

COMMENTARY

The European legislation on the restriction on intentionally added microplastics

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Abstract

The potential impacts of microplastics pollution on the environment and possibly human health have raised concerns in various parts of the world. Once in the environment, microplastics do not biodegrade and cannot be removed. Several Member States have adopted or proposed specific measures. However, a patchwork of national restrictions can hinder the functioning of the internal market and therefore requires harmonization at Union level.

The European Commission, on 9 November 2017, requested the European Chemicals Agency to prepare possible proposals for restrictions regarding oxo-plastics and intentionally added microplastic particles.

On 25 September 2023, the restriction on microplastics intentionally added was published on the *Official Journal of the European Union*.

By the end of 2024 it is envisaged the publication of a Guidance on the application of the microplastic restriction under Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Key words

- microplastics
- PBT/vPvB
- environment
- REACH restriction

INTRODUCTION

Microplastics are intentionally added to a variety of products used in different agriculture applications such as fertilizers and crop protection products, everyday products like cosmetics and household detergents and industrial cleaners, paints, and products used in the oil and gas industry.

In consumer products, microplastic particles are used for their characteristic of being abrasive (e.g., as exfoliating and polishing agents in cosmetics, known as microbeads).

It is estimated that about 145,000 tons of microplastics are used annually in the EU and, about 42,000 tons of microplastics end up in the environment due to the use of products containing them.

The largest source of pollution is granular infill material used for artificial turf fields, with a release of 16,000 tons. In addition, the release of unintentionally formed microplastics (when larger pieces of plastic wear out) is estimated at about 176,000 tons per year in European surface waters [1].

According to the European Chemical Agency (ECHA) "Microplastics are synthetic, water-insoluble

polymer items smaller than 5 mm, which are considered to be of particular concern for the aquatic environment" and "oxo-plastics or oxo-degradable plastics are conventional plastics that contain additives which promote the oxidation of the material under certain conditions. They are used in applications such as agricultural films, rubbish and carrier bags, food packaging, and landfill covers. They can break down into very small particles, potentially contributing to environmental contamination by microplastics" [2].

Intentionally added microplastics have been the subject of great interest in their management both in scientific and regulatory fields in Europe due to their persistence characteristics and their potential bioaccumulation. In fact, once in the environment, they do not biodegrade and tend to accumulate in organisms and environmental compartments.

Microplastics have been found in fish for food consumption and, as a result of biomagnification, they can penetrate and accumulate in the human body [3-5].

In a study conducted on different types of edible fish, microplastics were found in different areas (gastro-intestinal tract, dorsal muscle and gills) and oxidative

damage to lipids in the brain, muscles and gills and an increase in activity were found of cerebral AChE (acetylcholinesterase, an enzyme whose primary function is to degrade acetylcholine and complete neurotransmission) in fish containing microplastics [6]. Microplastics were recently found in human feces for the first time, indicating that humans ingest and eliminate these particles [7].

In 2016 the European Food Safety Authority (EFSA) reviewed the available evidence on micro- and nano-plastics in food identifying the need to generate more data on levels of presence in foods and potential effects on human health.

Where action needs to be taken to manage hazardous substances, restrictions under the European Regulation (EC) n. 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals – REACH regulation [8] – are used to limit or ban the production, placing on the market (including import) or use of a substance, and may also be used to impose any relevant conditions, such as technical measures or particular labelling.

The National Centre for Chemicals, cosmetics and consumer protection of the National Institute of Health (Istituto Superiore di Sanità, ISS), in Italy, deal with REACH regulation actively participating in both RAC and Member State Committee, by submitting both proposals for harmonised classification of chemicals and proposals for restriction.

THE REACH RESTRICTION ON ADDED MICROPLASTICS

Added microplastics, once released, remain in the environment for thousands of years due to their persistence and bioaccumulation properties. In addition, they are likely to raise human health concerns, and the impact of such long-term exposure on the environment cannot currently be determined. Based on these concerns, the restriction adopted under REACH to protect human health and the environment from the presence of solid particles of polymer-based materials is justified.

Laboratory studies have made it possible to link exposure to microplastics to a series of adverse (eco)toxic and physical effects on living organisms. Microplastic particles ingested by fish can cause several disruptions to regular metabolic activity and can damage the gastrointestinal tract and nervous system, leading to serious health implications, including reduced feeding capacity, impaired gill function, altered immune system function, and compromised endocrine and liver systems [9].

Several EU Member States have already adopted or proposed national bans on the intentional uses of microplastics in consumer products, such as a ban on the use of microbeads in cosmetics that are rinsed after use, or bans in cases where microplastics are used as abrasive and polishing agents [10].

In 2017 the Commission has requested ECHA to prepare an Annex XV restriction dossier concerning the use of intentionally added microplastic particles to consumer or professional use products of any kind and an Annex XV restriction dossier concerning the plac-

ing on the market and use of oxo-degradable plastics as potential risk to the environment may arise from the use of oxo-degradable plastics in various products for consumer and professional use, because of their potential to initiate the generation of microplastics.

On 17 January 2018 ECHA notified the intention to prepare the restriction proposals by Registry of the Intention (RoI).

On 8 May 2019, ECHA withdrew the intention to investigate the need for a restriction on oxo-degradable plastics.

The withdrawal comes after a Commission request following the adoption of the directive on the reduction of the impact of certain plastic products on the environment. The new legislation restricts the placing on the EU market of any product made from oxo-degradable plastics [11].

In 2019, ECHA, proposed a broad restriction on microplastics in products placed on the EU/EEA market to avoid or reduce their release into the environment.

The initial concern identified for microplastics is based on PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) properties. Given the wide variety of synthetic polymer microparticles (in terms of composition, properties, and size), the risk assessment was done on a case-by-case basis. The result was that the intentional use of microplastics, which inevitably leads to releases into the environment, presents a risk that is not adequately controlled unless a restriction is adopted under REACH. This measure prevents exposure to microplastics from causing adverse ecotoxicological effects, which would be difficult to address in the future.

The restriction process foresees the involvement of the Risk Assessment Committee (RAC) and the Socioeconomic Analysis Committee (SEAC) of ECHA. After the adoption of the final opinion by RAC and SEAC and after a positive evaluation by the Council and Parliament European Commission, the European Commission approved the restriction which was published in the European Official Journal on 25 September 2023 [12]. As a result, Annex XVII of Regulation (EC) n. 1907/2006 is amended by the addition of entry 78 for microplastics.

Once the restriction enters into force industry needs to comply with the restriction and Member States are responsible for enforcing the restriction.

The scope covers intentionally added microplastics in different types of commonly used products such as detergents and household cleaning products, cosmetics, encapsulated fragrances, and products such as medical diagnostic devices, synthetic turf football field infill materials, paints and coatings and fertilizers and pesticides in which microplastics are added to improve performance.

Given the complexity of the scope, exemptions have been provided for the entry into force of the restriction in consideration of both the socio-economic aspects and to allow some sectors (such as, for example, the production of diagnostic medical devices) to find adequate alternatives that do not affect the product reliability (Table 1).

Table 1
Summary scheme of application dates by product type

Product type	Derogations
Diagnostic medical devices	<ul style="list-style-type: none"> from 17 October 2029 for medical devices and accessories for human use within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council [13]
Detergents and home care products	<ul style="list-style-type: none"> from 17 October 2028 for detergents as defined in Regulation (EC) n. 648/2004 on detergents [14], waxes, polishes, and household fragrance products from 17 October 2029 if they contain microparticles for fragrance encapsulation.
Cosmetics*	<ul style="list-style-type: none"> from 17 October 2027 to rinse-off products from 17 October 2035 to lip and nail products
Fertilizers and pesticides	<ul style="list-style-type: none"> from 17 October 2028, to "fertilizer products" as defined in Article 2(1) of Regulation (EU) 2019/1009 [15], which do not fall within the scope of that Regulation from 17 October 2031, to plant protection products as defined in Article 2(1) of Regulation n. 1107/2009 of the European Parliament and of the Council ("Pesticides Regulation") [16] and seeds treated with such products, as well as to biocidal products as defined in Article 3(1)(a) of Regulation (EU) n. 528/2012 of the European Parliament and of the Council ("Biocidal Products Regulation") [17] from 17 October 2028 for products intended for agricultural and horticultural uses that are not pesticides or biocides, such as seeds coated with dyes or lubricants
Filling materials for the synthetic turf fields	<ul style="list-style-type: none"> from 17 October 2031 for granular infill for use on synthetic sports surfaces
Encapsulation of fragrances	<ul style="list-style-type: none"> from 17 October 2029 to synthetic polymer microparticles for use in the encapsulation of fragrances

*From 17 October 2031, and until 16 October 2035, lip and nail products containing synthetic polymer microparticles must include the statement, "This product contains microplastics" while products placed on the market before 17 October 2031, need not carry that statement until 17 December 2031.

CONCLUSIONS

The restriction on microplastics intentionally added, triggered by the great concern for the environment and human health, because of its complexity and wide range of uses covered, is a modern example of integration of risk assessment and management processes conducted on the basis of sound scientific information and current socio-economic considerations.

Transition periods and derogations for certain sectors proposed will allow industry to have enough time to develop and move to suitable alternatives, that is one of the aims of REACH Regulation.

Since the restriction on microplastics is based on current scientific knowledge and uses, the future impact of the proposed restriction may be different from what has been estimated now.

To take into account any scientific developments concerning polymer degradation and solubility, the Forum for Exchange of Information on Enforcement (Forum) recommends to review the standardised test methods and pass criteria to demonstrate degradability or solubility (including new test methods specifically developed to assess the degradability or solubility of synthetic polymer microparticles).

The Commission is working to finalize a guidance document containing explanation to better apply the

restriction with a Q&A section. The draft guidance document has been shared with participants in the *ad hoc* working group (in which CNSC researchers participate) and the first version of the Guidance is expected to be published by the end of 2024.

A rapid publication of the guidance is of essence, in particular for sectors to which the restriction applies as of 17 October 2023 because they were not granted a transitional period.

The effects of the restriction are expected to be significantly perceptible in the early 2030s as envisaged by the European Green Deal, which has as one of its goals a 30 percent reduction in the amount of microplastics released into the environment, with increasing effectiveness over the subsequent years. Over the 20 years period following its entry into force it is estimated that this restriction to result in a cumulative emission reduction of approximately 400 thousand tonnes of microplastics.

Conflict of interest statement

The Authors declare that there are no conflicts of interest.

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