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Restriction proposal on intentionally added microplastics – questions and answers

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Microplastic concern



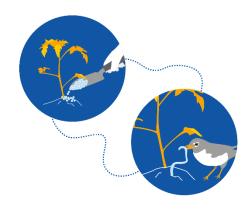
1. What are microplastics?

Microplastics are small, usually microscopic, solid plastic particles. They end up in our environment when larger articles, such as litter or car tyres, fragment or wear away. They are also deliberately manufactured and added to some products such as cosmetics, cleaning and laundry products, and fertilisers to give these products a certain texture or technical function¹. Microplastics are also used as the soft infill on artificial turf sports pitches.

2. Why are microplastics a problem?

Irrespective of their source, microplastics are persistent and universal pollutants. When products containing them are used, microplastics can be released to the environment where they stay for centuries, as they do not biodegrade.

Microplastics have been found in marine, freshwater and terrestrial ecosystems as well as in food and drinking water. Their continued release in massive quantities every year contributes to permanent and irreversible pollution of our ecosystems and food chains – we can



¹ In this Q&A, product only means a substance or a mixture. Microplastics in articles are not covered by the restriction proposal. Polymer-based articles that are less than 5 mm in all dimensions, for example, are not microplastics.

never clean them up. Exposure to microplastics in laboratory studies has been linked to a range of negative (eco)toxic and physical effects on living organisms.

Apart from certain locations in the oceans and seas, current concentrations of microplastics are not considered to pose widespread environmental risks. But if the releases continue, these risks will increase.

Currently, not much is known about microplastics in freshwater and terrestrial areas. In addition, research on the exposure and risks of microplastics to people is ongoing.

Each year, around 42 000 tonnes of microplastics end up in the environment after products containing them are used. The largest single source of pollution is the granular infill material used on artificial turf sports pitches, with releases of up to 16 000 tonnes alone.

Restriction proposal

3. What is the restriction proposal about?

ECHA's proposal, requested by the European Commission, will affect microplastics in products placed on the market in the EU/EEA.

The proposal would ban products that *contain* microplastics from the EU/EEA market if these microplastics are inevitably released to our environment when the products are used. Examples of such products are cosmetics, cleaning and laundry products, fertilisers, plant protection products and seed coatings.

Other products, such as paints and inks, may also contain microplastics, but their use does not inevitably lead to environmental releases. For example, when a paint dries, the microplastic particles of the paint join together and form a film. These uses are not proposed to be banned. However, the proposal requires companies to give instructions on how users can prevent or minimise any residual releases of microplastics to the environment. For example, instructions for paints that contain microplastics would need to describe how to clean paint residues from brushes and rollers without rinsing them into wastewater systems. Companies also need to report these microplastic uses and releases to ECHA to ensure that residual releases are monitored and, if necessary, controlled in the future.

The proposal outlines two options to control the releases of microplastic infill from artificial turf sports pitches: a ban on the placing on the market or the mandatory use of risk management measures. These options have different costs to society, but also different effectiveness in preventing releases.

ECHA's proposal includes derogations for some sectors, such as for the use of microplastics in medical diagnostics. Some of the derogations are time-limited. These time limits are set in such a way that they minimise the negative impacts to society, but do not unnecessarily delay the reduction of emissions.

The proposed restriction does not cover all polymers – it concerns only those that are consistent with the microplastic definition and relevant to the concern: less than 5 mm in size, solid, particulate, insoluble and non-biodegradable.

It also does not concern microplastics that are formed *unintentionally* in the environment (also called secondary microplastics). Examples of secondary microplastics are releases from car tyres while driving or from the degradation of plastic litter. The European Commission is considering measures to tackle these secondary sources as part of the EU's Plastics Strategy and the new circular economy action plan.

4. What is proposed as a means to control microplastic pollution from the granular infill material used on artificial turf sports pitches?

The granular rubber infill material added on artificial turf sports pitches is the largest single source of emissions – in the scope of ECHA's restriction proposal – with releases of up to 16 000 tonnes each year.

In its proposal, ECHA introduces two options to address the spreading of infill material from pitches. These are:

- 1) a ban on placing on the market after a transition period of six years after the entry into force; or
- 2) mandatory use of risk management measures (such as fences, brushes) to prevent the loss of infill from the pitches after a transition period of three years. You can see examples of infill containment in the annex to the background document, pages 360-362.

The two scientific committees have evaluated these options and given their recommendations. See the section on Committees' recommendations.

5. Why are there transition periods for some product groups like cosmetics?

When ECHA and its committees assessed the impacts of the restriction, they did this in terms of the different costs and benefits that would occur for both the environment and society.

The aim of the transition periods is to strike a balance between reducing microplastic pollution and impacts to society, such as availability of products to consumers or reformulation costs to companies. When a substance is commonly used in many products, like in the case of microplastics, a short transition period generally means that the costs to society are greater, as supply chains, including providers of alternatives, and consumers need to rapidly adapt to new regulation.

The different transition periods proposed for cosmetics consider factors such as the number of reformulations needed to comply with the restriction and the availability of alternatives. For example, microbeads, which are microplastics used as an abrasive, would not get any transition period. This is because microbeads can be easily replaced by alternatives such as ground almond, coconut shell or olive seeds.

For rinse-off and leave-on cosmetics, ECHA proposes four and six-year transition periods, respectively. This is because many products would be affected and reformulating them to be microplastic-free will take some time. For rinse-off cosmetics there are more alternatives available than for leave-on products, and the reformulation is also less complex, hence the shorter transition period.

Different roles in the restriction process

6. What are the roles of ECHA and the committees for Risk Assessment (RAC) and for Socio-economic Analysis (SEAC) in the restriction?

ECHA is the *dossier submitter*. This means that the Agency has prepared the initial restriction proposal also called an Annex XV report, which it submitted in January 2019. Along the process, ECHA has updated its proposal taking the comments received during the six-month consultation (March – September 2019) into account. These comments are available on ECHA's website.

The role of the committees for Risk Assessment (RAC) and for Socio-economic Analysis (SEAC) is to evaluate the strengths and weaknesses of the proposed restriction. RAC looks at the risks for the environment and to people's health, whereas SEAC evaluates the benefits of the proposal to people's health and the environment, and the associated costs and other socio-economic impacts.

During the opinion-making process, the 'restriction proposal' takes on the name of a 'background document'. RAC and SEAC evaluate this background document and form their own opinions based on its information and the comments received during the consultations.

ECHA's role during opinion making is to manage the stakeholder consultations and the committee meetings. ECHA also aims to ensure that the committees' evaluation is comprehensive and relevant to the European Commission and the EU Member States, who take the decision on the restriction.

Committees' recommendations

7. What does the Committee for Socio-economic Analysis recommend?

The Committee for Socio-economic Analysis (SEAC) finalised its evaluation of the costs and benefits of the proposal to European society in December 2020. It supports ECHA's proposal, but makes several recommendations to the European Commission, that will – together with the EU Member States – decide on the restriction.

Lower size limit for restricting microplastics: Currently, available analytical
methods cannot generally detect microplastics that are smaller than 100 nanometres
(nm) in mixtures, but they can detect particles smaller than 100 nm in raw materials.
This discussion became important from the perspective of how the restriction could be
enforced by EU Member States and the best way to deal with the current limitations of
analytical methods.

In its proposal, ECHA stated that nanoplastics (plastic particles between 1 and 100 nm) should not be knowingly added to products but set a lower size limit for the restriction as 100 nm. This is because the Agency recognised that it would not be possible, at least in the short term, to detect particles smaller than 100 nm in final products by using analytical methods.

SEAC recommended that the restriction should apply to all plastic particles that are larger than 1 nm, but noted that a temporary lower size limit of 100 nm may be necessary to ensure that the restriction can be enforced through detecting microplastics in products – if the restriction cannot be enforced by other means, such as through document checks.

- Use of microplastics as infill material on artificial turf sports pitches: SEAC does not prefer one of the assessed risk management options over the others, stating that the eventual choice would depend on policy priorities, specifically with regard to the priority put on reducing emissions relative to costs.
- **Transition periods:** SEAC recommends that the length of the transition periods proposed for medical devices, fragrance encapsulation and seed coating should be reevaluated after the restriction enters into force. By then we could expect to know more about how long it would take for companies to substitute microplastics with alternatives, particularly biodegradable alternatives.
- **Derogations:** During the 60-day consultation on SEAC's draft opinion, companies suggested further derogations for make-up, lip and nail products, sunscreens, lubricants and polymer emulsions. SEAC does not support these. It concluded that there is insufficient information to conclude that a ban would be disproportionate, which would be necessary to justify a derogation.

The committee recommends that, similar to natural and soluble polymers, polymers without carbon in their backbone or sidechains should not be in the scope of the restriction and should, therefore, be derogated as these materials cannot be considered as persistent or very persistent and are, therefore, not microplastics.

- Instructions for use and disposal: ECHA's proposal requires suppliers of products that are derogated from the ban to include 'instructions for use and disposal' for their customers (paragraph 7 of Table 3 of the restriction proposal). On this, SEAC concludes that although the available data does not allow an estimate to be made of the total costs of this obligation for companies, it is likely that these costs would not be prohibitive. SEAC, however, raises concerns about the transfer of confidential business information within supply chains, but also notes possible solutions to this such as the use of identifier numbers so that polymer identities are only disclosed to ECHA and not to other actors in the supply chain.
- **Reporting obligation:** ECHA's proposal includes an obligation for suppliers and users of products that are derogated from the ban to report their uses to the Agency (paragraph 8 of Table 3 of the restriction proposal). SEAC concludes that although the total costs of this obligation to companies could not be reliably estimated, they could be substantial, as many companies are likely to be affected. The committee, therefore, notes that excluding small and micro-sized companies or companies handling low volumes of microplastics from the obligation could reduce costs. In addition, SEAC notes that some supply chain actors (e.g. manufacturers and downstream users of preproduction pellets) are likely to be ready to report their uses to ECHA even before the 36-month timeline proposed.

8. What does the Committee for Risk Assessment recommend?

The Committee for Risk Assessment (RAC) finalised its evaluation of the risks of microplastics in June 2020. It supported the proposal while recommending more stringent criteria for derogating biodegradable polymers. Specifically, RAC recommended that the biodegradability of a polymer should be demonstrated in different parts of the environment (e.g. soils, marine environment, freshwater) before it is derogated. RAC also sees a need for more research so that the results of biodegradability testing can be more easily interpreted.

RAC also recommended a ban after a transition period of six years for microplastics used as infill material on artificial turf sports pitches, but also introduced an alternative 'hybrid' option. This option would require risk management measures to be installed on existing pitches while introducing a ban on the use of microplastic infill on new and refurbished pitches after a transition period.

RAC also recommended that the restriction applies to nanoplastics and that a lower size limit is not strictly needed for enforcement. RAC also considered that enforcement could be undertaken using document checks, rather than through analytical methods. More details in RAC's opinion.

Impacts of the restriction

9. What are the estimated impacts of the potential restriction?

ECHA's restriction proposal is the most comprehensive of its kind in the world. If adopted into law, it will prevent the release of 500 000 tonnes of microplastics to the environment over the 20 years following its introduction. When all the transition periods have expired, the emissions would be reduced by more than 90 %. In addition, any remaining releases will need to be reported to ECHA, which will help in determining future risk management actions to control them.

ECHA has assessed the costs of the proposed restriction on key areas or sectors including agriculture (fertilisers and plant protection products); cosmetic products; detergents and maintenance products; medicinal devices and products; food additives; oil and gas; paints and coatings; and polymer infill material on synthetic pitches.

The total costs of the restriction are estimated at ≤ 10.8 billion or ≤ 19.1 billion over 20 years, depending on which of the two proposed restriction options for the infill material is included. The costs consist mainly of:

- reformulation costs companies would need to reformulate a microplastic-free product that meets the demand with similar functions;
- raw material costs changing from microplastics to an alternative material which may be more costly; and
- enforcement and compliance costs the costs to society to comply with requirements
 of a restriction. These costs are likely to affect national enforcement authorities and
 industry placing microplastic-containing products on the market and include both
 administrative and analytical or testing costs.

What happens next?

10. How is the proposal taken forward? Who decides on the restriction?

ECHA will send its proposal (background document) and the opinions of the committees for Risk Assessment and for Socio-economic Analysis to the European Commission in early 2021.

The Commission is expected to prepare its proposal following ECHA's proposal and the opinions of the two committees. The Commission's proposal to amend the list of restrictions (Annex XVII) to the REACH Regulation² will be submitted to a vote before the EU Member States in the Commission's REACH Committee, followed by a period of scrutiny by the European Parliament and the Council.

The restriction could be adopted in 2021. The application dates of the restriction vary by use. For example, microbeads would be banned immediately whereas some other uses get a transition period.

Independence and transparency

11. How are stakeholders, e.g. NGOs and companies, involved in the restriction process? What about transparency?

Restriction proposals undergo two wide stakeholder consultations to which anyone can contribute. The consultation on the initial proposal (Annex XV report) is six months long. During the consultation on the microplastics proposal, ECHA received 477 comments from a wide variety of different stakeholder groups.

ECHA's scientific committees are obligated to take the comments received into account when assessing the proposal and developing their opinions. There is always a second 60-day long consultation on the draft opinion of SEAC, which allows stakeholders to provide additional information on the impacts of the proposal. For microplastics, this consultation took place from July to September 2020, and SEAC received 211 comments.

All non-confidential comments received during the consultations are published on ECHA's website. Regular and occasional stakeholders observe the meetings of RAC and SEAC to ensure transparency of opinion making.

 $^{^2}$ REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. The regulation entered into force on 1 June 2007.

12. How is it ensured that the two committees give independent opinions on ECHA's proposal?

The members of the two committees are independent scientists nominated by EU Member States and appointed by ECHA's Management Board. The members are not allowed to be given instructions by their nominating or employing Member State and must also declare any conflicts of interest on the proposal.

In addition, it is the role of the chairs, to ensure the evaluation is independent and consistent with other opinions made by the committees. ECHA supports the committee members appointed as rapporteurs.

Throughout the evaluation of the proposal, the scientific committees follow an evidence-based scientific approach.

Further information:

• Hot topics: microplastics

• Video: The problem with microplastics

• Restriction process