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Microplastics

**How the EU REACH Restriction Will
Impact Your Cosmetic Formulations**

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Francesca Rapolla

Scientific Affairs Manager



Caroline Rainsford

Head of Scientific Services



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Meet the Speakers

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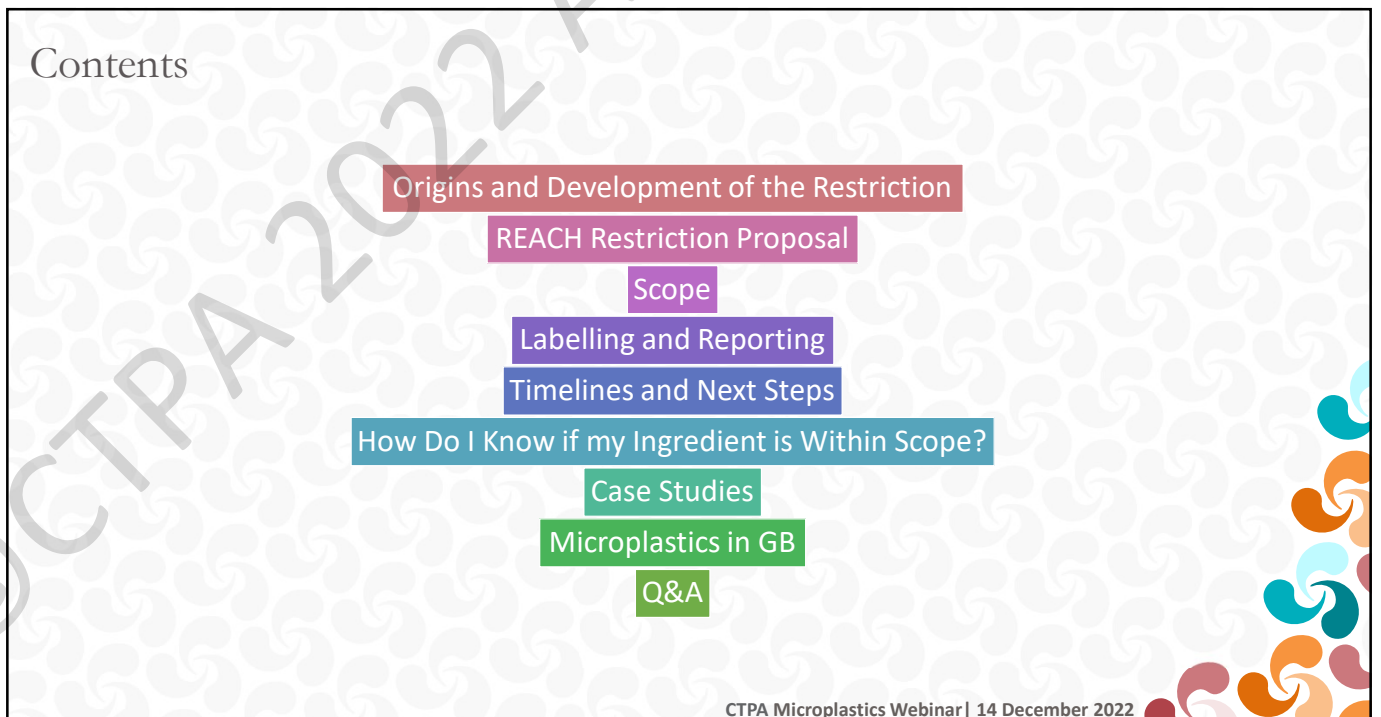
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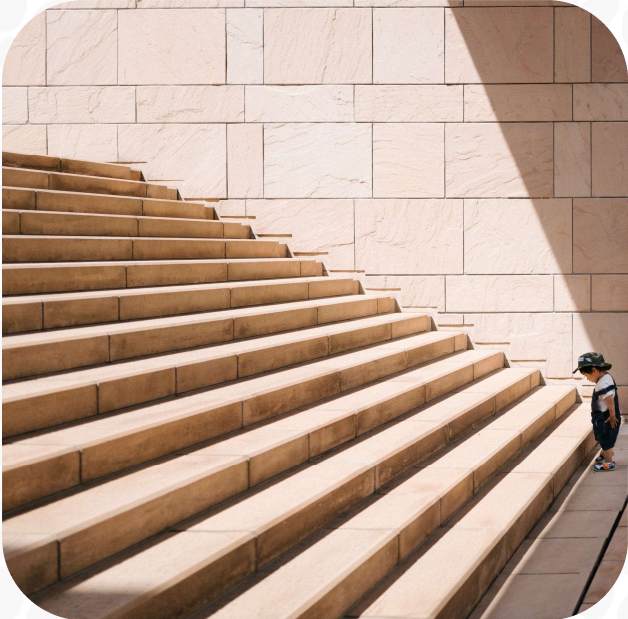


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Origins and Development of the Restriction

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NGO and Media Focus on Plastic Pollution



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EU Member State Legislation on Plastic Microbeads



Ban in rinse-off cosmetic products from January 2018 (manufacturing), and June 2018 (sales)



A bill to ban in rinse-off cosmetics and household products in June 2019



Ban in rinse-off cosmetic products for exfoliation or cleaning from 1 January 2018



Ban in cosmetic products that are intended to be rinsed off or spat out from 1 July 2018

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Global Legislation on Plastic Microbeads



Ban in cosmetic products for cleansing or hygiene from 1 July 2018



Ban in cosmetic products and sanitary aids (e.g. toothpaste) from 1 July 2017 and 1 May 2017 respectively



Ban in rinse-off cosmetic products for cleansing and exfoliation from 1 July 2017 (manufacture) and 1 July 2018 (sale)



Ban in rinse-off cosmetic products for cleansing and exfoliation from 7 June 2018

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EU Activities

EU Funded Scientific Research Projects

- EPHEMARE investigating ecotoxicological effects of marine microplastics
- PLASTOX investigating the ingestion, food chain transfer and ecotoxicological impact of microplastics

European Strategy for Plastics

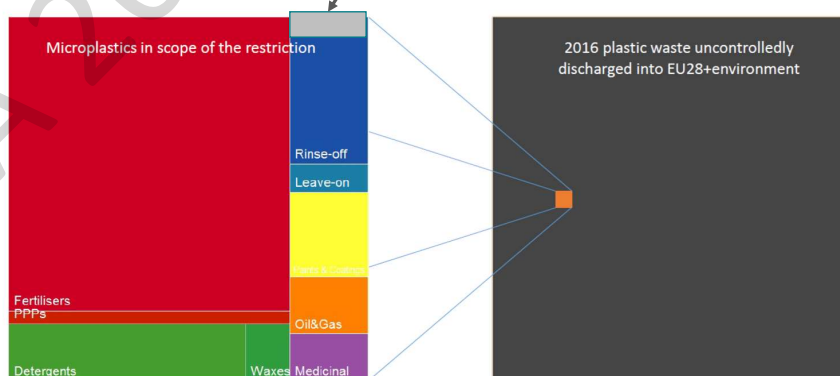
- Adopted in January 2018 by the European Commission
- EU Commission asked ECHA to prepare REACH restriction dossier on intentionally added microplastics

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Microplastics vs 'Microplastics' from Cosmetics vs Microbeads

Plastic microbeads are a subset of 'microplastics' as defined by ECHA, because the ECHA definition includes solid polymers that are not traditionally considered to be plastic



Microplastics and exfoliating plastic microbeads are not the same thing!

REACH Annex XV Restriction Proposal
March 2019

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REACH Restriction Proposal

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REACH

Registration, Evaluation, Authorisation, Restriction of Chemicals

- Protection of human health and the environment
- Polymers are exempt from registration and evaluation aspects of REACH

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REACH

Restriction

- Protection of human health and the environment
- Polymers are exempt from registration and evaluation aspects of REACH

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REACH Restriction

Any substance that poses unacceptable risk to human health and/or the environment that is deemed to require Community-wide action can be restricted

'Safety net' for addressing risks from chemicals that cannot or have not been addressed by means of other REACH processes or Community action

Under restriction, the manufacture, import, placing on the market or use of a substance can be made subject to certain conditions.

The substances to which restrictions apply and the terms of those restrictions are listed in Annex XVII of the REACH Regulation

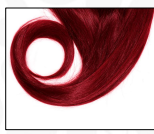
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Microplastics – An Unacceptable Risk?

The justification for grouping is underpinned by the similarity in physical and persistence properties. All substances with these properties are therefore identified as 'microplastics'.

- **Very broad scope** – any solid synthetic polymer as well as plastics
- **Hazard data** - studies investigating potential microplastic hazards are conducted on plastic particles (PET, PP, PE etc)
- **Exposure** - justification based on the fact that environmental concentrations will keep increasing
- **Justification for restriction** - Long-term environmental persistence



- **European industry impact estimate** - €5 billion per year

A scientific perspective on microplastics in nature and society

The best available evidence suggests that microplastics and nanoplastics do not pose a widespread risk to humans or the environment, except in small pockets. But that evidence is limited, and the situation could change if pollution continues at the current rate.

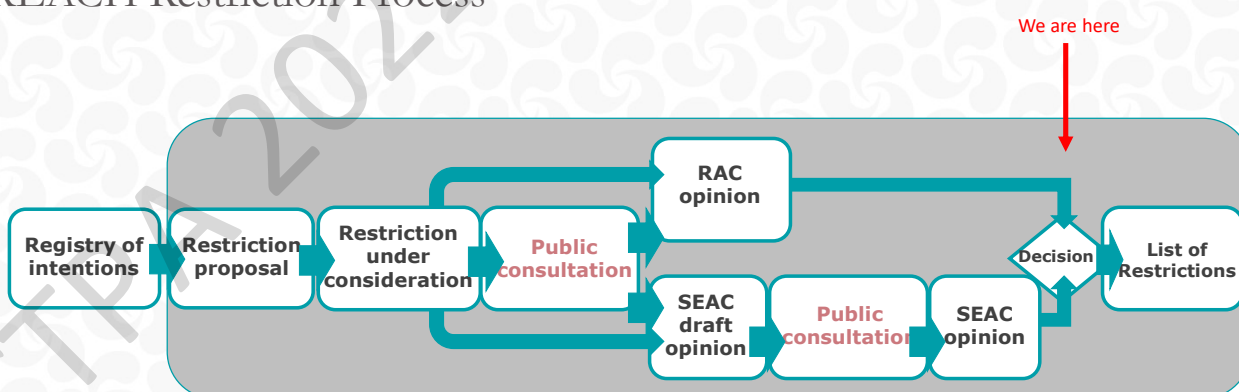
This is the verdict of SAPEA's Evidence Review Report on micro- and nanoplastic pollution, published in January 2019. The report is written by a group of world-leading experts nominated by academies across Europe, and informs Scientific Opinion 6 from the European Commission's Group of Chief Scientific Advisors.

Especially "from the fragmentation of larger plastic articles," (ECHA's Committee for Risk Assessment (RAC))

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REACH Restriction Process



ECHA 2015

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Scope

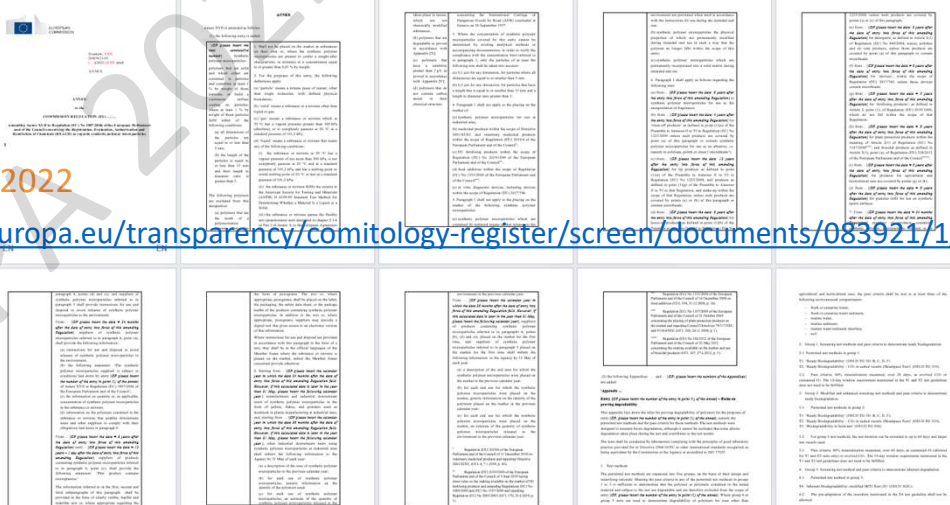
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Publication of the Draft Restriction

30 August 2022

<https://ec.europa.eu/transparency/comitology-register/screen/documents/083921/1/consult?lang=en>



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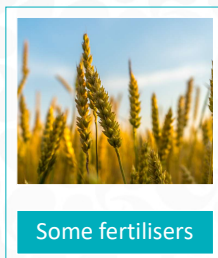
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Restriction Proposal and Scope

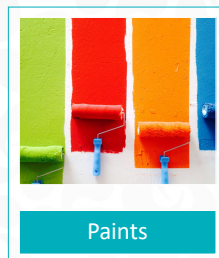
**Intentionally-added
'microplastics' in consumer
products**

'Microplastics' are:

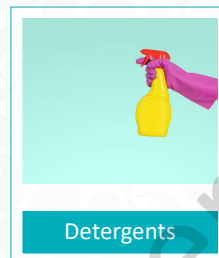
- **Polymers**
- **Either on their own or in coatings**
- **Specific size**
- **Contain carbon atoms**
- **Solid**
- **Synthetic**
- **Non-biodegradable**



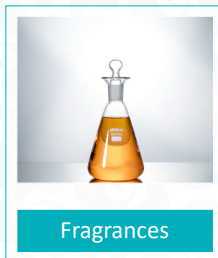
Some fertilisers



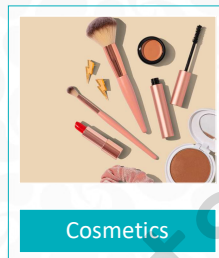
Paints



Detergents



Fragrances



Cosmetics



Artificial turf infill

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Objective of the Restriction

The **objective** is to **prevent the release of microplastics to the environment**

Rationale for the **derogations**:

Banned	Not Banned
If the product releases 'microplastics' (solid, synthetic, non-degradable polymers) into the environment	If the 'microplastics' lose their characteristics before the product enters the environment
	HOWEVER – instructions for use, labelling and reporting requirements in place to ensure microplastics not released to the environment

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Looking at the criteria in detail

‘Microplastics’ are:

- Either on their own or in coatings
- Specific size
- Contain carbon atoms
- Solid
- Synthetic
- Non-biodegradable polymers

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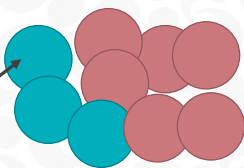
Either on their own or in coatings

Microplastics can be particles on their own

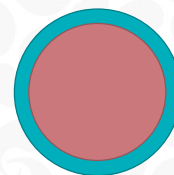


The substance is considered microplastic if
**at least 1% of the particles meet the
microplastic definition**

e.g. Synthetic
polymer
microparticles
make up more
than 1% **by
weight** of this
powdery
ingredient



Non-microplastic particles can become microplastics if
they have a coating, of any thickness, which meets the
microplastic definition



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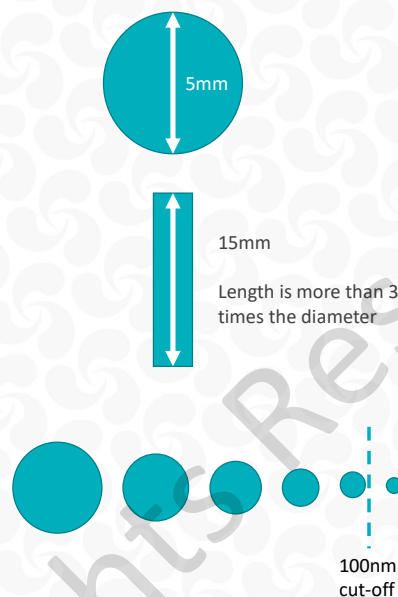
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Size criteria

All dimensions of the particles are equal to or less than 5 mm

The length of the particles is equal to or less than 15 mm and their length to diameter ratio is greater than 3

No lower size limit – nanoparticles are included in the scope. However for enforceability purposes a lower limit of 100nm is included if quantification is scientifically impossible

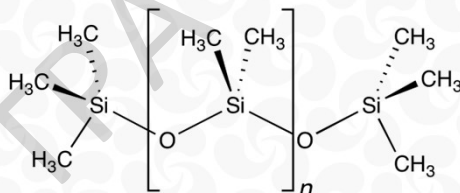


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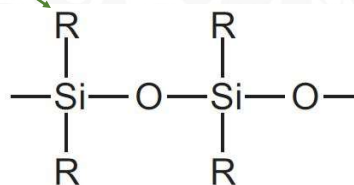
Carbon-containing criteria

To be excluded from the restriction, polymers must contain **no carbon atoms at all**



If solid, synthetic, non-degradable etc ... **in the scope of the restriction**

R contains no carbon



If solid, synthetic, non-degradable etc ... **out of the scope of the restriction**

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Solubility criteria

The restriction excludes *“polymers that have a solubility greater than 2 g/L as proved in accordance with Appendix [Y]”*

Appendix [Y] says:

- Test to be conducted by GLP laboratory
- Permitted test methods are OECD Guideline 120 and OECD Guideline 105 (**water** solubility)
- Test material has the same physical characteristics as the polymer in the product
- Temperature 20 °C, pH 7, Loading 10g/1000mL, 24 hr test time

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Naturalness criteria

The restriction excludes *“polymers that are the result of a polymerisation process that has taken place in nature, which are not chemically modified substances”*

Strict definition - **Naturally-derived** or **modified natural** substances are not exempted

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Biodegradability criteria

- Permitted OECD and ISO test methods are organised into five groups



Degradable substances need to meet the pass criteria in any of the permitted test methods in groups 1 to 3

If using group 4 or 5 tests, degradability in at least three environmental compartments needs to be shown

- If using a blend of polymers, both the individual polymer and the blend needs to be tested
- The polymer tested needs to have the same physical characteristics as the polymer used in the product

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Labelling and Reporting

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Who needs to label and report information?

For example, derogation 5b: "synthetic polymer microparticles the physical properties of which are permanently modified during intended end use in such a way that the polymer no longer falls within the scope of this entry"

Even if a product is **derogated out of the scope of the ban** because the 'microplastic' ingredient no longer meets the definition of a microplastic when the product is used, companies still have some obligations

Ingredient suppliers

- Instructions for use and disposal for downstream users, to avoid microplastic release to the environment
- Technical information on the polymers for downstream users
- Yearly reporting to ECHA

Manufacturers

- Instructions for use and disposal for consumers, to avoid microplastic release to the environment
- In some cases, product labelling
- Yearly reporting to ECHA

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Suppliers of ingredients meeting the microplastic definition

Can be communicated in a variety of ways e.g. using text, pictograms, on the label, or on the SDS. Digital information can be provided **in addition**

- **Instructions for use and disposal** for downstream users, to avoid microplastic release to the environment
- A **statement** that the product is subject to this REACH restriction, statement wording given in restriction
- Information on the **quantity or concentration** of microplastics in the supplied ingredient

- **Technical information** about the microplastics so that manufacturers can comply with their obligations

- **Reporting** to ECHA on:

Manufacturers and DUs of derogated products have to report estimated microplastics emissions to ECHA yearly. **Only the first actor in the supply chain** should report to ECHA.

Generic information is ok for ECHA but in the case of a request from authorities, more precise information is needed

- Description of the uses of the microplastics for the previous year
- Generic information on the identity of the polymers
- An estimate of the quantity of each microplastic type released to the environment the previous year

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Manufacturers or Brand Owners

Can be communicated in a variety of ways e.g. using text, pictograms, on the label. Digital information can be provided **in addition**

- **Instructions for use and disposal** for consumers, to avoid microplastic release to the environment
- **“This product contains microplastics”** labelling on nail and make-up products 8 years after publication of the restriction

Manufacturers and DUs of derogated products have to report estimated microplastics emissions to ECHA yearly. **Only the first actor** in the supply chain should report to ECHA.

- **Reporting** to ECHA on:

- Description of the uses of the microplastics for the previous year
- Generic information on the identity of the polymers
- An estimate of the quantity of each microplastic type released to the environment the previous year

Generic information is ok for ECHA but in the case of a request from authorities, more precise information is needed

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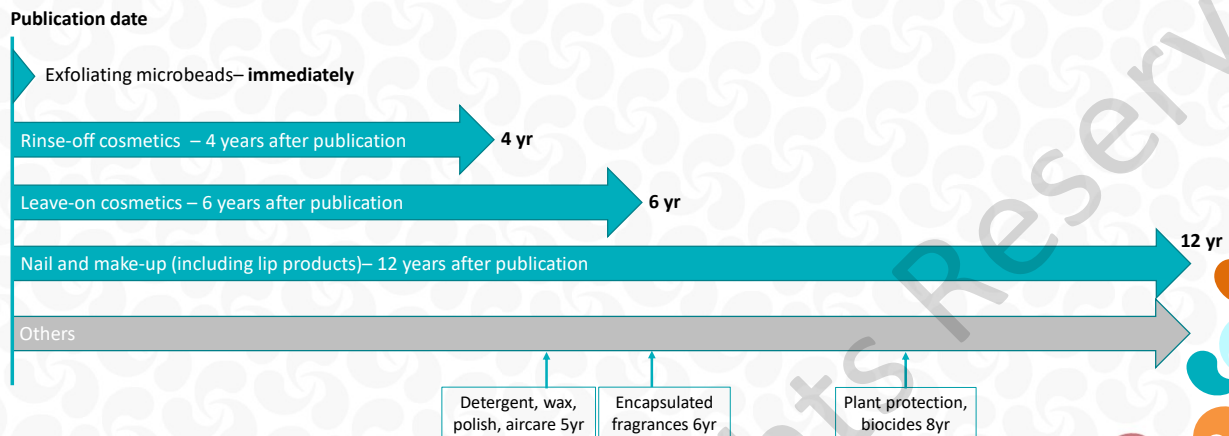
Timelines and Next Steps

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Transition Periods

It is important to remember that the restriction is currently in draft proposal stage. **Transition periods may change before the final restriction is published**

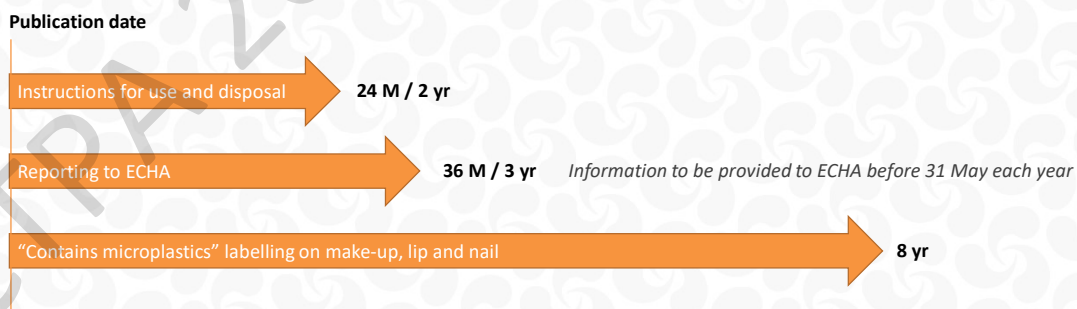


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Labelling and Reporting Transition Periods

Again, **transition periods may change before the final restriction is published**

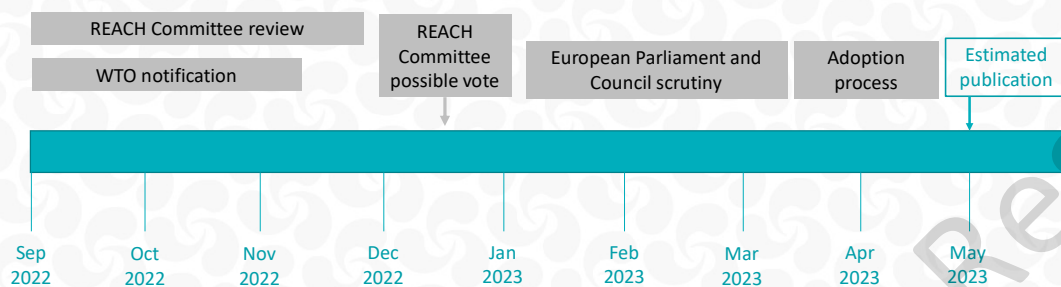


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Timeline to Publication

Current best estimates for publication of the restriction



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How Do I Know if My Ingredient is Within Scope?

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Is there a List of Ingredients?



No! The same INCI name could be a film-former, a solid, a wax, or dissolved in different formulations

The same INCI name could be in scope within some products and out of scope in others

Each company needs to evaluate their product portfolio and work with polymer suppliers, or downstream users, to understand the individual impact

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Example

It is a microplastic as raw material

Polymer Y, with C atoms, solid, synthetic, solid, non-biodegradable



When used in a shower gel

Remains in the solid form

In scope of the microplastics restriction

When used in a cream eye shadow

Does not remain in the solid form, as it's solubilised in the emulsion

In scope of the restriction, but derogated outside of the ban. Labelling and reporting requirements apply.

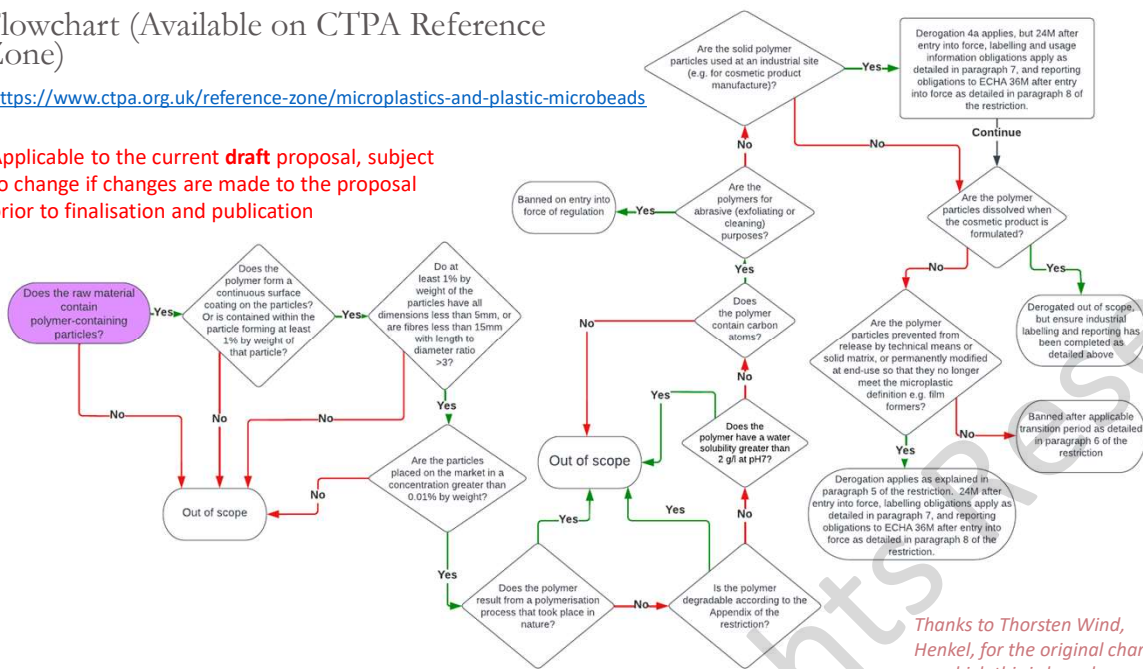
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Flowchart (Available on CTPA Reference Zone)

<https://www.ctpa.org.uk/reference-zone/microplastics-and-plastic-microbeads>

Applicable to the current **draft** proposal, subject to change if changes are made to the proposal prior to finalisation and publication



Thanks to Thorsten Wind, Henkel, for the original chart on which this is based

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Ingredient Case Studies

All case studies are applicable to the current **draft** proposal. Some answers may change depending on any changes made to the restriction proposal prior to finalisation and publication

Please note that the answers represent CTPA's interpretation of the restriction

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Scenario 1

- A body lotion contains starch taken from potatoes

Q: Is this ingredient in scope, or out of scope, of the restriction?

Out of scope – it is a natural polymer where the polymerisation has taken place in nature and it hasn't been chemically modified (e.g. the extraction process is mechanical and hasn't altered the chemistry)

It may also meet the biodegradation criteria, but this would need to be proven through the mandatory test methods

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Scenario 2

- A company is wondering if synthetic, non-degradable polymer A is in scope of the restriction in any of the products in which it is used. It is used across skincare, suncare and haircare products.
- Polymer A has a water solubility greater than 2g/l according to the test method in the restriction appendix.

Q: In which of these product categories can polymer A be used?

All of them! Polymers with a water solubility greater than 2g/l are out of scope because these polymers will not be solid if they reach the aquatic environment

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Scenario 3

- A company uses polymer B, a silicone with carbon-based side chains, in a shampoo and it does not dissolve in the shampoo. It has the following properties:

- Solid
- Synthetic
- Not water soluble
- Not biodegradable

Q: Is this polymer within scope of the restriction?

Yes! It meets the microplastic definition

Q: What is the transition period before the deadline for placing a shampoo containing this ingredient on the market?

4 years

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Scenario 4

- Manufacturer A purchases a raw material from supplier B which meets the definition of a microplastic.
- Manufacturer A formulates the raw material into a moisturiser at their manufacturing site in the EU.
- The raw material is not water soluble, but it dissolves when formulated into the moisturiser and is no longer a solid within the formulation.

Q: Is the moisturiser (the finished product) within scope of the restriction?

No because it does not contain a microplastic (a solid particle) when it is placed on the market

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- Is the raw material within scope of the restriction when sold by supplier B?

Yes – it is a solid synthetic polymer meeting the definition of a microplastic

- If so, what obligations does supplier B have?

The obligations for suppliers shown on slide 30

- Are there any obligations for manufacturer A when formulating at the manufacturing site with this ingredient?

Yes – although the finished product itself is out of scope, a 'microplastic' has been used at the industrial site so manufacturer A will have reporting obligations to ECHA

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Scenario 5

A mascara contains polymer X. Polymer X is:

- A microplastic according to the definition in the restriction
- A film former which loses its microplastic characteristics at point of use

Q: Is the mascara (the finished product) within the scope of the restriction?

Yes, but subject to derogation 5b because the microplastic loses its microplastic characteristic at point of use

Q: Does the mascara have any labelling and/or reporting obligations

Yes - both

Q: From when do these obligations apply?

Two years after publication for labelling and three years after publication for reporting

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- The mascara is manufactured outside the EU and imported by a brand owner (EU RP) to be sold in the EU.

Q: Are there any requirements for the manufacturing site?

- **No** reporting to ECHA or obligations at the factory site
- **No** instructions for use and disposal
- Technical information to help downstream user meet their legal obligations e.g. polymer identity and concentration in the product

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Microplastics in Great Britain

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Will the REACH Restriction Apply in Great Britain?

- UK REACH operates in Great Britain (GB) and **UK REACH will not automatically implement this restriction**
- Northern Ireland follows EU REACH – **it will apply in NI**
- The UK will shortly conduct an '**evidence project**' on microplastics to investigate possible risk management requirements.

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Q&A Session



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