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Challenges and controversies during the development of the REACH restriction of intentionally-added microplastics

Micro2022

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Today’s presentation

- → Quick recap on the proposed REACH restriction
- → Discussion on some of the more challenging and controversial issues that arose
- → Lessons learnt
- → Time for questions

What is REACH?

https://www.echa.europa.eu/web/guest/restriction-process

→ REACH is the EU's chemical safety legislation

→ REACH Restriction

- Any condition on the manufacture, use or placing on the market of substances, mixtures or articles
- 'Safety net' to control risks
- For it to be implemented it **must** be the most appropriate measure
  - **Effective** (targeted to identified risk and capable to addressing it)
  - **Practical** (including enforceable)
  - **Monitorable** (risk reduction achieved over time)
- Should be proportionate
  - Take into account the costs and benefits to society (including alternatives)
  - Least burdensome means to achieve the objective

Microplastic definition

Ban on 'placing on the market'

Uses where microplastic releases are inevitable

Derogated uses (can continue)

- natural, biodegradable and soluble polymers
- uses at industrial sites
- containment in solid matrix or by technical means
- loss of particle form at the point of use

Mandatory 'instructions for use and disposal'

For derogated uses - industrial sites; loss of particle form; matrix

Minimise potential for releases; enhance information flow

Mandatory 'reporting' for certain derogated uses

Polymer identity, use description, releases/year

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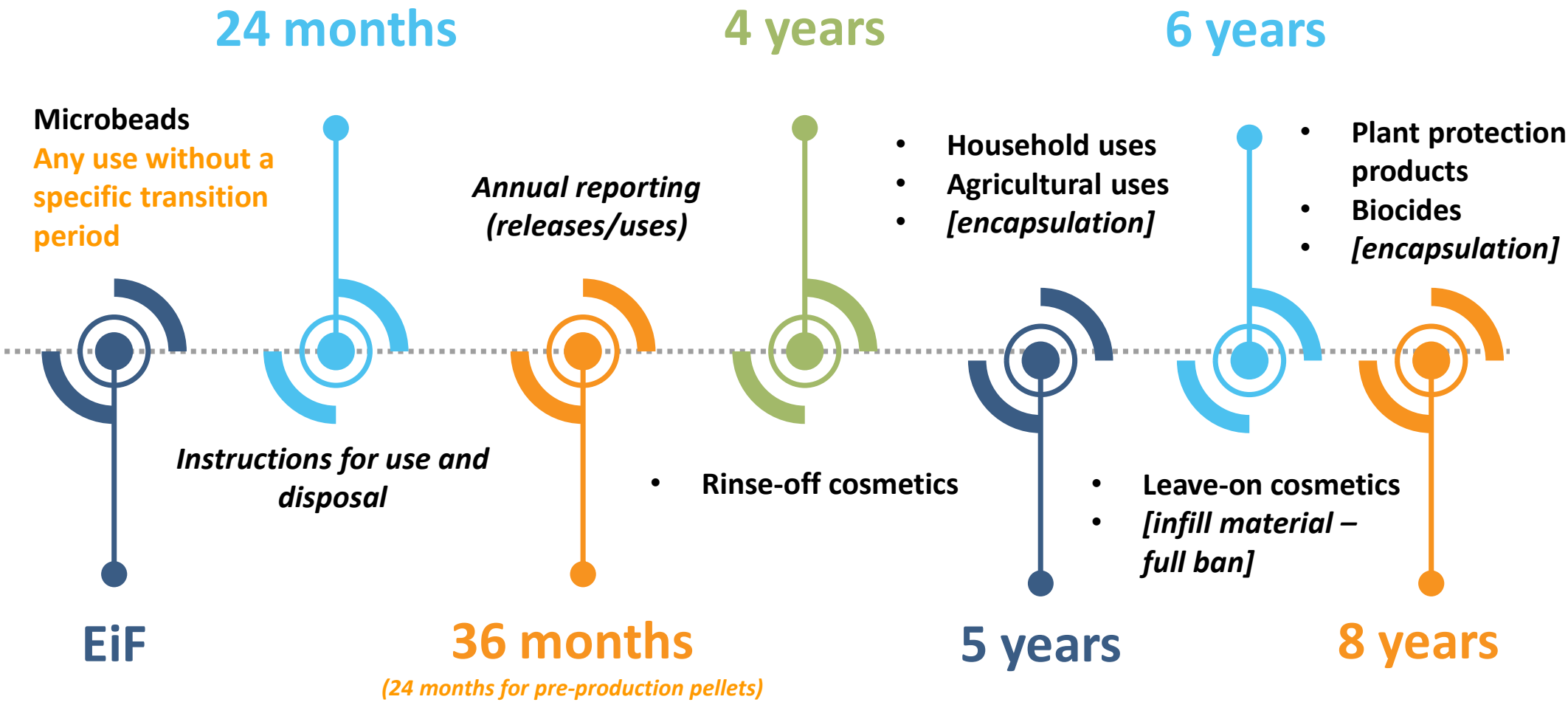
Implementation timeline



Regulatory definition of a microplastic

Challenge – what is a microplastic?

1. ISO define plastic as a *"material which contains as an essential ingredient a high polymer and which, at some stage in its processing into finished products, can be shaped by flow. Elastomeric materials, which are also shaped by flow, are not considered to be plastics."*
   - Elastomer particles clearly contribute to microplastic concern (tyres)
   - Other types of processing are also relevant 'emulsion polymerisation'
   - ISO definition therefore not consistent with the risk to be addressed
   - **Generic REACH polymer definition proposed as basis for regulation**
     - Prevent regrettable substitution (compared to a closed list)
     - Further elements needed to link the substance scope to identified risk
     - **Relevant size,** solid-state, particle, natural, **biodegradable**, **soluble**

Controversy – lower size limit

→ Original ECHA proposal for lower limit was **1 nm**

- Consistent with the lower limit of the EU nanomaterial definition

→ Consultation respondents stressed analytical difficulties at sub-micron (<1 µm) scales – particularly for complex mixtures

- Large macromolecules (could be >1nm) confound results
- Unstable aggregates or agglomerates (including micelles)
- Emulsions (liquid dispersions)

→ ECHA proposed that that lower limit for the 'conditions of the restriction' should be increased from 1nm to 100nm

- However, where MPs can be reliably characterised (i.e. as ingredients) particles <100 nm **should not be added to products**

Controversy

→ NGOs considered that this introduced a 'loophole' for nanoparticles – *generated lots of attention in the media*

→ Draft Commission decision states that the lower size limit (100nm) is only applicable where existing analytical methods or accompanying documentation cannot be used to verify compliance

- Ensures particles <100 nm cannot be deliberately added to products
- Allows analytical methods that can detect and quantify microplastics <100nm to be used for verification; should these exist in the future

→ Does this address the concerns raised?

Biodegradable polymers

Challenge

→ Starting point for the restriction is generic 'polymers'

- Restriction must be 'targeted' to the identified risk (persistence)

→ Allowed test methods in an Appendix to the restriction

FAIL

- Ready (and enhanced ready) biodegradation
  - ≥60% mineralisation in 28/60 days e.g. OECD TG 301

PASS

- Inherent biodegradation
  - ≥ 70% mineralisation e.g. OECD TG 302B/C

PASS

- Biodegradation relative to a reference material
  - ≥ 90% degradation e.g. crystalline cellulose / ISO 14851
  - 6 months (aquatic) / 24 months (soil or water/sediment)

PASS

- Higher-tier assessment (if necessary)
  - Half-life in relevant environmental conditions
  - < Annex XIII vP criteria (e.g. OECD TG 307, 308, 309)

PASS

Controversy - biodegradation

→ Is testing framework appropriate?
- Framework is based on existing practice for chemicals testing
- Testing must be on the form placed on the market i.e. the particle
- Additional requirements for 'blends' – to avoid confounding results

→ Environmental relevance of 'relative to reference material' 'ISO' test methods – degradation relative to cellulose
- Acknowledged as the only methods specifically developed for plastics
- Rate of degradation in the environment not estimated
- RAC recommended additional research to compare performance

→ Which compartments must biodegradation be tested in
- ECHA – most appropriate compartment
- RAC – testing in multiple compartments needed

Soluble polymers

Challenge – soluble polymers (liquid microplastics)

→ Starting point for the restriction is generic 'polymers'
- Restriction must be 'targeted' to the identified risk (particle)

→ Microplastic risk is associated with solid polymer particles

→ Soluble polymers do not exist as particles in the environment – they are not microplastics
- Derogated from initial proposal – but would have instructions for use and reporting requirements
- Proposal revised to explicitly exclude water soluble polymers (>2g/L @20°C) – Difficult to set a definitive threshold
- Limit based on maximum loading in ISO biodegradation test
- Environmental relevance of 2g/L (still) discussed
- Ecotoxicity of soluble polymers remains an ongoing debate

Infill material

Infill on synthetic sports pitches

→ Use was not assessed in original proposal (no information)

- Subsequently found to be greatest single emission source
  - **100 000 T/yr use; 16 000 T/yr release**
- Two restriction options assessed after consultation
  - **Option A** – Implement Risk Management Measures (RMMs)
    - Minimum 90% effectiveness – releases < 50 kg/pitch/year
    - 3 year transition period
    - Cost effectiveness of **4.5 €/kg** (avoided release)
  - **Option B** – ban on placing on the market
    - Would no longer to be possible to buy (e.g. for refill)
    - 6 year transition period
    - Cost effectiveness of **33 €/kg** (avoided release)

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Infill on synthetic sports pitches

- → RAC preferred a complete ban
  - Effectiveness of available RMMs to meet emission limit not known
  - Emissions at pitches with RMMs would continue – despite minimisation
  - Enforcement would be complex
- → ISO standard for RMMs published after opinion making
- → Commission requested a supplementary opinion on the effectiveness of RMMs from RAC
  - RMMs can be effective (particularly at new pitches) but some rely on the behaviour of players (to clean footwear and clothing)
  - Effectiveness to limit release of smallest particles not known
  - Other risks associated with infill (leaching of zinc, copper etc)
- → Commission draft decision **proposes a full ban** after 6 years

Lessons learnt

Lessons learnt

→ Management of emerging chemical risks is possible in a relatively short period of time!

→ Information from all stakeholders (industry, academia, NGOs) is of vital importance to properly understand the uses of substances and the impacts of regulation

→ 'Perfect is the enemy of good'?

- Restriction can be reviewed in the future
- Other legislation may be needed for other risks

→ 'Universal' restriction of all PFASs in the EU will be submitted in January 2023 by DE, NL, SE, DK and NO

Thank you

Proposal and opinions are available on ECHA website: https://echa.europa.eu/hot-topics/microplastics

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