



Microplastics REACH Restriction: Scope, Status of Adoption

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- ◆ Ales has a broad experience in EU product regulatory law, including REACH, CLP, POPs, biocidal legislation, food law, medical devices, electronic products, and product and food 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. Ales also advises on product recalls and withdrawals.
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- ◆ Marie Escorneboueu counsels clients on regulatory and compliance matters related to food and drug law, with an emphasis on food and drug packaging, cosmetics, chemical control, and environmental issues.
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Update on the REACH Revision



Update on the REACH Revision (1)

- ◆ Revision proposal still awaited: deadline officially ‘latest Q4 2023’
 - ◇ Recent announcements from Commissioner Sinkevičius that it could happen before the summer
 - ◇ Legislative procedure running through 2024-2025
- ◆ In the meantime, COM issued an updated overview of the content of the revision (CARACAL 48):
 - ◇ Extend information requirements for lower tonnage bands (incl. new requirements for ED endpoint)
 - ◇ Authorisation/restriction: initial idea of merging them, now seems they would be kept separate
 - ◇ Generic restrictions: general derogations directly in the text of REACH + ‘essential use’ derogations

Update on the REACH Revision (2)

- ◆ Polymer registration:
 - ◆ Notification of **all polymers**: global mapping, to define grouping criteria and organize the registration stage
 - ◆ Content of registration information to be defined at a later stage (possibly via COM act ?)
 - ◆ Criteria for PRRs (exp: fluorinated polymer, cationic polymer, polymer suspected to degrade to substance of concern)
 - ◆ Timeline for registration:
 - 8 years after entry into force for low molecular weight polymers
 - 12 years after entry into force for medium and high molecular weight polymers



Microplastics Restriction



Timeline

- ◆ COM requested ECHA to prepare an Annex XV restriction dossier
 - ◆ Submitted on 22 August 2019
 - ◆ Final Opinion from RAC and SEAC 10 December 2020
 - ◆ COM issued draft proposal to restrict intentionally added microplastics on 30 August 2022
 - ◆ Still pending before REACH Committee
 - Several versions circulated, [latest from 5 April 2023](#)
 - Disagreements remaining (incl. biodegradability criteria)

Scope – Notion of Microplastic (1)

- ◆ Restriction targets ‘synthetic polymer microparticles’ that are solid and either:
 - ◇ (a) are contained in particles and constitute at least 1% by weight of those particles; or
 - ◇ (b) build a continuous surface coating on particles
- ◆ Size requirement:
 - ◇ Where at least 1% by weight of those particles fulfil either of the following conditions:
 - (a) all dimensions of the particles are equal to or less than 5 mm;
 - (b) the length of the particles is less than or equal to 15 mm and their length-to-diameter ratio is greater than 3

Scope – Notion of Microplastic (2)

- ◆ The following polymers are excluded from the scope of the restriction:
 - ◇ ‘Natural polymers’: polymers that are the result of a polymerisation process that has taken place in nature, independently of the process with which they have been extracted, which are not chemically modified substances
 - Definition taken from ECHA Guidance for monomers and polymers
 - Excludes any polymerization in an industrial context, including polymers generated from bio-based elements
 - ◇ Polymers that have a solubility greater than 2 g/L
 - ◇ Polymers that do not contain carbon atoms in their chemical structure

Scope – Notion of Microplastic (3)

- ◆ Exclusion of polymers that are degradable:
 - ◇ Standard of proof laid down under Appendix X of the proposed restriction:
 - Incl. permitted test methods and pass criteria for the methods
 - ◇ Permitted testing methods organized into five groups:
 - Meeting pass criteria in any of the methods listed in Groups 1 to 3 is sufficient to demonstrate biodegradability
 - Group 1 & 2: demonstrate ready biodegradation
 - Group 3: demonstrate inherent degradation
 - For Group 4 (degradation relative to a reference material) and 5 (degradation under relevant environmental conditions):
 - Need to demonstrate that the pass criteria are met in three environmental compartments (water, sediment, soil)

What is Restricted

- ◆ The proposal restricts:
 - ◇ Placing on the EU market as substances on their own or in mixtures in a concentration equal to or greater than 0,01% by weight
 - Therefore, covering marketing to intermediaries and to final users
- ◆ E.g., polymers that are placed on the market in a microparticulate state
- ◆ Therefore, not affecting articles that have been manufactured using microplastics

Exemptions from the Restriction (1)

- ◆ For specific uses: medicinal products, fertilizers, food additives, in vitro diagnostic device
- ◆ Other exemptions based on the characteristics and use, requiring a case-by-case assessment
 - 1) Contained by technical means so that releases are prevented (Point 5(a))**
- ◆ Microplastics **retain their particle state** during intended use
- ◆ But is contained by a ‘technical barrier,’ e.g., chromatography columns, water filter cartridges, printer toners, with no potential for release
- ◆ Supplier shall provide instructions for use and disposal
 - ◇ Via text or pictogram, on the label, packaging, SDS, or leaflet

Exemptions from the Restriction (2)

2) Physical properties are permanently modified during intended use (Point 5(b))

- ◆ Microplastics placed on the market as such, **but permanently lose their particle state** when they are used
 - ◆ Consumed or cease to exist at point of use, via physicochemical process or chemical reaction e.g., swell, form a film, dissolve
 - ◆ Need to **exclude presence of any microparticle** in final product
 - ◆ E.g., pre-production pellets, flakes, or powders
- ◆ Information obligations: same as exemption 1)

Exemptions from the Restriction (3)

3) Permanently incorporated into a solid matrix during intended end use (Point 5(c))

- ◆ Microplastics **retain their particle state** during intended use
- ◆ But are contained within a solid matrix
 - ◇ Can be relied on when one is unable to exclude the presence of microparticles in final product (exemption 2)
- ◆ Information obligations: same as exemption 1)

Exemptions from the Restriction (4)

4) Use at industrial sites (Point 4(a))

- ◆ No definition for “industrial sites,” distinct from professional and consumer use
 - ◇ Typically use as raw materials in an industrial process, able to prevent leaks
 - ◇ Requires **exclusive** use at industrial site, i.e., in an industrial setting
- ◆ Entails specific information requirements:
 - ◇ Microplastics suppliers shall provide:
 - Instructions for use and disposal to prevent releases in the environment;
 - Statement that the product is subject to the restriction;
 - Quantity or concentration of microplastic in the substance or mixture;
 - Generic information on identity of the polymers

Exemptions from the Restriction (5)

- ◇ Manufacturers and industrial users (in the case of the industrial uses exemption), and suppliers (in the case of the other exemptions), shall report to ECHA, by 31 May each year:
 - Description of the uses;
 - For each use, generic information on the identity of the polymer;
 - For each use, an estimate of the quantity of microplastics **released in the environment, including the quantity released during transport**; and
 - A reference to the exemption relied on

Next Steps

- ◆ Timeline:
 - ◇ Scheduled for discussion, and vote at the REACH Committee of 26-27 April
 - ◇ Once adopted by the Committee, subject to scrutiny of the Council (around 6 weeks)
 - ◇ If no opposition from the Council, the Act is deemed adopted

- ◆ Transition period: 4-12 years, depending on the uses (Section 6 of the proposal); uses that are not mentioned: no transition period



Unintentionally Released Microplastics



Upcoming Commission Proposal (1)

- ◆ Legislative proposal aiming at the reduction of the presence of unintentionally released microplastics in the environment
 - ◆ Complementary with the REACH restriction, full life-cycle approach
 - ◆ Targeting microplastics emitted from:
 - Tire abrasion, loss of pre-production pellets and tear off of synthetic textiles
 - ◆ Measures could include:
 - For textiles and tires: eco-design requirements, recycling, mitigation of releases/capture
 - For pellets: staff training and labelling of pellet containers, liability, and compensation obligations, best practices across supply chain

Upcoming Commission Proposal (2)



- ◆ Timeline:
 - ◆ Public consultation ran until May 2022
 - ◆ Adoption scheduled for Q2 2023 – could be released alongside REACH restriction



Thank You

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