

EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND THE WINDSOR FRAMEWORK

C(2023)6419 FINAL + ANNEX

COMMISSION REGULATION (EU) / AMENDING ANNEX XVII TO REGULATION (EC) NO 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS SYNTHETIC POLYMER MICROPARTICLES

Submitted by the Department for Environment Food and Rural Affairs (Defra)

12 October 2024

SUBJECT MATTER

1. The European Commission is implementing an amendment to Annex XVII of Regulation (EC) No 1907/2006 of the European Parliament and of the Council, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) within the European Union (EU), in relation to the placing on the market or use of synthetic polymer microparticles.

Background to REACH Restrictions

2. REACH Restrictions are applied to the manufacture, placing on the market, or use of certain substances if they pose an unacceptable risk to human health or the environment. New Restrictions, or amendments to existing ones, are made by legislation. Currently, we apply a broadly similar Restrictions regime, amended to work domestically, under assimilated Regulation (EC) No 1907/2006 of the European Parliament and of the Council, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (assimilated REACH).

Background on Synthetic Polymer Microparticles

3. Synthetic polymer microparticles, commonly referred to as “microplastics”, are normally defined as plastic particles smaller than 5 millimetres in diameter and larger than 100 nanometres, but there is no internationally agreed and universally applied legal definition. Microplastics are insoluble in water, degrade slowly and can be ingested by living organisms. Microplastic particles are widespread in the environment.
4. Microplastics can be formed from breakdown of larger plastic pieces or intentionally manufactured. Microplastics formed by breakdown of larger plastics are outside the scope of this REACH Restriction which focuses on microplastics that are intentionally manufactured and placed on the market as substances on their own, or in mixtures.
5. Microplastics that are intentionally manufactured are used and placed on the market

globally in a range of products, such as paints, infill material on sports pitches, and detergents, to serve specific purposes.

Regulation of Synthetic Polymer Microparticles

6. The REACH Annex XVII amendment aims to address the risks of intentionally added synthetic polymer microparticles which build up in the environment due to insolubility in water and slow degradation. The regulation addresses synthetic polymer microparticles found in a range of products including make-up, detergents, fertilisers, personal care products, agricultural and horticultural products and synthetic sport surfaces. The REACH Restriction sets limits on the levels of synthetic polymer microparticles as substances on their own or, where the synthetic polymer microparticles are present to confer a sought-after characteristic, in mixtures in a concentration equal to or greater than 0.01% by weight.
7. The justification for the REACH Restriction includes concerns with the very high persistence of microplastics, which represents an irreversible environmental risk. Regarding effects on human health, there are few studies on the effect of microplastics in humans (direct or via food; EFSA 2016). However, there is some evidence that exposure to certain chemical additives present in microplastics could cause infertility, genetic disruption, poisoning, reduced feeding and increased mortality in marine organisms and in humans if ingested in very large quantities (Hollman et al., 2013, Galloway, 2015, Auta et al., 2018).
8. The REACH Restriction will mean that articles exceeding the set limits of synthetic polymer microparticles cannot be placed on the EU market from the following dates: from 17 October 2027 for rinse-off personal care products; from 17 October 2028 for detergents, waxes, polishes and air care products, fertilising products that are not in scope of Regulation (EU) 2019/1009, agricultural and horticultural products; from 17 October 2029 for synthetic polymer microparticles for use in the encapsulation of fragrances, leave-on personal care products, or medical devices; from 17 October 2031 for plant protection products and seeds treated with those products, biocidal products, granular infill for use on synthetic sports surfaces; and from 17 October 2035 for lip products, nail products, and make-up.
9. The REACH Restriction does not apply to synthetic polymer microparticles for use at industrial sites; in medical products (in scope of Directive 2001/83/EC); in veterinary medical products (in scope of Regulation (EU) 2019/6); in EU fertilising products (in scope of Regulation (EU) 2019/1009, as this EU Regulation already sets degradability criteria for polymers); in food additives (in scope of Regulation (EC) No 1333/2008); in in-vitro diagnostic devices or in food.
10. Additionally, the REACH Restriction does not apply to synthetic polymer microparticles whose release to the environment is prevented via containment by technical means when used in accordance with instructions; which are

permanently modified during intended usage so that they no longer fall within scope; or which during end use are permanently incorporated into a solid matrix.

SCRUTINY HISTORY

11. The Parliament Scrutiny history relevant to this Explanatory Memorandum (EM) is contained in Annex A.

MINISTERIAL RESPONSIBILITY

12. The Secretary of State for Environment, Food and Rural Affairs has responsibility for this policy area.

INTEREST OF THE DEVOLVED GOVERNMENTS (DGs)

13. This proposal relates to a regulation, REACH, that is subject to the provisional Common Framework on Chemicals and Pesticides. DG officials have been consulted in the preparation of this EM, and are awaiting the outcome of the evidence project (see paragraph 18 of this EM) due to report in 2025, before making any decisions on next steps.

LEGAL AND PROCEDURAL ISSUES

14.

i. Legal Base

The legal basis for this amendment is Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, and in particular Article 68(1) of REACH.

ii. Voting Procedure

The procedure used for amendments to REACH Annex XVII is regulatory with scrutiny (Article 5a paragraphs 1-5 of the Old Comitology Decision (Decision 1999/468/EC), as amended by Council Decision 2006/512/EC), with a qualified majority required.

iii. Timetable for adoption and implementation

The Regulation was adopted by the Commission on 25th September 2023 with synthetic polymer microparticles on their own, or in mixtures in concentrations exceeding the set limits not to be placed on the EU market from the following dates: from 17 October 2027 for rinse-off personal care products; from 17 October 2028 for detergents, waxes, polishes and air care products, fertilising products, agricultural and horticultural products; from 17 October 2029 for synthetic polymer

microparticles for use in the encapsulation of fragrances, leave-on personal care products, medical devices; from 17 October 2031 for plant protection products and seeds treated with those products, biocidal products, granular infill for use on synthetic sports surfaces; and from 17 October 2035 for lip products, nail products, make-up.

POLICY AND LEGAL IMPLICATIONS

15. To date, the UK has implemented environmental protection legislation to restrict microbeads, which are defined as water insoluble solid plastic particles of less than or equal to 5mm in any dimension, used in rinse-off personal care products. Following cooperation and collaboration between the four nations, identical provisions were entered into law in England (The Environmental Protection (Microbeads) (England) Regulations 2017), Scotland (The Environmental Protection (Microbeads) (Scotland) Regulations 2018), Wales (The Environmental Protection (Microbeads) (Wales) Regulations 2018), and Northern Ireland (The Environmental Protection (Microbeads) Regulations (Northern Ireland) 2019).
16. In relation to personal care products, this UK legislation regulates microbeads in the same way as the provision of the new REACH Restriction, which restricts rinse-off personal care products containing synthetic polymer microparticles for use as an abrasive (“microbeads”). The [Post-implementation Review](#) of the UK legislation, published in May 2024, suggests that the ban of microbeads in England has been successful in removing them from rinse-off cosmetics and personal care products. This UK legislation has set a level playing field to force action from companies who had not already voluntarily removed microbeads from their products.
17. In the UK, evidence indicates that industry is also currently taking voluntary action to replace rubber crumb for sports pitches that is made from recycled tyres (the largest source of intentionally added microplastics in the UK).
18. The current UK REACH Work Programme includes, as a priority, additional consideration of intentionally added microplastics. An evidence project was commissioned by Defra and is expected to report in 2025. The project will inform further UK action on intentionally added microplastics. This could include a new UK REACH Restriction or taking other legislative measures, taking into account impacts on both the UK internal market and trade with the EU and the rest of the world. Further action on microplastics would support Defra’s priorities of cleaning up rivers, lakes and seas, of moving us to a zero-waste economy and support our mission to speed up nature’s recovery and increase protection of the environment.
19. In order to secure access to the EU single market, Northern Ireland applies certain EU regulations in relation to chemicals - including REACH - meaning requirements listed in this amendment will apply in Northern Ireland. Synthetic polymer microparticles products placed on the market in Northern Ireland need to comply

with the synthetic polymer microplastics limits introduced by the updated Regulation. Currently, in practice, any practical impact is expected to be limited - noting that industry is already voluntarily moving away from the use of intentionally added microplastics.

20. No impacts or concerns have been raised by stakeholders from other sectors covered by the REACH Restriction, but we will continue to monitor the situation, including liaising with industry.

CONSULTATION

21. The evidence project on microplastics is supported by interviews with stakeholders, such as industry, academia, manufacturers, and regulatory experts.

FINANCIAL IMPLICATIONS

22. There are no financial implications for the UK Government.

A handwritten signature in black ink, appearing to read 'Emma Hardy', with a long horizontal line extending to the right.

12.10.24

EMMA HARDY MP
PARLIAMENTARY UNDER-SECRETARY OF STATE
DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS

PARLIAMENTARY SCRUTINY HISTORY RELEVANT TO:

COMMISSION REGULATION (EU) / AMENDING ANNEX XVII TO REGULATION (EC) NO 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL CONCERNING THE REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS (REACH) AS REGARDS SYNTHETIC POLYMER MICROPARTICLES

C(2023)4687: COMMISSION REGULATION (EU) / AMENDING ANNEX XVII TO REGULATION (EC) NO 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS FORMALDEHYDE AND FORMALDEHYDE RELEASERS

DEFRA EM DATED: 11/01/2024

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
SCRUTINY NOT COMPLETED (AGENDA 9, 7/2/24): Note: The European Scrutiny Committee was not reappointed after the 2024 UK General Election and no further scrutiny of this document will take place.	SIFTED FOR EXAMINATION TO THE WINDSOR FRAMEWORK SUBCOMMITTEE (CHAIR'S SIFT 45, 19/1/24). The Chair of the Sub-Committee wrote to the Government on 25 January 2024.

C (2022) 2142: COMMISSION REGULATION (EU) .../... OF 8.4.2022 AMENDING ANNEX XIV TO REGULATION (EC) NO 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL CONCERNING THE REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS (REACH)

DEFRA EM DATED 13/07/2022

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
CLEARED BY HOC LETTER 29/11/23	DRAWN TO THE ATTENTION OF THE PROTOCOL ON IRELAND/NORTHERN IRELAND SUB-COMMITTEE (AT CHAIR'S SIFT NO 22; 21/7/22)