be interpreted strictly. A derogation that significantly undermines the purpose of a restriction may not or only exceptionally be granted, with legitimate justifications. The two derogations below significantly undermine the restriction, without proper justification.

60. Case T-229/04 *Sweden v Commission* ; in appeal joined cases C-14/06 and C-295/06 EP v Commission regarding Directive 2002/95

Nanoparticles/Lower size limit

ECHA's modified restriction proposal includes a problematic lower particle dimension limit to define microplastics which would exclude nanoplastics from the definition (proposed paragraph 2a) and thus from the scope of the restriction. This lower limit should be deleted from the final version.

Nanoplastics are hazardous and a nonsensical alternative to microplastic - As the RAC detailed[61] and as evidenced by several scientific studies,[62] nanoplastics are expected to be even more harmful than microplastics due to an increase in the surface/volume ratio. Nanoplastics were notably analysed in waste sludge from water treatment plants,[63] raising the technical, economic and administrative burden of decontamination phases.

RAC's opinion stressed that nanoplastics are added to cosmetics[64] and an October 2020 opinion of the Scientific Committee on Consumer Safety (SCCS) on nanomaterials in cosmetics[65] listed polymers in cosmetic ingredients used at the nanoscale - some have been listed to raise concerns by the SCCS. Nanoparticles are particularly used in leave-on cosmetics, highlighting the risks of seeing more industries using nanoplastics in order to circumvent the restriction, as stressed by RAC.[66]

Defining microplastics with a lower size limit excluding nanoparticles will enable nonsensical substitutions from microplastics towards nanoplastics; a risk that was recognised by RAC.[67]

It is common practice to capture both nano and microplastics. In all national legislations[68] that have been adopted to restrict microbeads in cosmetics, personal care products and/or detergents, microplastics have always been defined according to an upper size limit but without a lower size limit mentioned. These national measures should have already prompted companies marketing products in these countries to reformulate their products in order to comply with the national restrictions. Therefore, should the Commission and Member States decide to introduce a lower size limit, the EU restriction, meant to strengthen the level of protection across the EU, would in fact lower the level of protection.

The restriction should be deemed enforceable even without a lower-size limit, based on the justifications developed under Section I.3) of this position paper.

Our recommendation

Define microplastics as "particles (...) having all dimensions below 5mm and fibres (...)." There should be no lower size limit to define microplastics.

Contact person

Dolores Romano, EEB
dolores.romano@eeb.org

61. RAC opinion, dated 11 June 2020, p.15
62. Triebskorn, R. Relevance of nano- and microplastics for freshwater ecosystems: A critical review. Trends in Analytical Chemistry 110 (2019) 375e392 and studies submitted by the EEB in the public consultation on Annex XV, RCOM 2, comment #2119
63. Draft Background Document, dated 11 June 2020, p.42
64. Catalogue of cosmetic ingredients from the European Union Observatory for Nanomaterials: https://euon.echa.europa.eu/catalogue-of-cosmetic-ingredients and Catalogue of nanomaterials in cosmetic products placed on the market - Version 2, DG Grow: https://ec.europa.eu/docsroom/documents/38284
65. SCCS (Scientific Committee on Consumer Safety), Scientific advice on the safety of nanomaterials in cosmetics, 6 October 2020, SCCS/1618/2020
66. Draft Background Document, dated 11 June 2020, p.184
67. RAC Opinion, dated 11 June 2020, p.15
68. RAC Opinion, dated 11 June 2020, Table 9, Overview of European regulatory action on intentionally added microplastics, p.73

Allegedly biodegradable microplastics

Considering that persistence is a key concern justifying the restriction of microplastic, it may be considered logical, *at first sight*, that non-persistent microplastics - if any truly exist to date - be derogated. However, the questions the Commission and Member States should ask themselves regarding this issue are:

1. Is persistence the only concern raised by microplastics?
2. What level of evidence should be required to allow such derogations and is this level achievable today based on existing tests?

Regarding the first question, the answer is straightforward: **no, persistence is not the only concern identified in the dossier**. As acknowledged by the RAC, in addition to persistence, microplastics raise other key concerns: "ease of ingestion, tendency for trophic transfer and expanding evidence of adverse effects on biota."[69] Hence, derogating alleged biodegradable microplastics would amount to unduly ignoring the other concerns carefully documented in the Annex XV dossier and reviewed by the RAC. This would thus be short-sighted. There is, in addition, growing evidence of the hazardous properties of chemicals present in bioplastics, similarly to conventional plastics.[70]

Regarding the second question, the Commission and Member States need to bear in mind the requirements to ensure a high level of protection of public health and the environment set out in the Treaty,[71] the main objective of the REACH Regulation to ensure a high level of protection of human health and the environment,[72] and the fact that this regulation is underpinned by the precautionary principle. All of this justifies a restrictive interpretation of conditions for derogations to a restriction.[73]

When there are important uncertainties on the scientific legitimacy of a derogation, as is the case for allegedly biodegradable microplastics, the precautionary principle warrants refraining from granting such derogation. To grant such a derogation and ensure at the same time a high level of protection, there would need to be much compelling scientific evidence showing that specific microplastics degrade *fast enough* to not contribute to the existing stock of microplastic in the environment and not harm ecosystems and wildlife.

69. RAC Opinion, dated 11 June 2020, p.48, see also section B.1.2.3
70. Zimmermann, L. et al., Are bioplastics and plant-based materials safer than conventional plastics? *In vitro* toxicity and chemical composition, 17 September 2020, https://doi.org/10.1016/j.envint.2020.106066, accessible at https://www.sciencedirect.com/science/article/pii/S0160412020320213; see also Green D.S., Biological and Ecological Impacts of Plastic Debris in Aquatic Ecosystems, 2020, In: The Handbook of Environmental Chemistry. Springer, Berlin, Heidelberg, section 3.2 (https://link.springer.com/chapter/10.1007/698_2020_509)
71. Judgment of the General Court in case T-31/07, para.145-146 and case-law cited
72. Judgment of the Court of Justice (Grand Chamber) of 7 July 2009, *S.P.C.M and Others v. Secretary of State for the Environment*, Food and Rural Affairs, C-558/07, EU:C:2009:430, para.45
73. See case successfully brought by the European Parliament and Denmark against a general exemption for the use of deca-BDE in electronic equipment: Joined Cases C-14/06 and C-295/06 EU:C:2008:176, para.74-75

‘Biodegradability’ in the microplastics restriction – the basics

According to paragraph 3(b) of ECHA’s proposed restriction, ‘(bio)degradable’ polymers fulfilling the criteria set out in Appendix X, are not covered by the restriction, meaning they are neither banned nor subject to any labelling or reporting requirements. In other words, even if these polymers fulfil the definition of ‘microplastic’ set out in Article 2 of the restriction proposal, they will still be allowed without any limitations or safeguards on the EU market.

The ability to reliably and accurately test biodegradability is therefore the keystone that will determine whether the derogation is justified, or not.

Appendix X as initially defined, sets out a testing scheme for ‘(bio)degradability’ which raised important scientific questions. In particular, NGOs highlighted three important issues:[74]

- The testing scheme initially proposed by ECHA did not prevent a microplastic composed of a **blend** of a biodegradable and a non-biodegradable polymer passing the tests and therefore being deemed – by error – entirely ‘(bio)degradable’;
- The testing scheme initially proposed by ECHA did not require the testing of degradation in **all environmental compartments** (i.e. soil, freshwater and marine environment) despite the fact that microplastics are emitted to different environmental compartments and are subject to transport between them;[75]
- The testing scheme initially proposed by ECHA allowed to rely solely on the Group 4 tests (i.e. ISO tests developed for plastic) assessing degradation only by comparing with a reference material, and not reflecting **realistic environmental conditions.**

While some of these concerns were taken into account by the RAC during the opinion making process, the Testing Scheme ultimately recommended by RAC still raises important uncertainties that call for caution, as further explained to the right.

Key definitions[76]

Screening versus **simulation** tests: Screening tests contribute information on the potential of substances to biodegrade irrespective of the environmental conditions whilst simulation tests aim to simulate environmental conditions and measure degradation in such conditions. Both types of tests are commonly used under the REACH Regulation.

There are two categories of screening tests:

- **Ready biodegradation tests** that indicate that chemicals passing the test do not offer a serious challenge to the metabolic capability of aerobic aquatic environments (given the presence of bacteria, nutrients, etc.) and that they would be readily degraded in the real environment (designated as ‘*Group 1 and 2*’ tests in the restriction dossier). These were developed with water soluble mono-constituent substances in mind, as opposed to solid polymer particles, but have been successfully applied to such particles;[77]
- **Inherent biodegradation tests** are also screening tests, but are performed using more favourable conditions than ready biodegradation tests. They are designed to show whether a potential for degradation exists (designated as ‘*Group 3*’ in the restriction dossier).

There are different types of simulation tests. The simulation tests commonly used under the REACH Regulation to establish the potential of a substance to have persistent or very persistent properties,[78] measure ‘**degradation half-lives**’ in a given environmental compartment (e.g. fresh/estuarine water, fresh/estuarine water sediment, marine water, marine sediment, and soil) (designated as ‘*Group 5*’ simulation testing in the restriction dossier).[79]

Other tests have been developed and standardised to measure the degradation of a material **in comparison to a reference material**. Some have been developed specifically for ‘plastic’ materials (designated as ‘*Group 4*’ ISO tests methods in the restriction dossier).[80]

74. See ClientEarth and ECOS additional contribution to the public consultation dated 20 September 2020, RCOM 7, comment #2707 and EEB additional contribution to the public consultation dated 20 September 2020 including a presentation made in RAC with corresponding scientific references, RCOM 7, comment #2729
75. RAC Opinion, dated 11 June 2020, p.28
76. Summary of relevant extracts from RAC Opinion, dated 11 June 2020, section 1.1.3.6 and ECHA Guidance R.11 on PBT vPvB assessments
77. RAC Opinion, dated 11 June 2020, p.24
78. See Annex XIII of the REACH Regulation
79. RAC Opinion, dated 11 June 2020, p.27
80. RAC Opinion, dated 11 June 2020, p.25

Remaining key uncertainties – the case for no derogation

The RAC identified many important uncertainties[81] in relation to each of the Testing Schemes envisaged. The Testing Scheme that was finally recommended by RAC is no exception. The main remaining uncertainty in relation to this scheme is due to its reliance on ISO tests that were developed for plastics and measure degradation by comparison to a test material ('Group 4'). Indeed, as explained by RAC, these Group 4 tests:

- Do not measure biodegradation under "*environmentally representative testing conditions*";[82]
- Do not measure the time it would take for the material to degrade (compared to Group 5 tests that estimate the 'half-life'), which means microplastic may be derogated even though they do not degrade "*sufficiently quickly to avoid them contributing to the microplastic concern*";[83]
- There is currently no sufficient information on the relationship between the results of Group 4 and Group 5 tests to allow validation of biodegradation results of Group 4.[84]

Considering these limitations, a derogation for allegedly (bio)degradable microplastic is, in our view, premature. A key piece of information is missing: what will be the 'half life' of these microplastics?

The RAC agreed with ECHA's assessment of the concerns raised by microplastics, and in particular the fact that they are considered extremely persistent.[85] To derogate microplastics from the restriction on the basis of tests that are not capable of showing how fast the microplastics will degrade in real life conditions amounts to accepting the continued use of microplastics without the necessary evidence that they will not, contrary to conventional microplastic, stockpile in the environment. It amounts to encouraging substitution in a direction without the guarantees necessary to avoid repeating the same mistakes.

Such derogation also fails to take into account the growing evidence regarding the hazardous properties of alternative plastics labelled as biodegradable.[86]

Considering the existing limitations in identifying truly 'biodegradable' and harmless microplastics, no derogation based on alleged biodegradability should be granted.

81. See full table 3 in RAC Opinion, dated 11 June 2020, p.32-36
82. RAC Opinion, dated 11 June 2020, p.32
83. RAC Opinion, dated 11 June 2020, p.27 and 32
84. RAC Opinion, dated 11 June 2020, p.29
85. RAC Opinion, dated 11 June 2020, p.46
86. Lisa Zimmermann, L., et al., Are bioplastics and plant-based materials safer than conventional plastics? *In vitro* toxicity and chemical composition, 17 September 2020, https://doi.org/10.1016/j.envint.2020.106066, see also Green D.S., Biological and Ecological Impacts of Plastic Debris in Aquatic Ecosystems, 2020, In: The Handbook of Environmental Chemistry. Springer, Berlin, Heidelberg, section 3.2 (https://link.springer.com/chapter/10.1007/698_2020_509)

The minimum guarantees to include in case of a (bio)degradation derogation

Should the Commission and Member State decide to maintain a derogation for '(bio)degradable' microplastic, they should, at the very least, take into account the following.

Requiring the RAC-52 Testing Scheme

Considering this state of scientific uncertainty regarding the tests, RAC had discussed (during the RAC-52 meeting) to recommend a Testing Scheme that would require Group 5 tests to be performed to validate positive Group 4 tests. In this scheme, a microplastic passing Group 4 tests would be derogated and placed on the market, but the company placing the product on the market would need to carry out Group 5 tests to validate these Group 4 tests within 10 years. This proposal would ensure a strong incentive for industry to perform the Group 5 tests (though the long duration of 10 years appeared discretionary).

The final Testing Scheme recommended by RAC deleted this validation step. This was based on the fact that there are technical difficulties in performing Group 5 tests on polymers and more specifically a difficulty in appropriately radiolabelling the test material.[87] However, as explained by RAC itself, "*radiolabelling of polymer particles would appear to be feasible as it is used in a medical context*".[88]

If the Commission and Member States were to adopt this scheme (thus without the need to perform Group 5 tests in case Group 4 tests are successful), they would, in essence, decide to trust that industry would produce the missing data voluntarily. Considering the state of the microplastic pollution in the absence of binding regulation, this trust seems misplaced.

If the Commission and Member States were to adopt the 'RAC-52 Testing Scheme', at least industry would have no choice but to produce the data needed to understand how reliable or relevant the Group 4 ISO test are to identify microplastic that would - in reality - degrade *fast enough* to avoid its stockpiling in the environment.

Prevent blends with conventional plastic

Following the public consultation, ECHA adapted its proposal to prevent a blend of non-biodegradable and biodegradable microplastic being erroneously considered 'biodegradable'.[89] According to the revised proposal, when the test material comprises a blend of polymers, it is required to either test each of the polymeric components of the blend separately, or perform chemical analysis to demonstrate that each polymeric component achieves the threshold of degradation.

RAC approved these changes as it considered that adequate assessment of blends of polymers is important.[90] This is important indeed and this improvement has to be maintained should the Commission and Member States decide to grant such derogation.

87. RAC Opinion, dated 11 June 2020, p.27 last paragraph
88. RAC Opinion, dated 11 June 2020, p.27
89. RAC Opinion, dated 11 June 2020, p 38
90. RAC Opinion, dated 11 June 2020, p.38

Test all environment compartments

Both the Testing Scheme agreed by RAC at the RAC-52 meeting and the final Testing Scheme RAC recommended in its opinion, require that ISO biodegradation tests (Group 4) and simulation tests (Group 5) be carried out for each of the three environmental compartments (Group 4: (1) soil, (2) marine and fresh water and (3) marine sediment or seawater/sediment interface; Group 5: (1) marine, fresh or estuarine water, (2) marine, fresh or estuarine sediment and (3) soil).

This is a positive development as it alleviates the scientific concern of RAC[91] that a material could be demonstrated as biodegradable in one compartment whilst remaining persistent for long periods in another bearing in mind that: microplastics are ubiquitous and even if the main releases are into soil and down the drain, it is difficult to determine in which compartment the microplastics will finally end up.[92] In addition, it is not possible to extrapolate results of Group 4 tests from one environmental compartment to another where it could be reasonably expected that biodegradation behaviour could be different in different compartments.[93]

This improvement also has to be maintained should the Commission and Member States decide to grant such a derogation.

Our recommendation

There should be no derogation for alleged '(bio)degradable' microplastics. If a derogation was adopted now, the Commission and Member States should, at least, follow the Testing Scheme discussed by the RAC at the RAC-52 meeting as well as the recommendations of RAC on the blend issue and the necessary testing in all environmental compartments.

Contact person

Elise Vitali, EEB
elise.vitali@eeb.org

91. RAC Opinion, dated 11 June 2020, p.36
92. RAC Opinion, dated 11 June 2020, p.28, 32 and 36
93. RAC Opinion, dated 11 June 2020, p.29

Sport pitches possibly derogated

The dossier submitter proposes to derogate the use of microplastics, in the form of rubber granules used in sport pitches where risk management measures are used to ensure that annual releases of microplastic do not exceed 7g/m^2.[94]

Sport pitches are the largest contributor at EU level in terms of quantities of intentionally-added microplastics both used and released to the environment.[95] A complete ban is preferable to any other risk management measure over the long term, as advised by RAC.[96] In the most optimistic scenario, ECHA's proposal would still allow the release of 1,600 tonnes/year of microplastics.[97]

It has been acknowledged that infill can be lost from pitches by being carried off by players, migrating from the edges of the pitch into local surroundings, or entering drains[98] and waterways. Storage and transport of granules, installation, removal and treatment of waste pitches all represent additional risks of leakage. While mitigation measures on-site can address some of these pathways, there have been only limited studies to assess the actual effectiveness of technical barriers. Considering that many pathways are dependent on behaviours of the wider pitch community as well as industry supply chains, it is evident that effective mitigation will be extremely difficult to enforce and can never be fully effective. Attempting to distinguish between the pitches that are under or over a set emissions standard is therefore doomed to undermine the objective of the restriction as well as the European Plastic Strategy.[99]

Such failure to address the biggest contributors of microplastic leakage in the environment does not even serve an essential purpose. A variety of natural alternatives exist and some have been used for more than a decade, although their current use is still limited to a small percentage of the market (e.g. cork, engineered wood chip, hemp, cellulose fibre and olive stones, coconut husk).

The restriction should ban rubber granules after a six-year transition period. This would promote the development of a wider market for alternatives and ensure the uptake of existing ones. The transition period will also ensure that the ban occurs with minimal disruption to community sports, while avoiding a sudden large influx of waste.

To avoid a new generation of pitches being built with SBR rubber over the next 6-8 years, exemptions to a restriction should only apply to existing pitches.[100] For those, mitigation measures to minimise loss need to be imposed. Simple retrofitting measures could be used to minimise costs, such as netting around pitch edges, mobile boot brushing stations, filters in drains and providing information for users/ maintenance staff. If effectively implemented, mitigation measures will also reduce the quantity of infill needed to top up the pitch for the remaining years of its life.

Our recommendation

Ban all new granular infill for sport pitches, with a six year transition period and a grandfathering clause for existing pitches. During the transition period, pitches that continue to use microplastics should be required to implement retrofitting measures to minimise losses where used beyond entry into force.

Contact person

Madeleine Berg, Fidra
madeleine.berg@fidra.org.uk

94. SEAC supports a derogation from the ban conditional upon technical risk management measures being implemented to prevent releases to the environment (with or without transitional period, 'RO4'). See SEAC Draft Opinion, dated 11 June 2020, p.43, 50 and 52.
95. RAC Opinion, dated 11 June 2020, p.55
96. RAC opinion, dated 11 June 2020, p.65
97. RAC Opinion, dated 11 June 2020, p.56
98. For a non-exhaustive list of studies, see Appendix A of Fidra, Microplastic loss from artificial (3G) pitches in context of the ECHA proposed restriction of microplastics intentionally added to products, accessible at https://www.fidra.org.uk/artificial-pitches/plastic-pitches/solutions/
99. European Commission, *A European Strategy for Plastics in a Circular Economy* (2018), COM/2018/028 final. See at:https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1516265440535&uri=COM:2018:28:FIN
100. As raised in the Fidra comment to the SEAC public consultation, ORCOM 2, comment #688

Soluble polymers

In response to demands from industry sector associations, the dossier submitter changed its restriction proposal to include an exemption for soluble microplastics. The basis for this derogation is that these polymers do not meet all of the necessary intrinsic properties associated with the microplastic concern i.e. they allegedly do not remain in the environment as particles for a long time after being released. However, RAC noted these derogations do not mean that these polymers are safe as they may have other hazards in addition to those associated with the microplastic concern.[101]

Water-soluble polymers meet the definition criteria as they are solid particles when used. These polymers pose a risk to the environment due to their persistency, mobility and toxicity and should, therefore, be restricted. Several soluble polymers (including PAMs, polycarboxylates) as well as their breakdown products are persistent and/or toxic; they can also act like flocculants and detergents in recipient waters and as conditioners of soils and sediments with long lasting ecological effects.[102]

A recent study in Italy showed the wide presence of liquid, semi solid and soluble polymers in consumer products (detergents for laundry, dishwashing and surfaces cleaning).[103] The same study documents the intention of companies such as COOP, one of the most important Italian retailers, and Unilever to stop using these ingredients within the end of 2020 for products sold on the Italian market. Alternatives are therefore already available.[104] If agreed upon, the derogation for soluble polymers will negatively impact the effectiveness of the restriction to reduce the environmental impacts of microplastics.

Our recommendation

Delete the derogation for water-soluble polymers. In the event where a derogation is granted, remaining uncertainties regarding the implementability of these derogations should be clarified before incentivising a market shift to these polymers.[105]

Contact person

Dolores Romano, EEB
dolores.romano@eeb.org

101. RAC Opinion, dated 11 June 2020, p.9
102. Huppertsberg, H. et al. Making waves: Water-soluble polymers in the aquatic environment: An overlooked class of synthetic polymers? Water Research 181 (2020) 115931; and Peter H. Arp and Heidi Knutsen. Environmental Science & Technology 2020 *54* (1), p.3-5 Https://doi.org/10.1021/acs.est.9b07089
103. Greenpeace Italy, Plastica Liquida, accessible at: https://storage.googleapis.com/planet4-italy-stateless/2020/07/8707a2f2-gp_report_detersivi.pdf
104. Ibid.
105. For example, ECHA said "a solubility criteria would not be straightforward to implement. For example, particles may appear to be dissolved in a solvent but are in fact present as a 'dispersion' of microscopic or nanosized particles suspended in the solvent" (Draft Background Document, dated 11 Juen 2020, p.26)

2 Unacceptable weakness of the reporting requirements on pellets

In its Annex XV Report, ECHA introduces reporting requirements (para. 8) for the substances or mixtures used at industrial sites, e.g. pellets, powders and flakes (para. 4(a)), and other derogated uses (para. 5b and 5c). The main purpose of this requirement is to "contribute to the monitorability of the effectiveness of the restriction and indicate if there is a need for further action related to those uses that are derogated, including for industrial uses."[106]

As noted in both the RAC opinion and SEAC draft opinion, the purpose of such reporting is different in the case of pellets compared to the other uses of microplastics subject to reporting requirements as their significant contribution to microplastic pollution is already sufficiently apparent to justify action now. Pellets are among the "greatest contributors" of annual releases of secondary microplastics emitted to EU surface waters.[107] Eunomia (2018) estimates that between 16,888 and 167,431 tonnes of pellets per year are emitted to the environment in the EU alone.[108] One of the primary objectives is therefore to improve the granularity of the dataset on pre-production pellet losses, understanding in more detail exactly where in the supply chain losses are ongoing, in line with the commitments of the European Plastic Strategy.

NGOs welcome the introduction of the reporting requirement, associated with instructions for use and disposal, and the specific mention by RAC and SEAC of pellet loss in their respective opinions.[109] However, as further explained below, the reporting requirements proposed in the end by ECHA are too weak to have impact.

106. Annex XV Report, p.91
107. Annex XV Report, p.10
108. Eunomia Report (2018), Investigating options for reducing releases in the aquatic environment of microplastics emitted by (but not intentionally added in) products; Report for DG Environment of the European Commission
109. See Fidra submission to the SEAC public consultation, ORCOM 2, comment #688

The reporting requirements can constitute a great support to parallel pellet loss prevention measures

For context, in the past years some measures have been initiated to address the problem of pellet loss outside the REACH context. Should the reporting requirements under this restriction be improved, they could provide significant insight into where and how losses occur, and support further parallel measures proposed.

Parallel work includes commitments by industry and policy-makers to create auditable standards to assess pellet loss prevention measures at industrial sites,[110] certification schemes that can verify compliance with these standards,[111] and exploration of potential voluntary or legislative options to ensure such accreditation of best practice can be effective across the whole plastics industry.[112] It has become clear in recent years that a drastic reduction in pellet pollution can be achieved best by reinforcing these solutions through legislation: implementing obligatory certification along the plastics supply chain,[113] as identified by a European Commission-funded report, as the preferred policy option.[114]

Reporting requirements introduced under REACH should not be seen as an alternative to such parallel actions or as sufficient in themselves. While they could help map out plastics supply chains more clearly, raise awareness of the problem within industry and provide a mechanism to measure improvements created by other solutions, other complementary solutions are required to stop pellet loss.

Under ECHA's initial proposal regarding reporting requirements, the downstream users handling microplastics at an industrial site or suppliers placing a product made of microplastics on the market for the first time, for an end use, would have had to report to ECHA information on its identity, and quantities used and emitted. Based on the data collected, ECHA would publish an annual report. Unfortunately, this proposal has been weakened partly due to specific industry sectors' demands that are unrelated to plastic pellets.[115]

110. E.g. BSI (2020) Project launch: First specification to prevent plastic pellet pollution, accessible at: https://www.bsigroup.com/en-GB/about-bsi/media-centre/press-releases/2020/june/project-launch-first-specification-to-prevent-plastic-pellet-pollution/
111. E.g. commitment by Plastics Europe to develop a certification scheme based around the voluntary Operation Clean Sweep guidelines, see Operation Clean Sweep report 2018, accessible at: https://www.plasticseurope.org/en/newsroom/press-releases/archive-press-releases-2019/operation-clean-sweepr-ocs-report-2018-published-today
112. OSPAR Background document on pre-production Plastic Pellets, 2018, https://www.ospar.org/documents?v=39764. Oswald et al., Preventing plastic pellet loss in supply chains: Design of a supply chain approach to prevent pollution from plastic pellets, 2019, Report for the Scottish Government by Eunomia Research & Consulting. Hann et al., Investigating Options for Reducing Releases in the Aquatic Environment of Microplastics Emitted by Products, 2018, Report for the European Commission by Eunomia Research & Consulting
113. Rethink Plastic, Our Ocean Needs Action not Promises, Towards A Regulatory Approach to Pellet Loss in the EU, 2019 https://rethinkplasticalliance.eu/wp-content/uploads/2020/04/bffp_rpa_pellets_paper.pdf
114. Hann et al. 2018
115. See PlasticsEurope contribution to the first public consultation on the restriction proposal, RCOM 2 , comment #2187 at: https://echa.europa.eu/fr/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73

Weakening the content of the requirement risks undermining its *raison-d'etre* and impact

One issue concerns the requirement to report *generic*, rather than *specific*, information on the identity of the polymer(s) used. Knowing the type and physical properties of each polymer is key to consider the whole life cycle impact of the substances used, including their potential chemical or physical toxicity. Requiring such information would support the European Commission's work on polymers registration under REACH.[116]

A second issue relates to the information required on the quantities used. ECHA decided to remove reporting on tonnage handled at each stage of the supply chain, instead relying solely on estimated releases to the environment. Knowing the quantity of microplastics used is however essential for assessing the risks of spills. ECHA attempted to justify this change by stating that it was "to avoid double counting".[117] Such double-counting is necessary for pellets since each time a material is being handled, there is a potential for loss. Moreover, it is unclear which methodologies for monitoring losses will be enforced, since no standardised method currently exists.[118] ECHA did not include in its proposal any mandatory best practice or compliance mechanism to ensure each company relies on adequate and effective methods for calculation of emissions. As a result, the reporting requirements are currently too weak to enable the collection of any valid or reliable data on quantities of material handled and lost, and how risk management measures relate to reductions in loss. Without such clarity, the information collected will do very little to accurately monitor losses, or contribute towards improvement in the uptake of best practice across the industry.

Furthermore, it is unclear how ECHA can ensure greater traceability for plastic pellets along supply chains when it asks for a "broader level" summary of the data reported, "without disclosing any identifiers of the specific stakeholders or products."[119] The transparency of information on hazardous substances along the supply chain and to the consumer is a key requirement under REACH. Providing specific information is an "appropriate and effective means to achieve risk reduction"[120] and should therefore be a critical component of the reporting requirement.

Finally, it is not justifiable that ECHA postponed the entry into force of the reporting requirements for plastic pellets, from 18 to 36 months after the adoption of the restriction. Sectors involving many professional users such as paints and coatings expressed concerns with regards to the reporting requirement in terms of costs, administrative burden but also in terms of double counting of emissions. Yet, in the unique context of pellets, there are examples of companies that have already volunteered to monitor and report on spills, e.g. through the OCS Blue programme[121] in the United States. With regard to the resources needed to prepare the reports, even the SEAC acknowledged in its draft opinion that reporting can be done in a cost-effective manner in 18 months.[122]

116. Rethink Plastic alliance, "Comments on the registration of polymers" (2019), accessible at: https://rethinkplasticalliance.eu/wp-content/uploads/2019/10/Briefing-Polymer-Registration-Oct-19.pdf
117. Draft Background Document, dated 11 June 2020, p.101
118. See: Eunomia and ICF, Investigating Options for Reducing Releases in the Aquatic Environment of Microplastics Emitted by (But Not Intentionally Added In) Products (Final Report, 23 February 2018),
119. Draft Background Document, dated 11 June 2020, p.102
120. RAC Opinion, dated 11 June 2020, p.20
121. See the Operation Clean Sweep Pledge, accessible at: https://www.opcleansweep.org/pledge/ocs-blue/. Data to be reported annually includes the number and volume of incidents of any unrecovered release of plastic pellets, flakes, powders, or granules, within the physical custody of a member company, from containment to ground or water outside member-operated facilities and estimated to be greater than 0.5 litres or 0.5 kilograms per incident.
122. SEAC Draft Opinion, dated 11 June 2020, p.57

Similarly, SEAC suggested to enforce biennial, instead of annual, reporting in order "to achieve a sound evidence base within a reasonable time frame and [will] reduce the resources needed for industry as well as authorities to process the information generated."[123] This is not acceptable. First, it is not clearly justified why reducing the frequency of pellet loss reporting would be beneficial. Second, annual reports provide a realistically broad window of time for data to be collated and analysed in order to adaptively inform best practice requirements. It is aligned with companies' internal accountability mechanism for materials bought/produced/sold/transported, which happens on an annual basis.

To conclude, the reporting requirements proposed in the end by ECHA are too weak to have any positive impact. In addition, beyond REACH, it is urgent to start instigating mandatory supply chain accreditation of all pellet handlers with certification and standards to verify the functioning of containment measures.[124]

Our recommendation

Pellets, flakes and powders should be treated in a separate provision from other derogated uses to provide the level of specificity that is necessary to yield useful data and support additional regulatory supply chain measures. This should include:

1. **Requirements to report the quantities of material handled per calendar year at site-level along the supply-chain;**
2. **Reporting obligations which apply to all companies handling pellets, including producers, processors, transporters and recyclers;**
3. **Guidance on the methodology for monitoring losses;**
4. **Ground-truthing estimates of loss with real monitoring to ensure accuracy and accountability;**
5. **Encouraging communication and cross-collaboration during the development of supply chain accreditation systems and reporting mechanisms to maximise compatibility of solutions;**
6. **Reducing transitional periods from 36 to 24 months.**

Contact person

Madeleine Berg, Fidra
madeleine.berg@fidra.org.uk

Tom Gammage, EIA
tomgammage@eia-international.org

Frédérique Mongodin, Seas At Risk
fmongodin@seas-at-risk.org

123. SEAC Draft Opinion, dated 11 June 2020, p.64
124. Eunomia and ICF, Investigating Options for Reducing Releases in the Aquatic Environment of Microplastics Emitted by (But Not Intentionally Added In) Products, Final Report, 23 February 2018

3 Unduly long and/or unjustified transition periods

Introductory remarks on the justification of transition periods

As awareness rose around the environmental impacts of microplastics on the environment, the 2018 EU Plastics Strategy encouraged industry to "pursue and implement cross-industry agreements to reduce the release of microplastics in the environment."[125] The political context was set for industry to address microplastics that needed to reduce their release to the environment, substitution and transition to other alternatives.

The industry has been aware of the environmental problems caused by microplastics for more than 15 years.[126] It has been closely following the discussions at political level running for years on regulating microplastic ingredients in their products, particularly in cosmetics.[127] It had the opportunity to observe the first legal developments to stop microplastic pollution deriving from their deliberate incorporation into products at national level - legislation has been adopted, initiated or settled at national level in the US, Canada, South Korea, Taiwan, France, New Zealand, Sweden, UK, Italy and Belgium.[128]

Only strong justifications may support the inclusion of transitional periods as they enable the continued release of microplastics into the environment. While every release to the environment is considered a risk by RAC, industry must swiftly adapt to its regulatory obligations. While the microplastics restriction will not enter into force before 2022, the proposal includes unjustified transition periods, ranging from 2 to 8 years depending on sectors and product types, that risk affecting the impact and effectiveness of the restriction.

Uncertainties on the information provided by industry relating to the absence of alternatives or their unsuitability should be interpreted as a failure to demonstrate the need to adopt a transitional period. This should prompt authorities not to grant a derogation, as part of the EU's commitment to improve the restriction process under the 2018 REACH REFIT evaluation.[129] Derogations to restrictions should remain exceptional and thoroughly justified.

125. Annex to the European Commission's Communication on a European Strategy for Plastics in a Circular Economy, 2018, accessible at https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1516265440535&uri=COM:2018:28:FIN
126. See Thompson R.C., et al, 'Lost at Sea: Where Is All the Plastic?', 2004, 304 Science 838, https://doi.org/10.1126/science.1094559
127. See UNEP report already from 2015: Plastic in Cosmetics: Are We Polluting the Environment Through Our Personal Care?
128. Kentin E, Kaarto H., An EU ban on microplastics in cosmetic products and the right to regulate. *RECIEL*, 2018;27:254–266, https://doi.org/10.1111/reel.12269266
129. See paragraph 1, Action 8 of the General Report on the operation of REACH and review of certain elements Conclusions and Actions Conclusions and Actions, COM/2018/0116 final, 2018, accessible at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:116:FIN

To determine whether the substitution of microplastics is proportionate or not, SEAC went beyond the cost-effectiveness analysis and suggested using the concept of 'essential use.' This approach requires assessing whether a substance provides for vital functions and is currently without established alternatives. The concept was developed under the Montreal Protocol on Substances that Deplete the Ozone Layer and recently has been further discussed in the context of PFAS regulation, "which are of similar concern to microplastics in terms of their environmental persistence". In its draft opinion, SEAC used the essential use concept to assess the relevance of having mandatory instructions for use and reporting requirements, instead of a ban, for microplastics in in vitro diagnostics, given their essentiality for the healthcare sector.

This concept may be of great help to assess the proportionality of derogation measures including transition periods.[130] Following this approach, when a use is *essential,* transition periods may be justified, assuming there is no available alternative on the market. By analogy, having transition periods for *non-essential* uses should never be considered proportionate in light of the objectives of the restriction. Thus, in application of the essential use concept, it does not appear logical to propose, on the one hand, a six-year transition period for medical devices, deemed 'essential' for health and the functioning of society according to SEAC, and yet, on the other hand, suggest longer transition periods for less or non-essential uses, e.g. cosmetics. The reasoning based on essentiality of uses is hence particularly relevant to assess the proportionality of the various transition periods under this Section 2).

The overall estimates of yearly releases represent a considerable amount of pollution, which decision-makers would tolerate, should the less stringent transitional periods be granted. The accumulated transition periods postpone the effectiveness of the restriction to 2030 for some sectors.

General recommendation on transition periods

Because introducing transitional periods will automatically increase the environmental pressure by microplastics, no delay in the entry into force of the ban should be foreseen unless the following cumulative conditions are met:

1. **The specific use is essential (based on the Montreal Protocol definition);**
2. **There is no available alternative on the market;**
3. **The time period is necessary for companies to transition to alternative options and justified based on reliable data;**
4. **Companies have proven that they are working towards those alternatives (R&D program in place, strategy etc.).**

When assessing the necessity of transition periods, it should not be forgotten that, if adopted, the restriction would enter into force in 2022, i.e. in two years. This delay would come in addition to the time that has already elapsed since ECHA started drafting its proposal in 2018. As a consequence, companies cannot reasonably claim that the restriction comes as a surprise; they have already had time to discuss and anticipate the possible impacts of the restriction on their businesses.

130. An 'essential use' would be a "use of a substance, which is necessary for (i) health and safety or is critical for the functioning of society and (ii) for which there are no available technically and economically feasible alternatives" - See SEAC Draft Opinion, dated 11 June 2020, p.65

4 years for ‘rinse-off’ cosmetics and 6 years for ‘leave-on’ cosmetics (make-up, lip and nail care)

Without a restriction in place, emissions to the environment from these sectors are significant, especially for rinse-off products for which RAC estimated that 3,100 (with a range between 1,400 – 4,900) tonnes per year are released to the environment; for leave-on cosmetics RAC estimated that 600 (300 – 900) tonnes per year are released to the environment.[131] These emissions represent a little more than 10% of the overall environmental releases of intentionally added microplastics, equivalent to an estimate of 42,400 tonnes per year.[132]

Companies did not provide supporting information to sufficiently justify the transition period requested. More precisely, one of industry’s major arguments submitted to the public consultations is the impact on small and medium-sized enterprises (SMEs), that will have to invest substantial resources in the reformulation of their ingredients.[133] Microplastic-free formulations are already available and various commitments for microplastics-free products are already in the market. For example, the Beat the Microbead campaign[134] showcases microplastic-free leave-on cosmetic products such as after-sun lotions, deodorants, facial care lotions and body oils, providing a list of 2,134 microplastic-free products - initiatives branded as “slow cosmetics”. This information was provided during the development of the scientific opinion.[135]

Both RAC and SEAC agree that alternatives are available for all cosmetic product categories.[136] An assessment of certification programs also demonstrated “the availability of microplastic-free products in all rinse-off (as well as leave-on) categories of cosmetic products (...).”[137] Finally, the process concluded that “[a]lternative products (i.e. cosmetic products that do not contain microplastics according to the definition of the proposed restriction) represent between 70% and 90%.”[138]

SEAC points at uncertainties (on the impacts on industry and the releases) but indicates that there is no sufficient information to determine the optimal transition period, it concludes that proportionality “depends on policy priorities to reduce microplastic emissions.”[139] In the Plastic Strategy, the Circular Economy Action Plan, the Chemical Strategy and the announcement of the Zero-Pollution Strategy, the Commission has announced the waste of resources and the reduction of persistent environmental pollution a high priority. The result, in this context, should be no, or extremely short, transition periods.

The uncertainties arising from contradicting industry information on the presence of alternatives should be treated as a failure of the industry requiring the transition period to demonstrate the absence of alternatives. The adoption of the restriction should represent the start of a swift transition towards microplastic-free cosmetics as a range of the market has already operated this change.

This should shorten the transition period as research and development are limited to reformulations, not to the technical development of alternative methods.

In addition, microplastics in cosmetic applications should be considered as a non-essential use as they do not meet the criteria for being necessary for health and safety or critical to the functioning of society.[140]

Our recommendation

There should be no transitional periods for rinse-off and leave-on cosmetics as they represent non-essential uses, for which alternatives are marketed. If a transition period is to be granted, it cannot go beyond the short time necessary for reformulation.

Contact person

Elise Vitali, EEB
elise.vitali@eeb.org

131. RAC Opinion, dated 11 June 2020, p.67
132. RAC Opinion, dated 11 June 2020, p.67
133. RCOM response, p.36
134. See https://www.beatthemicrobead.org/product-results/?c=Zero
135. See for instance, non exhaustively, Beauty Kitchen’s comment on SEAC draft opinion #756 in ORCOM 3; EEB’s Comment on SEAC draft opinion #783 in ORCOM 3; Fauna and Flora International’s comment on SEAC draft opinion #808 in ORCOM 4; NABU comments on Annex XV Restriction Report #2690 in RCOM 7; further evidence was also mentioned during RAC and SEAC meetings
136. SEAC Draft opinion p.66, accessed on 5 October 2020 and complementary Draft Annex to the Background Document, p.168, accessed on 5 October 2020
137. Draft Annex to the Background Document, dated 11 June 2020, p.169
138. Draft Annex to the Background Document, dated 11 June 2020, p.169
139. SEAC Draft Opinion, dated 11 June 2020, p.67
140. As further developed in Section II. 2) of this position paper

5 to 8 years for the encapsulation of fragrances in detergents and cosmetic products

After the cosmetics industry submitted numerous comments[141] seeking a derogation for fragrance encapsulation or a ten-year transitional period, a revised eight-year transition period was also proposed by ECHA, alongside the five years initially proposed. The option was left open.[142]

SEAC considered that "a longer transition period would involve higher emissions (~600t) of microplastics in total and hence lower the effectiveness of the proposed restriction (see Annex D.6.7 in the BD)."[143] SEAC considered that* an eight-year transition period "would require further substantiation"[144] and eventually decided to support a five-year transition period, with a review of the appropriateness of the period proposed after the entry into force of the restriction.

Developments of alternative fragrance delivery technologies may not yet be fully available but are well under way and other natural ingredients may be used instead of microplastics. Interestingly, major companies such as Henkel have pledged not to use microplastics for fragrance encapsulation in fabric softeners and detergents by 2022.[145]

More importantly, the need for fragrance encapsulation is questionable since it is also possible to produce "fragrance-free" detergents. Cleaning products are essential for health and safety, but fragrances are not; from the standpoint of health, safety or criticality for the functioning of society.[146] Microplastics in those fragrances are however found to be harmful for the environment while their risks cannot be adequately controlled.

Our recommendation

Transition period for the non-essential uses that are the encapsulation of fragrance in detergent and cosmetics must be deleted from the final restriction.

Contact person

Elise Vitali, EEB
elise.vitali@eeb.org

Madhuri Prabhakar,
Plastic Soup Foundation
madhuri@plasticsoupfoundation.org

141. See Comments on Annex XV Report and on SEAC draft opinion, files accessible at https://echa.europa.eu/fr/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73
142. SEAC Draft Opinion, dated 11 June 2020, p.68
143. SEAC Draft Opinion, dated 11 June 2020, p.67
144. SEAC Draft Opinion, dated 11 June 2020, p.78
145. This evidence was submitted in EEB's Comment on SEAC Draft Opinion, ORCOM 3, comment #783
146. As developed under Section II. 2) of this position paper

5 years for detergents, waxes, polishes and “air care” products

According to the RAC opinion,[147] the detergents and maintenance product group release to the environment an estimated 8,500 (with a range between 5,600 – 11,600) tonnes per year. A five year transitional period for these applications is not justified for the following reasons.

These joint releases represent a considerable burden on the environment, particularly for uses that may be avoided, as microplastic-free products for these uses are currently marketed. As regards detergents, Ecolabel products are required not to contain microplastics in industrial,[148] handwash,[149] dishwashing,[150] laundry[151] detergents, and products meeting these criteria are currently placed on the market.

The long transition period is not proportionate to the emissions into the environment from these applications. In particular for the waxes, polishes and “air care” product categories since the five-year derogation would apply for the reformulation of only 60 mixtures.[152]

The “air care” product category should also be regarded as non-essential for society as these products cannot be characterised as necessary for health and safety or critical to the functioning of society. On the contrary, “air care” products might represent an additional burden on indoor air pollution, unnecessarily amplifying the cocktail effects and exposure to human-made chemicals.[153]

Our recommendation

There should be no transition period for these uses, which should either be considered as non-essential (this is the case for “air-care” applications), or when they already benefit from existing marketed alternatives (detergents and waxes).

Contact person

Elise Vitali, EEB
elise.vitali@eeb.org

Madhuri Prabhakar,
Plastic Soup Foundation
madhuri@plasticsoupfoundation.org

147. This is despite the initial estimations of 6,000 reformulations required directly linked to the ban, which were declared unfounded by ECHA, RAC opinion, dated 11 June 2020, p.67
148. See criteria for EU Ecolabel industrial detergents accessible at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.180.01.0016.01.ENG&toc=OJ:L:2017:180:TOC
149. See criteria for EU Ecolabel handwash detergents accessible at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.180.01.0001.01.ENG&toc=OJ:L:2017:180:TOC
150. See criteria for EU Ecolabel dishwashing detergents accessible at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.180.01.0001.01.ENG&toc=OJ:L:2017:180:TOC
151. See criteria for EU Ecolabel laundry detergents accessible at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.180.01.0063.01.ENG&toc=OJ:L:2017:180:TOC
152. Annex to the Draft Background document, dated 11 June 2020, p.245
153. For complementary information on the issue: see Steinemann, A., Ten questions concerning air fresheners and indoor built environments, 2017, Building and Environment, Volume 111, January 2017, p.279-284 https://doi.org/10.1016/j.buildenv.2016.11.009; or Mary B. Johnson, et al., Exploring the science, safety, and benefits of air care products: perspectives from the inaugural air care summit, Inhalation Toxicology, 2019, 31:1, p.12-24, https://doi.org/10.1080/08958378.2019.1597221

Specific transitional periods intended for agriculture-related uses of microplastics

Paragraph 6 (f, g and h) of ECHA's proposal suggests the following transitional periods for microplastics used in agricultural products:

- 5 years for fertilising products that are not regulated in the EU under the new Fertilisers Regulation (No 2019/1009) and that do not meet the requirements for biodegradability contained in that Regulation.
- 8 years for plant protection products and biocides (covered by the EU Plant Protection Products Regulation (PPPR))
- 5 years for other agricultural and horticultural uses including seed treatments

ECHA's justification for including these periods is that time would be required for developing biodegradable polymers suitable for the agricultural functions at stake.[154] For plant protection products, ECHA also explained that time would be necessary for regulatory reapproval in addition to the development of alternatives.

However, the length of the periods proposed, together with their underlying unconvincing justifications, must be opposed for several reasons.

First, the significant environmental impact of the agricultural uses ECHA's proposal refers to cannot be overlooked. RAC's opinion reads that "the direct releases from agriculture to soil is one of the most significant pathway"[155] with yearly estimates "at 10,000 tonnes, with a range between 3,500 to 18,000 t[onnes]/y[ear]."[156] The uses targeted in the proposal, including controlled release fertilisers, fertiliser additives, treated seeds, capsule suspension PPPs/biocides, have a 100% overall potential for direct release to the environment.[157]

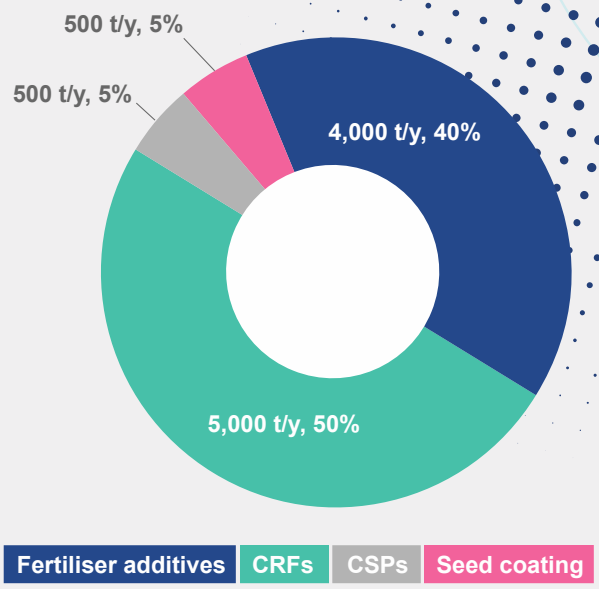


Figure 1: Estimated annual tonnage of polymeric material emitted by the different product groups within the EU A&H sector. Extracted from the figure in Annex to Draft Background Document, dated 11 June 2020, p.135

Figure 1[158] showcases the quantity of polymers likely to be emitted to the environment over the coming years, assuming the proposed transitional periods are implemented. Granting, for example, a five-year transition period for agricultural and horticultural uses would amount to an estimated 50,000 tonnes emitted into the environment.[159]

First of all, it is highly regrettable that the restriction proposal does not question the use of microplastics in the agricultural and horticultural sectors. Chemicals present in fertilisers, pesticides and microplastics are known for building up in soil and contaminating food.[160]

154. Draft Background Document, dated 11 June 2020, pp. 94-95
155. RAC opinion, dated 11 June 2020, p.58
156. RAC opinion, dated 11 June 2020, p.59
157. Draft Background Document, dated 11 June 2020, p.36
158. Annex to Draft Background Document, dated 11 June 2020, p.135
159. Based on yearly estimates included in the RAC opinion, dated 11 June 2020, Table 8, p.67
160. European Environment Agency, State of the Environment Report (2020), p.244

ECHA's proposed transition periods amount to allowing the continued use of microplastics presumed to be highly harmful to the environment and potentially human health. This logic contradicts the EU's pledge to move towards sustainable food systems, as emphasised in the European Green Deal or the Farm to Fork Strategy.[161] The microplastics restriction should instead constitute an opportunity for EU institutions to start implementing their commitments and incentivise the shift to alternative farming methods. It is well known that moving towards sustainable food production requires using resilient farming practices such as agroecology, which involves less reliance on pesticides and mineral fertilisers.[162] That is also the position the Food and Agriculture Organisation has been advocating for years.[163] For that reason, no sound argument can reasonably justify any of the delays to the ban on microplastics in agricultural uses under the current restriction.

Moreover, it has been demonstrated that microplastic-free alternatives already exist for most of the agricultural uses. RAC mentioned that polymer-free substitutes in fertiliser additives[164] and in controlled-release formulations, for fertilisers and plant protection products (typically as microencapsulation), e.g. silica, currently exist and are being marketed.[165] Evidence also shows that several large seed producers use coatings based on potato starch, molasses and other biodegradable materials.[166]

Companies have raised the issue of performance loss when replacing microplastics in some products, although SEAC noted that it could not draw "firm conclusion on the magnitude of the losses in product performance."[167] It is unfortunate that SEAC market analysis does not take into consideration the socio-economic opportunities linked with the uptake of sustainable production methods and integrated pest management techniques, including in terms of product performance. Companies have also claimed that substituting microplastics would incur major reformulation costs, notably for capsule suspension plant protection products.[168] SEAC has nuanced this concern by emphasising that not all products would need to be reformulated in response to the restriction: "depending on the market conditions of a specific product (e.g. when there is sufficient supply of microplastic-free products), the functionality of the microplastic in the product and the capacity of a company to reformulate, industry may choose to rather discontinue its production."[169] In fact, the cost per reformulation is likely to decrease as the number of products that need to be reformulated increases "because of both learning effects and economies of scale."[170] In many cases, missing data also makes it very difficult to estimate whether, and to what extent reformulations would be necessary.

Finally, it can be inferred from ECHA's proposal and the scientific opinions of its committees that many uncertainties impede the drawing of clear conclusions on the necessity of transition periods for those uses. In general, there is limited data on most of the agricultural uses and little information on the exact function of microplastics for some of these uses, and associated legal status.[171] Notably, it is still unclear whether microplastics may qualify as active substances, or co-formulants, under the PPP and Biocidal Products Regulations.[172] Moreover, the development of the scientific committees' opinion has shown that shorter transitional periods, in particular for controlled-release fertilisers, would be reasonable.[173]

161. "The Commission will take additional action to reduce the overall use and risk of chemical pesticides by 50% and the use of more hazardous pesticides by 50% by 2030", EU Farm to Fork Strategy, 2020, accessible at https://ec.europa.eu/food/farm2fork_en
162. European Environment Agency, State of the Environment Report (2020), p.299
163. FAO, 2014, Agroecology for food security and nutrition, Food and Agriculture Organization of the United Nations, Romen p.xi
164. Draft Annex to the Background Document, p.138 and p.146, accessed on 19 October 2020
165. ECHA Annex to the restriction proposal, p.140
166. Draft Annex to the Background Document, p.146, accessed on 19 October 2020
167. SEAC Draft Opinion, dated 11 June 2020, p. 46
168. SEAC Draft Opinion, dated 11 June 2020, p. 39
169. SEAC Draft Opinion, dated 11 June 2020, p. 45
170. SEAC Draft Opinion, dated 11 June 2020, p. 45
171. Draft Annex to the Background Document, dated 11 June 2020, p.129
172. Annex to Background Document, dated 11 June 2020, p.122
173. Draft background document, dated 11 June 2020, p.16

Uncertainties and inconsistencies are notably visible in ECHA's choice to include a five-year transitional period for fertilising products which are not regulated under the Fertilisers Regulation (FPR). The FPR already sets a period of five years, from its entry into force in June 2019, to transition to biodegradable polymers, i.e. by 2024 the latest. On the other hand, the five-year transition period proposed by ECHA under the current microplastics restriction proposal, which would enter into force in 2022, means that "non-(bio)degradable" microplastics would continue to be marketed until 2027. While preventing double regulation, ECHA's proposal amounts to setting two separate, double-speed, regimes for CE-marked fertilising products, with the consequence of having microplastics kept longer on the market.[174] This obviously contradicts the objective of both the restriction proposal and the FPR.

A final striking example of the lack of clarity in ECHA's proposal is the suggested five-year transition period for "other agricultural and horticultural uses including seed treatments". This delay provides, in essence, for a non-exhaustive, hence open and unlimited, derogation. Again, the lack of strict interpretation of a derogation is inconsistent with EU law, as the Court of Justice of the EU has recalled.[175]

Our recommendation

Take into account the EU policy commitment to move away from unsustainable food production in determining the need for transition periods for microplastics in agricultural and horticultural uses. By principle, no transition period should be granted unless it is proven that no alternative is currently available, and the period is strictly justified and framed in light of the reduction objective. Uses proposed under any transitional period should be further specified. The five year-transition period for fertilising products is not justified and should not be accepted. The eight-year transition period for pesticides covered by the PPPR must be clarified, and thoroughly justified, in the event where it is needed. There should be no five-year transition period for a broad derogation for agricultural and horticultural uses.

Contact person

Elise Vitali, EEB
elise.vitali@eeb.org

Hélène Duguy, ClientEarth
hduguy@clientearth.org

174. See the ClientEarth contribution to public consultation in May 2019, RCOM 2, comment #2121, also accessible at: https://www.documents.clientearth.org/wp-content/uploads/library/2019-05-20-clientearths-contribution-to-the-public-consultation-on-echas-proposal-to-restrict-intentionally-added-microplastic-ce-en.pdf

175. See Case T-229/04 *Sweden v Commission* ; in appeal joined cases C-14/06 and C-295/06 EP v Commission regarding Directive 2002/95

4 Derogations lacking clear definition or justification

Paragraph 5 of the restriction proposal provides for several end-use specific derogations from the ban on the placement on the market, which are not properly framed. These uses are only subject to use instruction and reporting requirements:

Microplastics contained by technical means (5a);

Where the physical properties of the microplastics are permanently modified (5b);[176]

When microplastics are permanently incorporated into a solid matrix during end use at industrial sites (5c).

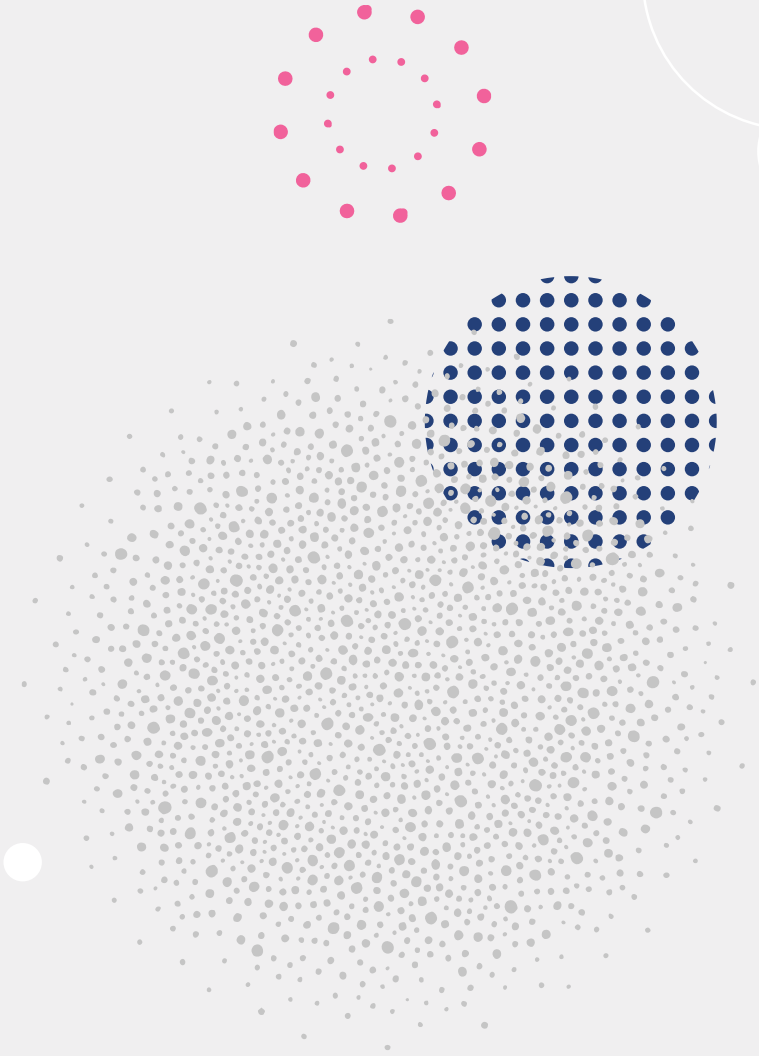
First, the justification for this group of derogations, namely that no polymer will be emitted to the environment, is ambiguous.[177] While ECHA argues that under those circumstances no polymer will be released into the environment, the proposal still sets the obligation for downstream users to both report the quantities of microplastics used and released and to communicate use instructions. It implies that microplastics could be released into the environment under reasonably foreseeable conditions of use, a point also emphasised by RAC in its opinion.[178]

In addition, the derogations are very vaguely framed, as acknowledged by ECHA itself following the public consultation.[179] The blatant lack of precision risks leading to the exemption of a wide number of microplastics from the restriction, as explained below.

176. Forum said this derogation would be difficult, even impossible to enforce due to the complexity of the issue and considered that an elaboration of the criteria by means of guidance would be helpful (RAC Opinion, p.81)
177. As reported by ClientEarth in its May 2019 contribution to the public consultation on ECHA proposal, see p.5
178. RAC Opinion p.81
179. RCOM, p.25: "the Dossier Submitter notes that there were no strong disagreement with the proposal, but rather a request for further clarifications of what these derogations would mean in practice".

Derogation for microplastics “contained by technical means”

Paragraph 5a sets a derogation “where the microplastic is contained by technical means to prevent releases to the environment during end use”.[180] In its Annex XV Report, ECHA clarified that this derogation was intended to cover uses of microplastics mainly “in non-industrial laboratory settings, including *in vitro* medical diagnostic uses at clinical laboratories”, e.g. at healthcare centers.[181] Following industry’s comments on the derogation, ECHA widened its understanding of the derogation to target microplastics used in “non-industrial professional or consumer settings”. According to the revised proposal, this could include continence pads, menstrual pads and nappies, both being in direct contact with the human body.[182] There is absolutely no justification for broadening the framing in that way, nor an essential use that may account for this derogation. Additionally, it remains to be seen how ‘technical means’ gets interpreted in practice, since ECHA does not provide any criteria to identify the exact technical means that may effectively prevent microplastics from leaking into the environment. In particular, it is well documented that sanitary products like nappies or menstrual pads oftentimes end up in landfills, incinerators or waste water after being used once. This poses significant environmental and public health issues, with subsequent costs for public administrations in charge of the collection, management and treatment of waste, in addition to clean-ups and the associated public sewage issues. These products are in fact one of the most commonly found single-use plastic items in the marine environment.[183]



180. Initially, the derogation targeted “substances or mixtures containing microplastic where the microplastic is both (i) contained by technical means throughout their whole lifecycle to prevent releases to the environment and (ii) any microplastic containing wastes arising are incinerated or disposed of as hazardous waste”

181. Annex XV Report, p.88

182. The proposal specifically targets: “uses of microplastics in non-industrial professional or consumer settings, including water purification applications (cartridges containing Ion Exchange Resins), continence pads, nappies or menstrual pads.”

183. See Zero Waste Europe, “The environmental and economic costs of single-use menstrual products, baby nappies and wet wipes”, November 2019. See at: https://zerowasteeurope.eu/wp-content/uploads/2019/12/bffp_single_use_menstrual_products_baby_nappies_and_wet_wipes.pdf

Derogation for microplastics “where the physical properties of the microplastic are permanently modified during end use at industrial sites”

This derogation (para. 5b) covers microplastics that are “consumed” or cease to exist at the point of use “through various physico-chemical processes or chemical reactions”. The public consultation on ECHA’s proposal made clear that stakeholders have varied and broad practical interpretations of this derogation.[184] Following interrogations from the Enforcement Forum, ECHA clarified that the term “permanently” refers to the “intended service life of the solid matrix”, as opposed to the waste stage. RAC has identified a long list of uses of microplastics that might fulfil this definition and would, as a consequence, escape the restriction.[185] RAC agreed there should be a reporting requirement applying to “[the potential] releases from solid matrices during the waste life-cycle state.”[186] Even with the derogation in place, “there could be some releases of unconsumed microplastics.”[187] The Enforcement Forum concluded that this derogation would be “difficult or even impossible to enforce.”[188]

184. SEAC Draft Opinion, dated 11 June 2020, p.72
185. RAC Opinion, dated 11 June 2020, p.81
186. RAC Opinion, dated 11 June 2020, p.82
187. Annex XV Report, p.93
188. RAC Opinion, dated 11 June 2020, p.81

Derogation for microplastics "permanently incorporated into a solid matrix during end use"

ECHA finally proposed a derogation "where microplastics are permanently incorporated into a solid matrix during end use" (5c). This would derogate certain non-film forming uses of microplastics in paints and coatings, and in construction materials. While it might seem logical to derogate microplastics that would be permanently contained, i.e. no release into the environment, the concept of a "solid matrix" requires clarification. RAC indeed mentioned that "there could be some releases of 'unconsumed' microplastics under reasonably foreseeable conditions of use."[189] Additionally, it is questionable whether the use of microplastics in some of those solid matrixes is essential from a technical point of view, e.g. in the construction sector known to heavily rely on plastics.[190] Exempting microplastics for some of its most widespread uses, and where suitable alternatives prove to exist, e.g. to produce lightweight concrete,[191] is unlikely to drive innovation in the right direction.

It should always be kept in mind that, according to settled case-law, all EU policies and activities concerning the environment are to aim at a high level of protection, based on the principles of precaution and preventive action.[192] This requires justification and strict interpretation of any condition for exemption.[193]

Our recommendation

1. **The derogations granted under Paragraph 5 of the restriction proposal must be scientifically justified and strictly interpreted.**
2. **If sound clarifications cannot be brought, the derogations should not be granted as uncertainties on the risk call for a precautionary approach.**

Contact person

Hélène Duguy, ClientEarth
hduguy@clientearth.org

189. RAC Opinion, dated 11 June 2020, p.78
190. See for example microplastics used in concrete: http://www.guidebeton.com/beton-leger
191. Chirag Garg and Aakash Jain, "Green concrete: Efficient and Eco-friendly construction materials", IMPACT Journal, Vol 2, Issue 2, 259-264 (2014). See also https://www.archireport.com/construction-ecologique-alternatives/
192. See to that effect: Case C-127/02 *Waddenvereniging and Vogelbeschermingsvereniging* [2004] ECR I-7405, para.44
193. See Joined Cases C-14/06 and C-295/06, para.75

Further microplastics to be tackled in parallel with this restriction

The restriction proposal of ECHA excludes a number of uses under Paragraph 4, which might be found to be of further concern in the future. These cover intentionally (microplastics used at industrial sites as well as liquid and semi-solid polymers) but also non-intentionally added microplastics (food and feed as well as sludge and compost); as a result, some of these uses might contain microplastics due to contamination.

Decision-makers should keep monitoring these uses, even after the adoption of the restriction, and prospect whether regulatory measures would be needed to prevent harm from these excluded applications: sectoral restrictions on the placement on the market, reporting requirements, might be required. A clause for monitoring and potential revision should be included to assess these applications on, for example, a five-year basis.

Substances or mixtures containing microplastics for use at industrial sites

(sub-paragraph 4 a.). A summary of the environmental impacts is included under section II, 1 of this position paper. The Commission should develop without delay a proposal to regulate emissions of microplastics from industrial sites, in parallel to the minimum reporting requirements developed in section II, 1 of this position paper. We highlight that France already obliges sites to include risk management measures to prevent pellets loss as of 2022.[194]

Liquid and semi-solid polymers

ECHA excluded them from the original restriction proposal by limiting the definition of microplastics to “solid particles”. However, liquid and semi-solid polymers also pose a risk to the environment due to their persistency, mobility and toxicity and should, therefore, be restricted. They are widely present in consumer products as shown in a Greenpeace report.[195] The Commission should propose a mandatory monitoring system and determine if risk management is needed for the currently exempted liquid and semi-solid polymers, for which SEAC stated that the environmental risks might be relevant.

Substances or mixtures containing food additives as defined in EU Regulation (EC) No. 1333/2008 and food and feed (respectively sub-paragraphs 4 d. and g.)

The scientific opinion excludes food additives from the scope of the restriction to avoid potential double regulation or market distortions. There is no information available on specific types of polymers and their quantities used or released and their potential impacts on human and animal health. Contamination of food will continue to increase, notably via trophic transfer, in parallel with the increase of microplastics concentration in the environment.[196] We acknowledge that the unintentional microplastics present in food would not fall under the scope of this restriction, but invite decision makers to develop research and monitoring programs.

Microplastics included in sewage sludge and compost (sub-paragraph 4.f.)

These microplastics do not fulfil the “intentional” criterion required by the scope of this restriction. We highlight the importance for the Commission to monitor these applications to determine if risk management is needed.

Contact person

Dolores Romano, EEB
dolores.romano@eeb.org

194. Loi n° 2020-105 du 10 février 2020 relative à la lutte contre le gaspillage et à l'économie circulaire
195. Greenpeace Report mentioned in section II.1 of this document
196. RAC opinion, dated 11 June 2020, p.69

Conclusion

Only an ambitious restriction - without unjustified derogations and delays - could ever be considered in line with the Plastics Strategy, the European Green Deal commitments and the recently adopted Chemicals Strategy for Sustainability,[197] which many EU Member States have pushed for.[198]

It is only if the Commission and EU Member States meet these ambitions that the restriction will:

Ensure a high level of protection of the environment and human health, in line with EU Treaties,[199] Charter of Fundamental Rights,[200] and the primary[201] objective of the REACH Regulation;

Send a strong message within and outside the EU that regulatory action on microplastics is necessary and a first step before tackling other sources of plastic pollution such as secondary microplastics;

Send a signal to the market that microplastic is not a sustainable solution so that innovation is pushed in a direction beneficial to society at large.

Level the playing field, thus rewarding frontrunner companies[202] that have already phased-out or never used microplastics in their products, or that offer suitable alternatives;

Be beneficial to local authorities, water treatment plants and water supply companies that will not have to pay the heavy cost of cleaning microplastics from their water;[203]

Enhance the people's trust in the EU and its ability to walk the talk on topics people have shown to care about;

Contribute to the European Commission fulfilling its commitments, including to strive towards zero pollution and non-toxic circular economy, on topics that EU people have shown to care about.[204] Conversely, renouncing an ambitious restriction would discredit the EU.

197. European Commission, Communication on the Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, COM(2020) 667 final, 14 October 2020, available at: https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf
198. See opinion piece from 10 Member States published on 30 September 2020 in ChemicalWatch, available at: http://files.chemicalwatch.com/Safe%20chemicals%20letter.pdf
199. In particular Articles 168 and 191 TFEU
200. In particular Article 37 of the Charter of Fundamental Rights
201. Judgment of the Court (Grand Chamber) of 7 July 2009, *The Queen, on the application of S.P.C.M. SA and Others v. Secretary of State for the Environment, Food and Rural Affairs*, C-558/07, EU:C:2009:430, §45 regarding registration, a reasoning also applicable to restrictions
202. See for example Beauty Kitchen, a UK based company whose representative supported NGOs during the SEAC discussions
203. Evidence of microplastics' impacts on wastewater treatment plants was submitted during the public consultation: see RCOM 2, comment #2189, and RCOM4 comment #2388, RCOM 7 #2704, and RCOM #2080
204. EU Special Barometer 501, 2019, accessible at: https://ec.europa.eu/commfrontoffice/publicopinion/index.cfm/Survey/getSurveyDetail/search/environment/surveyKy/2257

Annex

Our proposed restriction changes (in red) are the following:

Polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006)	**1. Shall not, from [entry into force (EiF)], be placed on the market as a substance on its own or in a mixture as a microplastic in a concentration equal to or greater than 0.01% w/w.** **2. For the purposes of this entry:** a. 'microplastic' means particles containing solid, semi-solid or liquid polymer, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions ~~0.1µm ≤~~ x≤ 5mm, or (ii), for fibres, a length of 0.3µm ≤ x≤ 15mm and length to diameter ratio of >3. b. 'microbead' means a microplastic used in a mixture as an abrasive i.e. to exfoliate, polish or clean. c. 'particle' is a minute piece of matter with defined physical boundaries; a defined physical boundary is an interface. Single molecules are not particles. d. 'particles containing solid polymer' means either (i) a particle of any composition with a continuous solid polymer surface coating of any thickness or (ii) particles of any composition with a solid polymer content of ≥ 1% w/w. e. 'solid' means a substance or a mixture which does not meet the definitions of liquid or gas. f. 'gas' means a substance which (i) at 50 $_{o}$C has a vapour pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at 20 $_{o}$C at a standard pressure of 101.3 kPa. g. 'liquid' means a substance or mixture which (i) at 50 $_{o}$C has a vapour pressure of not more than 300 kPa (3 bar); (ii) is not completely gaseous at 20 $_{o}$C and at a standard pressure of 101.3 kPa; and (iii) which has a melting point or initial melting point of 20 $_{o}$C or less at a standard pressure of 101.3 kPa; or (b) fulfilling the criteria in ASTM D 4359-90; or (c) the fluidity test (penetrometer test) in section 2.3.4 of Annex A of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). **3. Paragraph 2a and 2b shall not apply to:** a. Natural polymers (as defined in REACH Guidance on monomers and polymers) that have not been chemically modified (as defined in REACH Article 3(40)) [clarification required] ~~b. Polymers that are (bio)degradable, according to the criteria in Appendix X.~~ ~~c. Polymers with a solubility > 2 g/L, according to the criteria in Appendix Y.~~

Table continued:

Polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006)	**4. Paragraph 1 shall not apply to the placing on the market of:** a) Substances or mixtures containing microplastics for use at industrial sites. [clarification required] b) Medicinal products for human or veterinary use as defined in EU Directives 2001/83/EC and 2001/82/EC. ~~c) Substances or mixtures that are regulated in the EU under Regulation (EC) No 2019/1009 on Fertilising Products.~~ d) Substances or mixtures containing food additives as defined in EU Regulation (EC) No. 1333/2008. e) In vitro diagnostic devices f) Sewage sludge (as defined in Directive XXX/XXX) and compost. g) Food and feed ~~h) [OPTION A: granular infill used on synthetic sports surfaces where risk management measures are used to ensure that annual releases of microplastic do not exceed 7g/m^2]~~ **5. Paragraph 1 shall not apply to the placing on the market of:** a. Substances or mixtures containing microplastic where the microplastic is contained by technical means to prevent releases to the environment during end use. [clarifications required] b. Substances or mixtures containing microplastic where the physical properties of the microplastic are permanently modified during end use such that the polymers no longer fulfil the meaning of a microplastic given in paragraph 2(a). [clarifications required] c. Substances or mixtures containing microplastics where microplastics are permanently incorporated into a solid matrix during end use. [clarifications required] Paragraph 1 shall apply from: a. EiF for cosmetic products (as defined in Article 2(1)(a) of Regulation (EC) No 1223/2009) and other substances or mixtures containing microbeads. b. EiF + 6 years for medical devices as defined in Directive 93/42/EEC or in the classification rule 21 set in Annex VIII to the Regulation (EU) 2017/745. c. EiF ~~+ 4 years~~ for 'rinse-off' cosmetic products (as defined in Regulation (EC) No 1223/2009) not already included in paragraph 6(a). d. EiF ~~+ [5/8] years~~ for the encapsulation of fragrances in detergents (as defined in Regulation (EC) No 648/2004), cosmetic products (as defined in Regulation (EC) No 1223/2009) or other mixtures.

Table continued:

Polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006)	e) EiF ~~+ 5 years~~ for detergents (as defined in regulation (EC) No 648/2004), waxes, polishes and air care products not already included in paragraphs 6(a) or 6(d). f) EiF ~~+ 5 years~~ for fertilising products not regulated in the EU as fertilising products under Regulation (EC) No 2019/1009 that do not meet the requirements for biodegradability contained in that Regulation. g) EiF ~~+ 8 years~~ for plant protection products as defined in Regulation (EC) No 1107/2009 and biocides as defined in Regulation (EU) 528/2012. h) EiF ~~+ 5 years~~ for other agricultural and horticultural uses including seed treatments. i) EiF ~~+ 6 years~~ for 'leave-on' cosmetic products (as defined in regulation (EC) No 1223/2009). j) [Either ~~○ EiF + 3 years for granular infill used on synthetic sports surfaces (if 4(h) retained – OPTION A) or,~~ ○ EiF + 6 years for granular infill used on synthetic sports surfaces (if 4(h) not retained– OPTION B)] 6. From [EiF + 24 months] any supplier[2] of a substance or mixture containing a microplastic derogated from paragraph 1 on the basis of paragraphs 4(a), 4(b), 4(d), 4(e) or 5 shall ensure that, where applicable, either the label and/or SDS and/or 'instructions for use' (IFU)and/or 'package leaflet' provides, in addition to that required by other relevant legislation, any relevant instructions for use to avoid releases of microplastics to the environment, including at the waste life-cycle stage. The instructions shall be clearly visible, legible and indelible. Instructions may be in the form of pictograms Where written instructions are given, these shall be in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. In addition, any supplier of a substance or mixture containing a microplastic derogated from paragraph 1 on the basis of paragraph 4(a)shall identify, where applicable, either on the label and/or SDS and/or 'instructions for use' (IFU)and/or 'package leaflet' that (i) the substance or mixture is subject to the conditions of this restriction and (ii) the quantity (or concentration) of microplastic in the substance or mixture and (iii) sufficient information on the polymer(s) contained in the substance or mixture for downstream users or suppliers to comply with paragraph 8.

Table continued:

Polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006)	7. From [EiF +12 ~~36~~ months], any [industrial] downstream user using microplastic(s) derogated from paragraph 1 on the basis of paragraph 4(a) shall send to ECHA in the format required by Article 111 of REACH, by 31 January of each calendar year: a. a description of the use(s) and quantities of microplastic in the previous calendar year, b. For each use, ~~generic~~ specific information on the identity of the polymer(s) used, c. For each use, ~~an estimate of~~ the quantity of microplastics released to the environment in the previous calendar year. d. Information on the release certification scheme in place Any supplier placing a microplastic derogated from paragraph 1 on the market for the first time for a professional or consumer end use allowed on the basis of paragraphs 4(b), 4(d), 4(e), or 5 shall send to ECHA in the format required by Article 111 of REACH, by 31 January of each calendar year: e. a description of the intended end use(s) and quantities of microplastic placed on the market in the previous calendar year, f. For each intended end use~~, generic~~ specific information on the identity of the polymer(s) placed on the market, g. For each intended end use, an estimate of the quantity of microplastics released to the environment in the previous calendar year. ECHA shall publish a report summarising the information received by 30 June every year.

Key reference documents

Communication from the European Commission, A European Strategy for Plastics in a Circular Economy (2018):

https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1516265440535&uri=COM:2018:28:FIN

ECHA, Annex XV Report, Proposal for a Restriction (22 August 2019):

https://echa.europa.eu/documents/10162/05bd96e3-b969-0a7c-c6d0-441182893720

ECHA, Background document to the Opinion on the Annex XV report proposing restrictions on intentionally added microplastics (11 June 2020):

https://echa.europa.eu/documents/10162/2ddaab18-76d6-49a2-ec46-8350dabf5dc6

ECHA, Annex to Background document (11 June 2020):

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ECHA, Response to Comments (RCOM, 11 June 2020):

https://echa.europa.eu/documents/10162/ddf89aed-5bb8-ebf3-48d4-b06134641179

RETH!NK PLASTiC

Rethink Plastic, part of the Break Free From Plastic movement, is an alliance of leading European NGOs working towards ambitious EU policies on plastics. It brings together the Center for International Environmental Law (CIEL), ClientEarth, Environmental Investigation Agency (EIA), European Environmental Bureau (EEB), European Environmental Citizen's Organisation for Standardisation (ECOS), Greenpeace, Seas At Risk, Surfrider Foundation Europe, and Zero Waste Europe. Together they represent thousands of active groups, supporters and citizens in every EU Member State working towards a future free from plastic pollution.

#breakfreefromplastic

#breakfreefromplastic is a global movement envisioning a future free from plastic pollution made up of 1,400 organisations from across the world demanding massive reductions in single-use plastic and pushing for lasting solutions to the plastic pollution crisis

With contributions from:

ClientEarth

EEB European Environmental Bureau

eia environmental investigation agency

Fidra

PLASTIC SOUP FOUNDATION

SEAS AT RISK

SURFRIDER FOUNDATION EUROPE

Supported by:

Bund für Umwelt und Naturschutz Deutschland
BUND FRIENDS OF THE EARTH GERMANY

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ECOS

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HEAL HEALTH AND ENVIRONMENT ALLIANCE

Health Care Without Harm

hej!support health . environment . justice

HUMUSZ szövetség

MIO-ECSDE

Naturvernforbundet Friends of the Earth Norway

NO PLASTIC IN MY SEA

Recycling Netwerk Benelux

wecf

ZERO associação sistema terrestre sustentável

Authors:

Alice Bernard, ClientEarth
Dolores Romano, European Environmental Bureau
Elise Vitali, European Environmental Bureau
Frédérique Mongodin, Seas At Risk
Gaëlle Haut, Surfrider Foundation Europe
Hélène Duguy, ClientEarth
Madeleine Berg, Fidra
Madhuri Prabhakar, Plastic Soup Foundation
Tom Gammage, Environmental Investigation Agency

Reviewers:
Chelsea Robinson, ClientEarth

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