

Tackling intentionally added microplastics

ClientEarth's contribution to the public consultation on ECHA's Proposal to restrict intentionally added microplastics

ClientEarth welcomes this Restriction Proposal (the Proposal) and in particular its scope, which covers all sources of microplastics (intentionally added), irrespective of the sector or specific use (Section 1). The derogations and transitional periods, however, raise concerns, which we will be detailed below (Section 2).

1 A welcomed inclusive approach to the restriction: tackling all uses at once

This inclusive scope is justified considering the breadth of the environmental disaster and in particular, as rightly pointed out in the Proposal:

- the widespread use of microplastics across varied sectors;
- the various hazards associated with microplastic particles, including obstruction or interference with the normal functioning of feeding; toxicological hazards introduced by the polymers themselves, or via the presence of additives within the polymer matrix (such as plasticisers and flame-retardants); persistent environmental pollutants adsorbed by microplastic particles in the environment and potentially released if microplastics are ingested¹;
- the need to prevent potentially new uses of (intentionally added) microplastics which would raise the same issue.

ClientEarth welcomes the extensive work carried out by ECHA to gather and present the current knowledge on the risks arising from the use of intentionally added microplastics.

As clearly shown by ECHA in this Proposal, the property of microplastics to persist in the environment results in a situation in which any release contributes to its arguably permanent²

¹ ECHA Restriction Proposal, p. 14.

² The Proposal, at p. 65, highlights how, when considering the appropriate risk assessment for microplastics, its "[...] extreme, arguably permanent, persistence in the environment" needs to be taken into account.

May 2019

accumulation in the ecosystem. “In this respect, the relevant risk characterisation could be considered in terms of *when* will safe thresholds be exceeded, rather than *if* safe thresholds will be exceeded”³.

The aforementioned features, associated with the vast amount of microplastics released into the environment, led ECHA to consider microplastics as a “proxy for risk”⁴. ECHA estimated the quantity of microplastics that are eventually released into the environment, under reasonably foreseeable conditions of use, to be around 36.000 tonnes per year. This figure is comparable to an amount of plastic waste in the environment “corresponding to approximately six times the present size of the ‘Great Pacific Garbage Patch’ or the releases of microplastics that could occur per year from about 10 billion plastic bottles”⁵. Moreover, while the occurrence of microplastics in the marine environment is documented by extensive literature, microplastic particles have also been found in wastewater, sewage sludge, freshwater, the terrestrial environment and even in some species of marine fish and shellfish.

The Proposal concludes, on the basis of the extensive scientific evidence gathered, that the risks derived from the release of intentionally added microplastics into the environment are not adequately controlled and thus justify a restriction under REACH.

In light of the available evidence, ClientEarth welcomes the approach taken by ECHA to cover all uses of (intentionally added) microplastics, taking duly into account the extent of this environmental disaster.

ClientEarth would like to raise some concerns, however, on two issues:

1. The proposed derogations from the scope of the restriction allowing companies to continue their business as usual, without preventing release of microplastics into the environment
2. The long and unjustified transitional periods for the entry into force, unnecessarily delaying the actions required to put risks under control

2 Derogations and transitional periods weaken the restriction Proposal in unjustifiable ways, undermining its effectiveness

Annex XV, Paragraph 3, of the REACH Regulation lays down general principles for preparing dossiers to propose and justify restrictions on the manufacture, placing on the market or use of substances within the EU.

³ ECHA Restriction Proposal, p. 4.

⁴ ECHA Restriction Proposal, p. 90.

⁵ ECHA Restriction proposal, p. 5.

May 2019

The proposal for a restriction has to include the identity of the substance; information on related hazards and risks; evidence that implemented risk management measures are not sufficient, as well as available information on alternative substances. The restriction has to be justified at EU level, by explaining why action is required on an EU-wide basis and why a restriction is the most appropriate measure⁶. This latter assessment is carried out using notably the effectiveness criteria of the measure⁷.

It follows that any derogation or transitional period embodied in the Proposal must not prevent the restriction from effectively controlling the risk. These “exceptions” to the scope and to the entry into force of the restriction need to be supported by a reasoning that is relevant, consistent and complete⁸, as well as based on reliable and cogent information gathered through a thorough scientific evaluation⁹. As compliance with the criteria of effectiveness is mandatory, it must be demonstrated that even with the inclusions of transitional periods and derogations this requirement is fulfilled.

Once ECHA has established a lack of control of a risk across sectors, it is for companies to prove that the risk is adequately controlled in their specific case. If no relevant data is provided to show this, it means that the derogation is not justified and weakens the restriction and its ability to control the risk, i.e. calls into question its effectiveness.

2.1 Derogations from the scope of the Restriction do not prevent future release of microplastics to the environment

The Proposal includes several derogations¹⁰ from the scope of the restriction. Depending on the arguments outlined in the Proposal to support their inclusion, the derogations can be divided into two groups:

The first group is justified in the Proposal by the need to avoid double regulation

They are derogations 4.a, 4.b and 4.c, of Table 19¹¹, respectively, on mixtures containing microplastics used at industrial sites, medicinal products for human or veterinary use and mixtures that fall under the new Fertiliser Regulation¹².

⁶ After this assessment, an analysis of the socio-economic impacts of the restriction may be added. This means comparing the net benefits to human health and the environment of the proposed restriction with its net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole. Information on any consultation of stakeholders and how their views have been taken into account must also be included in the dossier.

⁷ Annex XV, Paragraph 3, REACH Regulation.

⁸ Judgement of the General Court, 7 March 2019, Case T-837/16, Kingdom of Sweden v European Commission, Paragraph 68. Available at <http://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=T-837/16#> (last access 16th May 2019).

⁹ Judgment of the General Court, 14 November 2013, Case T-456/11, International Cadmium Association (ICdA) and Others v European Commission, Paragraph 52. Available at <http://curia.europa.eu/juris/liste.jsf?num=T-456/11&language=EN> (last access 16th May 2019).

¹⁰ Derogations 3.a and 3.b are not included in this analysis as they regard biodegradable polymers that do not fulfil the requirements of the definition of microplastics adopted by the restriction proposal.

¹¹ ECHA Restriction Proposal, p. 80.

¹² The regulation on CE marked fertilisers has been voted by the Parliament in plenary at the end of March 2019 but it has not been published in the Official Journal yet.

May 2019

ClientEarth's main concern regards the exclusion of fertilising products from the scope of this restriction. Indeed, fertilisers¹³ constitute 58% of the total share of emissions of microplastics¹⁴, representing the main source of microplastics pollution in the environment. Such an exclusion from the scope of the restriction represents serious cause for alarm.

The new Fertilisers Regulation¹⁵ will require all CE-marked fertilising products to contain exclusively biodegradable polymers. We understand that the Proposal builds on this obligation to justify the inclusion of such a derogation. However, the expected timeline for the complete phase-out of microplastics from fertilising products is worrisome.

In order to assess the biodegradability of the polymers used in fertilisers, manufacturers will have to comply with biodegradability criteria that the European Commission is required to develop within 5 years from the entry into force of the new Fertilisers Regulation, meaning 2026. The new Fertilisers Regulation includes also a safety clause: in case no agreement on the biodegradability criteria is reached within 7 years from the entry into force of the new regulation, non-biodegradable polymers will have to be phased out anyway. In this latter case, the criteria to assess whether a polymer is biodegradable will make reference to the test methods currently in use and potentially updated by the European Commission, under this restriction's framework, the so-called "*interim criteria*".

This means that, in the best-case scenario, emissions of microplastics into the environment, due to use of CE marked fertilisers, will continue for another 5 years from the entry into force of the regulation, i.e. until mid-2026. In the worst-case scenario, instead, it will be necessary to wait until 2028. Moreover, the new Fertilisers Regulation covers only 50% of the total EU fertiliser market¹⁶, while the remaining 50% of fertilising products that are not CE marked are not subject to any specific biodegradability requirement¹⁷.

Such a timeline does not seem reasonable in light of the risk assessment performed by ECHA. The need for restricting microplastics stems from the urgency to stop any further release, due to its persistence in the environment. Maintaining the current level of exposure will only amplify the risks. A more effective way to address this while, at the same time, avoiding double regulations, would be not to derogate until the new Fertilisers Regulation ban enters into force. This way, microplastics released will be initially controlled thanks to the entry into force of this restriction and, afterwards, thanks to the new Fertilisers Regulation, all types of biodegradable polymers will be phased-out from CE marked fertilisers.

¹³ With the generic term "fertilisers", here, reference should be made to control release fertilisers and fertiliser additives.

¹⁴ Please, refer to p. 121 of ECHA Restriction Proposal.

¹⁵ It regulates exclusively CE-marked fertilisers, namely those fertilisers that have the CE marking (European Conformity marking). CE marking proves that a product has been assessed and meets EU safety, health and environmental protection requirements.

¹⁶ European Parliamentary Research Service, 2017.

¹⁷ Non-CE marked fertilisers are covered by this Proposal, which grants industries 5 years from the entry into force to develop suitable biodegradable alternatives.

May 2019

The second group of derogations is justified according to the Proposal by the expectation that no polymer will be emitted to the environment

Derogations 5.a – 5.b – 5.c, Table 19, regard:

1. mixtures where microplastics are contained by technical means throughout their use to prevent releases to the environment and incinerated or disposed of as hazardous waste at the end of their life-cycle;
2. mixtures where the physical properties of microplastics are permanently modified when the mixture is used such that the polymers no longer fulfil the meaning of a microplastic given in paragraph 2(a)¹⁸;
3. substances or mixtures where microplastics are permanently incorporated into a solid matrix at the point of use.

In the explanation for the inclusion of this second group of derogations, the Proposal adds that “use benefitting from this derogation shall be required to communicate appropriate use instructions to minimise releases to the environment and report the quantities used and released to the market to the Agency”¹⁹.

The justification at the basis of this second group of derogations – namely that no polymer is expected to be emitted to the environment – does not appear to be substantiated in the Proposal itself. On the one hand, the Proposal states that microplastics are not expected to be released into the environment in particulate forms for these uses. On the other hand, the Proposal sets for downstream users obligations to both report the quantities of microplastics used and released and communicate use instructions to minimise releases.

It follows that there will likely be some release of microplastics under reasonably foreseeable conditions of use. This contradicts the very reason relied upon to grant the derogation, namely that no polymer will be emitted to the environment. This shows that these derogations are not justified.

2.2 Long transitional periods for the entry into force unnecessarily delay the actions required to put risks under control

The Proposal introduces a number of transitional periods depending on sectors and product types:

¹⁸ Reference to the definition of microplastics.

¹⁹ Column “Explanation” of the entries 5a, 5b, 5c, Table 19, p. 81-82.

May 2019

1. medical devices²⁰ and *in vitro* diagnostic medical devices²¹ are granted two years from the entry into force of the restriction;
2. other²² rinse-off cosmetics have four years from the entry into force of the restriction;
3. detergents containing polymeric fragrance encapsulation, other²³ detergents, waxes and polishes are all granted five years from the entry into force;
4. mixtures not regulated in the EU as fertilising products under the new Fertiliser Regulation that do not meet the requirements for biodegradability contained in that Regulation;
5. mixtures [or articles] used as non-CE marked fertilising products that do not meet the requirements for biodegradability contained in the New Fertiliser Law have five years from the entry into force of the Proposal;
6. plant protection products²⁴ and biocides²⁵ have five years from the entry into force of the restriction;
7. leave-on cosmetic products are granted 6 years from the entry into force of the restriction.

Firstly, some clarifications are needed on what types of products will fall under the transitional period for “mixtures not regulated in the EU as fertilising products under Regulation (EC) No xxx/xxx on Fertilising Products that do not meet the requirements for biodegradability contained in that Regulation”²⁶. Without this clarification it is not possible to ensure that all fertilisers are covered by the obligation to phase out non-biodegradable polymers, either under the new Fertilisers Regulation or under this proposed restriction.

Secondly, the transitional periods proposed are not only long – ranging from 2 to 6 years from the entry into force of the restriction – but they are also very vaguely justified and potentially able to undermine the effectiveness of the Proposal. The Proposal gives prominent consideration to industry's needs to smoothly shift towards alternatives to microplastics. In order to allow companies sufficient time for reformulations, unnecessary delays are created in minimising exposure to microplastics. The consideration that microplastics accumulate and persist in the environment must drive future actions.

²⁰ As defined in Regulation (EU) 2017/745.

²¹ As defined in Regulation (EU) 2017/746.

²² As many cosmetics containing microbeads have been already phased out through national laws, here “other” means the remaining rinse-off products, not covered by sectoral domestic legislations.

²³ It is a residual category to include all the detergents that are not already covered by this Proposal or by national regulations.

²⁴ Regulation (EU) 2009/1107.

²⁵ Regulation (EU) 2012/528.

²⁶ ECHA, Restriction Proposal, Table 20, p. 83.

May 2019

The transitional periods are not justified based on cogent and reliable data

ClientEarth understands the logic behind the inclusion of transitional periods. The Proposal acknowledges that they have to be “balanced against the need to minimise emissions to the environment, as each additional transitional year of the restriction would lead to further releases of microplastics, increasing the environmental pressure from their rising stock in the environment”²⁷. However, the justification for companies needing further time to develop alternatives is general and not properly documented: industries should demonstrate what plans they will actually put in place to substitute microplastics, detailing a timeline for substitution.

Companies should be granted transitional periods only if they are able to demonstrate that:

- there are no alternative to microplastics already available on the market;
- a certain amount of time is needed to transition towards biodegradable options, on the basis of cogent and reliable data;
- they have developed a research and development strategy to phase out microplastics.

On the contrary, this type of information is missing in the Proposal, which vaguely refers to the need “[T]o allow sufficient time to reformulate and transition to alternatives” or to the fact that “[T]ime is required for the development of biodegradable polymers suitable for this function”²⁸. The way in which the transitional periods are designed lacks proper justification, preventing the adequate control of the risks to human health and the environment, arising from the manufacturing, use or placing on the market of microplastics.

The transitional periods are not proportional and they risk undermining the effectiveness of the restriction

Pursuant to paragraph 3, Annex XV, of the REACH Regulation, effectiveness is an essential element of any lawful restrictions. The effectiveness is measured, verifying that it:

- targets the effects or exposures that cause the risks identified;
- is capable of reducing these risks to an acceptable level;
- reduces the identified risks in a time that is reasonable and proportional to the risk²⁹.

It follows that a restriction is effective when it achieves its objective - i.e. having the risks under control - in a time that is reasonable and proportionate in light of the risks that it aims to prevent. In order for this restriction to be the optimal strategy needed to tackle the microplastics issue, it has to be fast in limiting the exposure, as any further release contributes to “a progressively

²⁷ ECHA Restriction proposal p. 117, footnote n. 57.

²⁸ Both quotations refer to ECHA Restriction Proposal, Table 20, p. 83-84.

²⁹ Letter (i) - under “Justification for restrictions at community level” - Paragraph 3, Annex XV, REACH Regulation.

May 2019

increasing environmental stock, which would eventually result in exposures exceeding safe thresholds in the future"³⁰. Long transitional periods, on the contrary, are contradictory to the need for urgent actions, rather they jeopardise the objective to protect public health and the environment. According to the current Proposal, the risks arising from microplastics will be reduced to an acceptable level only in a timeframe that ranges from two to six years' time from the entry into force of the restriction. This is not in line with the requirements under Annex XV of REACH.

The purpose of the restriction is to have the identified risks under control. In order to be proportional, it is necessary that this objective be fulfilled in a timely manner. The urgency to minimise the likelihood of adverse effects of microplastics occurrence in the environment is strictly related to its ability to persist and bioaccumulate, potentially creating irreversible damage to ecosystems today or due to continued use in the future³¹. Such characteristics should be mirrored in the timeline set for the entry into force. Any other solution will translate into severe consequences for ecosystems in the years to come.

The lack of proportionality of these transitional periods is clear, for example, when considering the risks posed by current practices in the agricultural and horticultural sector, as described in the Proposal. The intensive use of fertilisers, control release fertilisers³² (CRFs) as well as capsule suspension pesticides³³ (CSPs) constitutes the highest source of microplastics pollution in the environment³⁴. The polymers used in CRFs, for instance, are non-degradable and 100% of the polymeric material is directly emitted to the environment, where it accumulates for hundreds of years. While the main application of this type of products is currently limited to the cultivation of ornamental plants and the maintenance of turfs for sports, the use of CRFs in agriculture and forestry is predicted to rise. With this, also the occurrence of microplastics in the environment is likely to increase. All this evidence described in the Proposal cannot be reconciled with the length of the transitional periods (five years from the entry into force of the restriction granted) to phase out non-biodegradable polymers.

Proportionality requires taking this data into account when setting the timeline for the entry into force of the restriction. Increased release means increased urgency in tackling the issue. Furthermore, according to the data submitted in the Call for Evidence, not only are CRFs and CSPs often offered by large agrichemical producers, but some biodegradable alternatives are already available on the market³⁵. The reasons for granting large agro-chemical companies such a long time to shift towards biodegradable alternatives are not clear.

³⁰ ECHA Restriction Proposal, p. 4.

³¹ ECHA Restriction Proposal, p. 116.

³² CRFs are granulated fertilisers that release nutrients gradually into the soil. As they are more efficient in terms of labour, fertiliser quantity and run-off compared to conventional fertiliser technologies, they have been widely adopted, particularly in the ornamental industry where they are used by 90% of the 25.000 nurseries in the EU. ECHA, Annex to the Restriction Proposal, p. 113.

³³ CSPs are based on a combination of an active ingredient encapsulated in a polymer shell suspended in water with dispersant and wetting agent.

³⁴ Annex D (p. 112) of ECHA's Restriction Proposal is entirely dedicated to the A&H sector.

³⁵ Such as the one for fertiliser additives that rely on silica instead of on microplastics, ECHA Annex to the Restriction Proposal p. 140.

May 2019

Conclusions

The Proposal is ambitious and positively underpins the consideration that the risks posed by the release of microplastics into the environment needs to be urgently tackled. In order to guarantee the effectiveness of such restriction ClientEarth makes the following recommendations:

- Derogations must be granted only if the identified risks are under control in the specific case and for the specific applications.
- The derogation on CE-marked fertilisers, considering the timeline for the entry into force of the new Fertilisers Regulation is not adequate to tackle the microplastics disaster. It would be more effective to derogate only when the biodegradability criteria will be adopted under the new Fertilisers Regulation.
- The transitional periods are currently not justified on the basis of cogent information and undermines the effectiveness of this restriction in controlling the risk. The risk assessment carried out by ECHA demonstrates that, due to their ability to persist and accumulate in the environment, the release of microplastics should be minimised without any further unnecessary delay.
- Finally - as already stressed - in order to ensure that all fertilisers are covered either by this restriction or by the new Fertilisers Regulation, some clarifications are needed on what types of products will fall under the transitional period for "Mixtures not regulated in the EU as fertilising products under Regulation (EC) No xxx/xxxx on Fertilising Products that do not meet the requirements for biodegradability contained in that Regulation"³⁶.

³⁶ ECHA, Restriction Proposal, Table 20, p. 83.

May 2019

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ClientEarth is a non-profit environmental law organisation based in London, Brussels and Warsaw. We are activist lawyers working at the interface of law, science and policy. Using the power of the law, we develop legal strategies and tools to address major environmental issues.

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