REACH Restriction on intentionally-added microplastics

Peter SIMPSON, ECHA

72\textsuperscript{nd} meeting of the EFSA Advisory Forum
04 July 2019
University of Iceland - Reykjavik
What is ‘microplastic’

- Not consistently defined
  - Typically considered to refer to small solid particles composed of synthetic polymers – *non degradable*
  - <5mm size criterion often used
- Formed as larger pieces of ‘plastic’ degrade *in situ*
  - Litter (e.g. fishing gear), synthetic clothing, tyre abrasion
- Microplastics also deliberately manufactured and *intentionally added* to products
Quantities used per year

- Control release fertilisers & fertiliser additives: 37.9%
- Coated seeds & control release plant protection products: 2.2%
- Exfoliators/cleansers: 0.2%
- Other rinse-off cosmetics: 14.0%
- Leave-on cosmetics: 5.8%
- Paints & coatings: 11.4%
- Oil & gas: 2.5%
- Detergent containing fragrance encapsulates: 0.3%
- Other detergents: 15.4%
- Waxes & polishes: 5.3%
- Medicinal products (matrix, film CR): 3.5%
- Medicinal products (IER): 1.4%
What is the concern?

- Small size means particles are easily ingested
  - Mistaken for food – suspension feeders
  - Potentially liable for ‘trophic transfer’ within food chains, including humans – predators/scavengers
- Various adverse effects reported in literature in biota (laboratory studies)
  - Direct ‘particle’ effects
  - (eco)toxicological effects via additives, impurities, adsorbed HOCs
- Very resistant to (bio)degradation leading to a long-term, irreversible, environmental stock
  - (bio)degradation, where this occurs, is via progressive fragmentation - nanoplastics
Restrictions under REACH

• Any condition on the manufacture/import/use of a substance (also in a mixture/article)
  • to address a risk that is not adequately controlled
  • Where action is required at the Union level
• ‘safety net’ for other REACH and EU processes
Risk assessment

• Several risk assessment approaches under REACH
  1. **Threshold-based** (PEC/PNEC) type approach
  2. **Non-threshold based** – e.g. PBT/vPvB hazards
  3. ‘**Case-by-case**’ approach for particular hazard properties where 1 and 2 are impracticable

• ECHA considered all approaches

• ECHA’s assessment concludes that releases of intentionally added microplastics pose a risk that is **not adequately controlled**
  • Acknowledges that the currently available data only allows an incomplete assessment
Elements of the proposed restriction

- **Prohibition on ‘placing on the market’**
  - uses where MP releases to the environment are inevitable

- **Derogated uses**
  - Natural/biodegradable polymers; uses with no MP release; already regulated

- **Mandatory ‘labelling’**
  - uses where MP release can be minimised with instructions for use

- **Mandatory ‘reporting’**
  - identity, description of use (function), tonnage, releases
Phased implementation

- To avoid disproportionate impacts as society adapts to restriction
  - Transition to the use of (biodegradable) alternatives
  - Time for users to implement additional Risk Management Measures

- MICROBEADS in INFORMATION REQUIREMENTS
- MEDICAL DEVICES
- AGRICULTURE & HORTICULTURE
- LEAVE-ON COSMETICS
- 12M
- 18M
- 2 yrs
- 4 yrs
- 5 yrs
- 6 yrs
- EIF
- OTHER USES
- LABELLING REQUIREMENTS
- RINSE-OFF COSMETICS
- DETERGENTS & MAINTENANCE
Evaluation and public consultation

• The proposal is currently undergoing scrutiny by ECHA’s committees for risk (RAC) and socio-economic analysis (SEAC)

• Public consultation ongoing 20 September 2019

• Final opinions March 2020

• Opinions sent to Commission for decision-making
Thank you!

echa.europa.eu/contact

Subscribe to our news at echa.europa.eu/subscribe

Follow us on Twitter @EU_ECHA

Follow us on Facebook Facebook.com/EUECHA
Backup slides
Proposed restriction

• Polymers shall not, from (approx. 2020), be placed on the market as a substance on its own or in a mixture as a microplastic in a concentration equal to or greater than 0.01% w/w (paragraph 1)

• Definitions (paragraph 2):
  • ‘polymer’ means as defined in Article 3(5) of REACH
  • ‘microplastic’ means a material consisting of solid polymer-containing particles, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have:
    • (i) all dimensions 1nm ≤ x ≤ 5mm, or
    • (ii), for fibres, a length of 3nm ≤ x ≤ 15mm and length to diameter ratio of >3
Microplastic definition

Solid polymer-containing particles

Size [1nm-5mm] ≥ 1% w/w?

Particle size distribution

[Graph showing particle size distribution with a peak around 3-5 mm]
Definitions (I)

- ‘particle’ is a minute piece of matter with defined physical boundaries; a defined physical boundary is an interface.

- ‘polymer-containing particle’ means either
  - (i) a particle of any composition with a continuous polymer surface coating of any thickness, or
  - (ii) a particle of any composition with a polymer content of ≥ 1% w/w.
What is a solid?

- If it is not a gas
- If it is not a liquid
- ...then it is solid
- CLP Regulation / GHS
(Bio)degradability criteria

- Tiered approach (clear pass/fail criteria)
- Screening tests
  - Ready (and enhanced ready) biodegradation
    - ≥60% mineralisation in 28/60 days e.g. OECD TG 301
  - Inherent biodegradation
    - ≥70% mineralisation e.g. OECD TG 302B/C
  - Bio(degradation) relative to a reference material
    - ≥90% degradation e.g. crystalline cellulose / ISO 14851
    - 6 months (aquatic) / 24 months (soil or water/sediment)
- Higher-tier assessment (if necessary)
  - Half-life in relevant environmental conditions
    - < Annex XIII vP criteria (e.g. OECD TG 307, 308, 309)
- ISO 17025 quality assurance required
Microbeads vs microplastics

• ‘microbead’, for the purposes of this restriction, means a microplastic used in a mixture as an abrasive i.e. to exfoliate, polish or clean.

• If a microplastic has another function e.g.
  • opacifying
  • encapsulation
  • decorative

• then this is **not a microbead** for the purposes of the restriction.
Derogations from scope

• 3(a) Polymers that occur in nature that have not been chemically modified
  • other than by hydrolysis
• 3(b) Polymers that are (bio)degradable
• Both are not microplastics and are not subject to any restriction on placing on the market, labelling or reporting
• No requirement to submit information to ECHA, but would be subject to normal enforcement
Derogations from paragraph 1

- 4(a) Use at industrial sites
  - See ECHA R.12 Guidance

- 4(b) Medicinal products for human and veterinary use
  - EU Regulation No 726/2004

- 4(c) Substances or mixtures regulated under the revised EU regulation on Fertilising Products
  - Regulation already contains provisions for use of biodegradable polymers
‘consumer/professional’ derogations from paragraph 1

- 5(a) Microplastics that are **contained by technical means** throughout life-cycle / hazardous waste disposal
  - *In vitro* diagnostic medical devices / or similar
- 5(b) Microplastics that are **permanently modified** when used such that they are no longer microplastic – *loss of particulate form*
  - e.g. film-forming in paints, coatings, cosmetics
  - ‘soluble’ polymers
- 5(c) Microplastics that are **permanently incorporated** into a solid matrix when used
  - Intended for building/construction applications
Films-forming derogated – para 5(b)

Other microplastics derogated – para 5(c)

Sources:
https://www.acs.org/content/dam/acsorg/events/technology-innovation/Slides/2017-01-11-iss11-dow-paint-slides.pdf
Labelling

• Required in certain cases when derogated from para 1

  • the [label/SDS/‘instructions for use’/‘package leaflet’] provides, in addition to that required by other relevant legislation, any relevant instructions for use to avoid releases of microplastics to the environment, including at the waste life-cycle stage

    • e.g. Remove as much excess paint from rollers and brushes as possible (and dispose in the bin) before cleaning in sink

    • e.g. Do not dispose medicines down the drain

• Official EU language, visible, legible, indelible
Annual Reporting

• Industrial uses derogated under 4a
  • Downstream user
• Placing on the market derogated under 4b, 5b or 5c
  • Importer or DU (not consumer or professional)
• Requirements
  • the identity of the polymer(s) used
  • A description of the use of the microplastic
  • the quantity of microplastics used in previous year
  • the quantity of microplastics released to the environment (estimated or measured)