

Update on PFAS REACH Restriction and Microplastics

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Ales Bartl

- ♦ Ales Bartl has a broad experience EU product regulatory law, including Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) regulation, the Classification, Labelling, and Packaging (CLP) regulation, Biocidal Products Regulation (BPR), medical devices, electronic products, and general product compliance and product safety. He advises on regulatory compliance of a broad range of products marketed in the EU and represents clients before EU and national competent authorities on compliance and enforcement issues, including product withdrawals and recalls.
- ♦ Ales also represents clients before the Court of Justice of the European Union and the Board of Appeal of European Chemicals Agency.



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Alejandra Martínez Perea



- ♦ Alejandra Martínez Perea counsels clients on regulatory and compliance matters related to food and drug packaging, food and feed, medical devices, data sharing, and product safety. She also advises companies on REACH matters; the Classification, Labelling, and Packaging (CLP) Regulation; and the Biocidal Products Regulation (BPR).
- ♦ Alejandra also helps companies navigate the process of securing regulatory approvals for food contact materials within the European Union (EU) and at the level of individual Member States.



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I. Update on PFAS REACH Restriction



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A. Procedure So Far



PFAS Restriction - Scope

- ◆ REACH Restriction [proposal](#) by 5 Member States published in March 2023
- ◆ Ban of all PFAS (including fluoropolymers)
- ◆ On their own, and in mixtures and articles above certain limits (25 ppb, 250 ppb, 50 ppm – the same as under PPWR)
 - ◇ 50 ppm limit based on total fluorine content
- ◆ Main element in risk characterization of PFAS: emissions during manufacturing and disposal

Procedure So Far



- ◆ **First public consultation:** March – September 2023
 - ◇ More than 5000 comments, mainly related to fluoropolymers
- ◆ ECHA's committees RAC and SEAC now working on their Opinion
 - ◇ Discussions organized by sectors
 - ◇ Big delays
 - ◇ Limited public information
- ◆ Chemical Package to be adopted by the end of 2025 to provide 'clarity on PFAS'

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B. Recent Commission Statements



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Commission Statements



- ◆ Latest Commission public statements: restriction should primarily target consumer uses
 - ◇ But what should be understood as 'consumer use'? Example: is PFAS in an integrated circuit of a fridge with no consumer exposure potential a 'consumer use'?
- ◆ Other measures also envisaged (in addition?), such as waste management rules
 - ◇ It could be measures to prevent landfilling or require controlled incineration + recycling, coupled with EPR scheme
- ◆ There will still be advocacy possibilities with the Commission at the later stage (possibility to invoke competitiveness arguments)

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C. Amended Background Document



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Amended Background Document



- ◆ In the meantime, dossier submitters are working on amended PFAS proposal ('Background Document') incorporating feedback from the first public consultation
- ◆ Not expected to be significantly different as compared to 2023 proposal (e.g., fluoropolymers likely remain in the scope)
- ◆ But: likely more derogations, following stakeholder feedback
- ◆ Likely published before end of September 2025

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Additional Derogations?



- ◆ Additional derogations (based on public statements):
 - ◇ Essential sectors (batteries, semiconductors...)
 - ◇ Industrial settings (e.g., fluoropolymers for use in machinery, sealing applications, cables...)
 - ◇ Additional specific fluoropolymers derogations for professional use
 - ◇ Additional specific derogations where critical and no alternatives, based on stakeholder feedback (additional medical devices, etc.)
- ◆ All derogations likely to be time limited (6.5 years or 13.5 years like in the proposal?)
- ◆ Derogations for consumer uses with direct exposure not likely (e.g., textiles, packaging, cookware, cables for consumer applications...)

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D. Second Public Consultation



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Second Public Consultation

- ◆ **(Draft) SEAC opinion crucial as it will be subject to second public consultation (60 days)** (likely early 2026)
 - ◆ Draft SEAC opinion will likely include additional derogations from the Background Document
 - ◆ Missing (or insufficient) derogation? Submit comments!

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Lessons Learned from Second Consultation



- ◆ Lessons learned from first public consultation:
 - ◇ Gather your data well ahead of start of second consultation
 - Check questions asked in previous second consultations: likely to be similar (e.g., check PFCAs restriction file)
 - Check amended Background Document
 - Assume worst case
 - ◇ Avoid general two-pagers (generic statements not supported by data)
 - Submit specific data that can be referenced in the opinions
 - ◇ Request realistic derogations (scope/timing) based on a solid analysis of alternatives

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E. Timing



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Timing



- ◆ Final restriction likely not before 2030
 - ◆ + transition period (18 months or longer?)

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II. Update on Microplastics



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A. REACH Microplastics Restriction



REACH Restriction on Microplastics

- ◆ [Commission Regulation \(EU\) 2023/2055](#) introduced Entry 78 to Annex XVII of REACH to restrict intentionally added synthetic polymer microparticles (SPM) and introduced reporting requirements for certain derogated uses

New Commission Guidance Documents



- ◆ Published in April 2024
 - ◇ [Explanatory Guide](#)
 - ◇ [Q/A document](#)
 - Scope, definitions, exemptions, specific examples, etc.
 - ◇ [Borderline Cases](#)
- ◆ [Guidance document](#) for reporting requirements for uses of SPMs that are exempt from the restriction but still subject to reporting

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Reporting Obligation Guidance



- ◆ **Derogated uses from the definition of SPM which are still subject to reporting include:**
 - ◇ synthetic polymer microparticles, as substances or in mixtures, for use at industrial sites
 - ◇ medicinal products and veterinary medicinal products
 - ◇ food additives
 - ◇ in vitro diagnostic devices
- ◆ Reporting requirements apply to manufacturers, industrial downstream users, and suppliers placing SPM on the market for consumer and professional uses for the first time (distributors have no reporting obligations)

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B. Preventing Plastic Pellet Losses



Proposal for a Regulation on Preventing Plastic Pellet Losses to Reduce Microplastics Pollution (1)

- ◆ Context: October [2023 European Commission proposal](#)
- ◆ After adopting their positions in 2024, the European Parliament and the Council adopted a [Provisional Draft Agreement](#) on 08 April 2025.
- ◆ Next step: The Council's first reading position is expected to be adopted in the fall, followed by a second EP vote recommending final approval.
- ◆ After publication in the OJEU, the Regulation will come into effect after a [two-year transitional period](#) (with one more year applying to maritime transport).

Proposal for a Regulation on Preventing Plastic Pellet Losses to Reduce Microplastics Pollution (2)



- ◆ Regulation objective: to ensure the safe handling of plastic pellets at every point in the supply chain, regardless of their intended end use.
- ◆ Applies to:
 - ◇ economic operators in the EU handling quantities of plastic pellets equal to or exceeding five tonnes per year, based on the previous calendar year,
 - ◇ economic operators of facilities within the EU that clean plastic pellet containers and tanks,
 - ◇ EU and non-EU carriers.



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Proposal for a Regulation on Preventing Plastic Pellet Losses to Reduce Microplastics Pollution (3)



- ◆ Main obligations for operators include:
 - ◇ Duty to take immediate action to contain and clean up any pellet losses + notify the relevant national authorities about each installation involved in pellet handling
 - ◇ Develop a risk management plan for each of their installations + DoC to be submitted to the relevant Competent Authority
 - ◇ Certification regime depending on company's size
 - ◇ New labelling obligations for any manufacturer, importer, downstream user, or distributor placing on the market plastic pellets that qualify as synthetic polymer microparticles under Annex XVII REACH.
 - Image to add to the label, packaging, packaging leaflet, or safety data sheet.



Harmful to the environment - avoid losses

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C. Status of UN Plastics Treaty



Status of the United Nations Plastics Treaty (1)

- ◆ [Resolution](#) adopted by the United Nations Environment Assembly on 2 March 2022 recognized the plastic pollution coming from microplastics
- ◆ First step to develop an international legally binding instrument on plastic pollution, including the marine environment which takes into account the full lifecycle of plastic
- ◆ Negotiations extended more than expected through 2024 and 2025, with the next session scheduled to take place on 5-14 August 2025.

Status of the United Nations Plastics Treaty (2)



- ◆ Current draft still under negotiation, includes definitions on “plastic product,” “plastic waste,” and “plastic pollution.”
- ◆ Article 3 includes an obligation of result to take appropriate measures in order to prohibit/reduce/address/manage as appropriate single use or short-lived plastic, including hazardous highly likely to be littered, containing hazardous chemicals and containing internationally added microplastics (among others).
- ◆ For now, raw materials (e.g., hydrocarbons) and intermediate products, such as virgin primary polymers (which have to be further processed to serving end uses) are excluded.

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Status of the United Nations Plastics Treaty (3)



- ◆ Parties to the Treaty **shall** take necessary measures to ensure sustainable production of plastic to prevent and mitigate the impact on the environment
- ◆ This includes, establishing global and national targets, science-based procurement policies and guidelines, and assessing alternative materials
- ◆ Special focus on hazardous chemicals, single-use plastics, and intentionally and unintentionally added micro- and nano- plastics
 - ◇ Legal text is very flexible depending on the Parties' national capabilities and circumstances
 - ◇ Exemptions provided in particular circumstances for Parties who do not reach the established targets
 - ◇ To be seen if final agreement is reached after the difficult negotiations and impasse due to oil-producing nations push back

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Upcoming Events



Please join us at 10:00 AM Eastern U.S.
Wednesday, August 27, 2025
www.khlaw.com/REACH-3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, June 18, 2025
www.khlaw.com/OSHA3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, August 13, 2025
www.khlaw.com/TSCA-3030

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Thank You

Any questions?



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