

REACH Restriction on intentionally-added microplastics

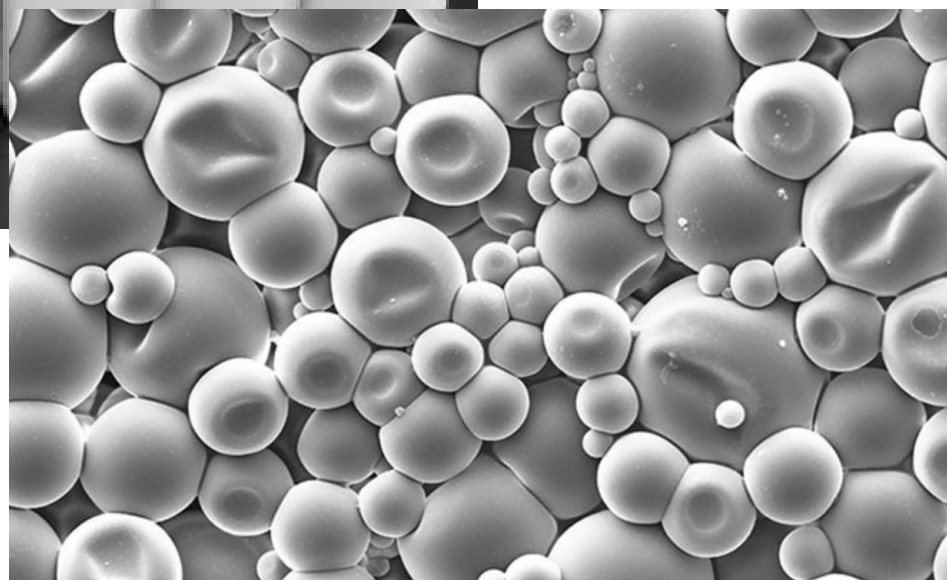
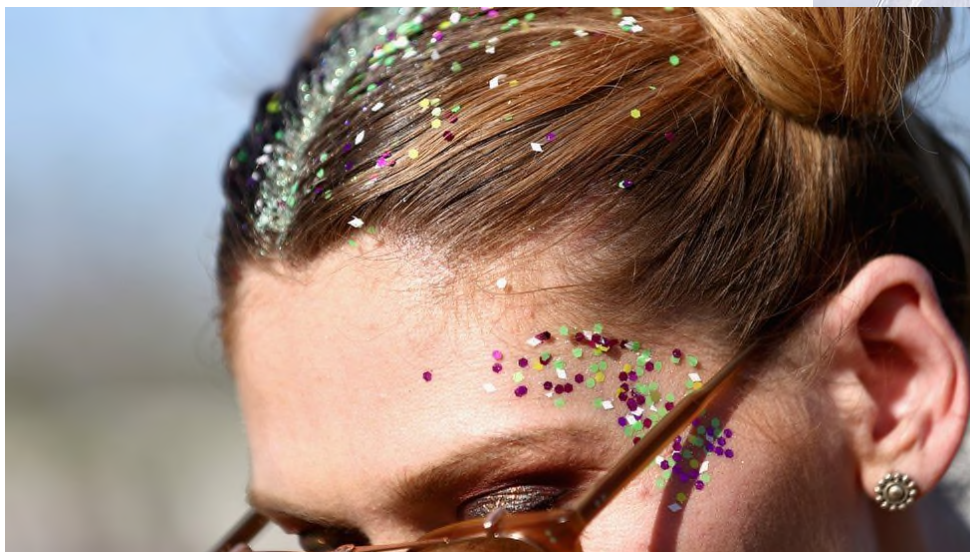
Peter SIMPSON, ECHA

72nd meeting of the EFSA
Advisory Forum
04 July 2019
University of Iceland - Reykjavik

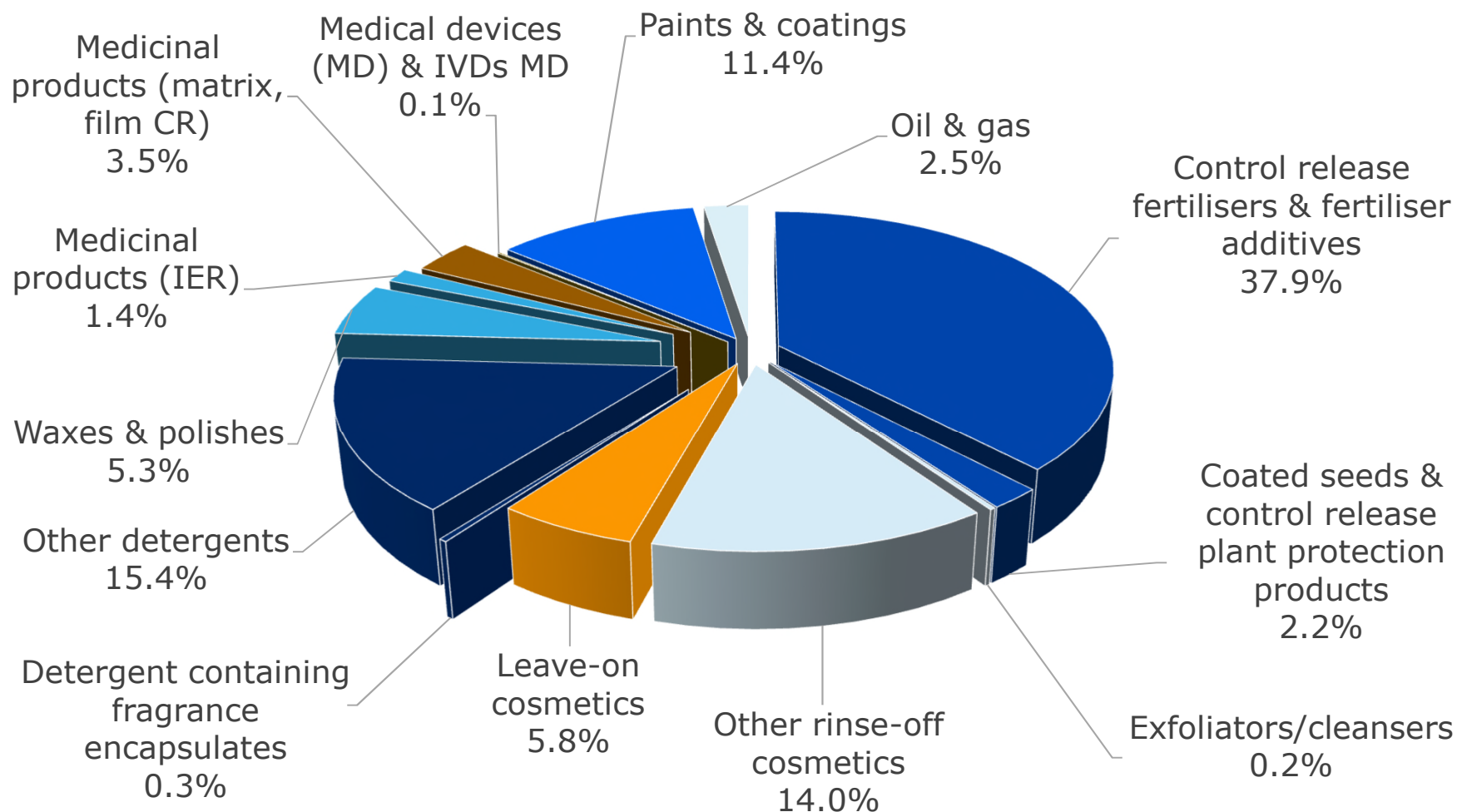


What is 'microplastic'

- 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



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

Microplastic definition



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

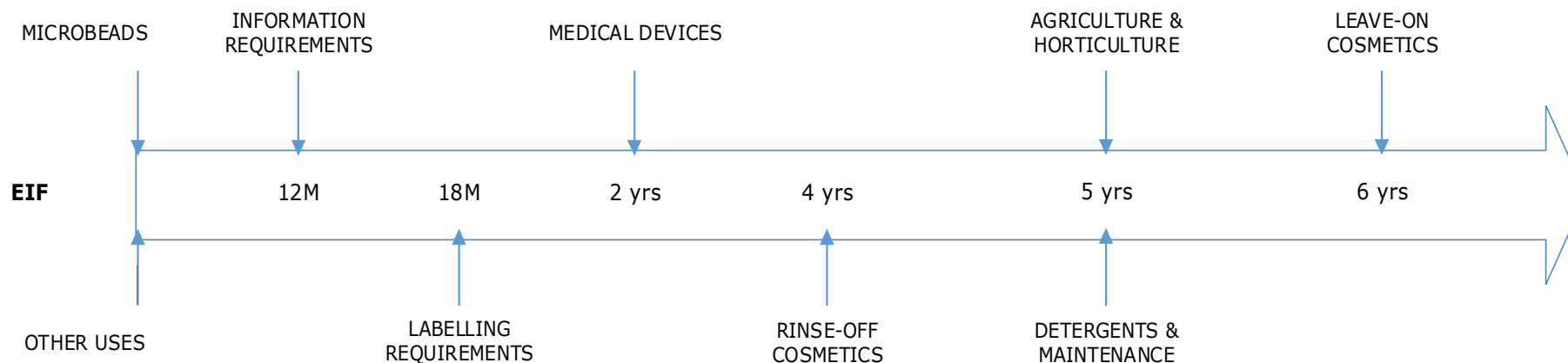


Mandatory 'reporting'

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



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
 - <https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/22921/term>
- Final opinions March 2020
- Opinions sent to Commission for decision-making

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Backup slides





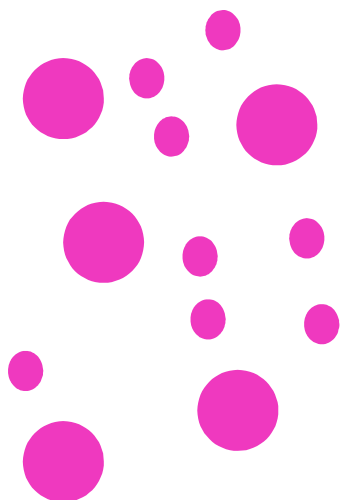
Proposed restriction

- 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 $\geq 1\%$ w/w of particles have:
 - (i) all dimensions $1\text{nm} \leq x \leq 5\text{mm}$, or
 - (ii), for fibres, a length of $3\text{nm} \leq x \leq 15\text{mm}$ and length to diameter ratio of >3



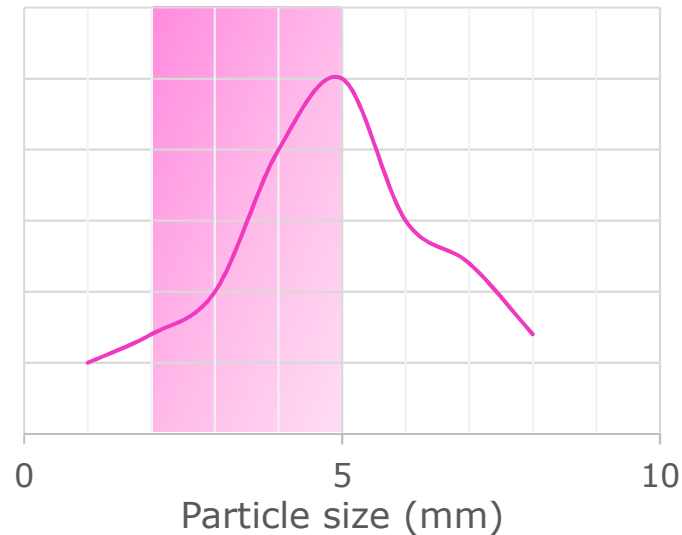
Microplastic definition

Solid polymer-
containing particles



Size [1nm-5mm]
 $\geq 1\%$ w/w ?

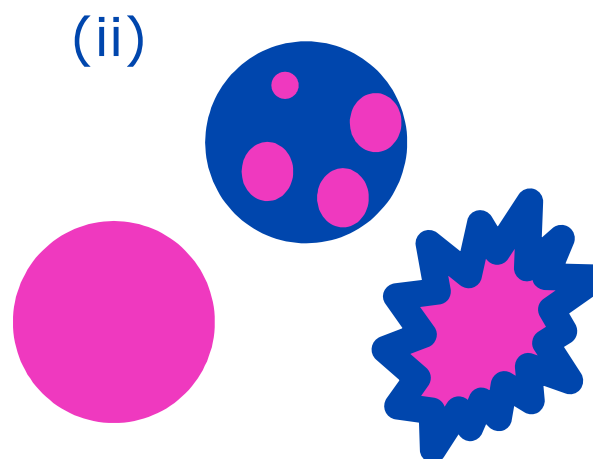
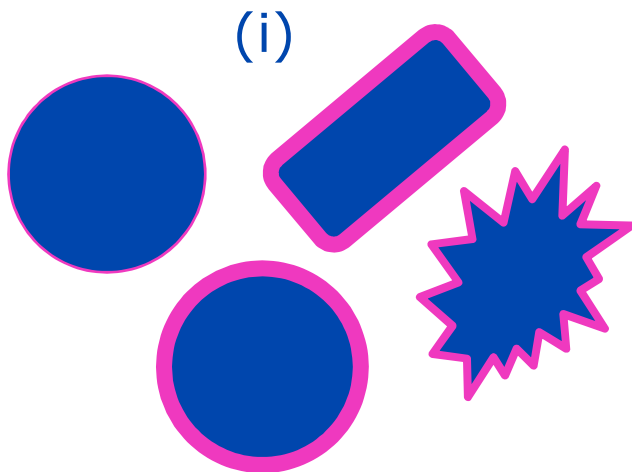
Particle size
distribution





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 $\geq 1\%$ 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

02008R1272 — EN — 01.03.2015

▼B

ANNEX I

CLASSIFICATION AND LABELLING REQUIREMENTS FOR HAZARDOUS SUBSTANCES AND MIXTURES

This annex sets out the criteria for classification in hazard classes and in their differentiations and sets out additional provisions on how the criteria may be met.

1. PART 1: GENERAL PRINCIPLES FOR CLASSIFICATION AND LABELLING

1.0. Definitions

Gas means a substance which:

- (i) at 50 °C has a vapour pressure greater than 300 kPa (absolute); or
- (ii) is completely gaseous at 20 °C at a standard pressure of 101,3 kPa;

Liquid means a substance or mixture which:

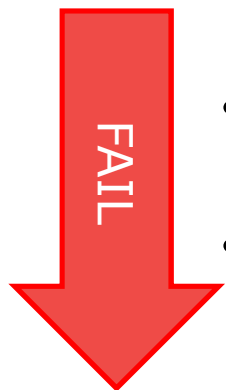
- (i) at 50 °C has a vapour pressure of not more than 300 kPa (3 bar);
- (ii) is not completely gaseous at 20 °C and at a standard pressure of 101,3 kPa; and
- (iii) which has a melting point or initial melting point of 20 °C or less at a standard pressure of 101,3 kPa;

Solid means a substance or mixture which does not meet the definitions of liquid or gas.



(Bio)degradability criteria

- Tiered approach (clear pass/fail criteria)
- Screening tests
 - Ready (and enhanced ready) biodegradation
 - $\geq 60\%$ mineralisation in 28/60 days e.g. OECD TG 301
 - Inherent biodegradation
 - $\geq 70\%$ mineralisation e.g. OECD TG 302B/C
 - Bio(degradation) relative to a reference material
 - $\geq 90\%$ 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



PASS

PASS

PASS

PASS



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

Labelling/reporting

- 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

Labelling

- 5(a) Microplastics that are **contained by technical means** throughout life-cycle / hazardous waste disposal

- *In vitro* diagnostic medical devices / or similar

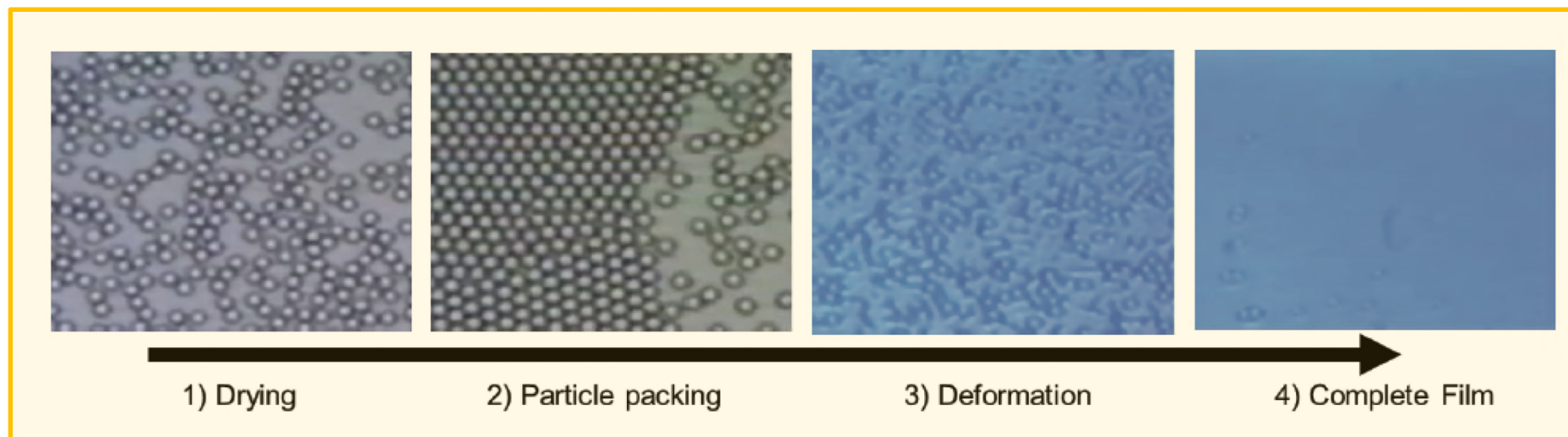
Labelling/reporting

- 5(b) Microplastics that are **permanently modified** when used such that they are no longer microplastic – *loss of particulate form*

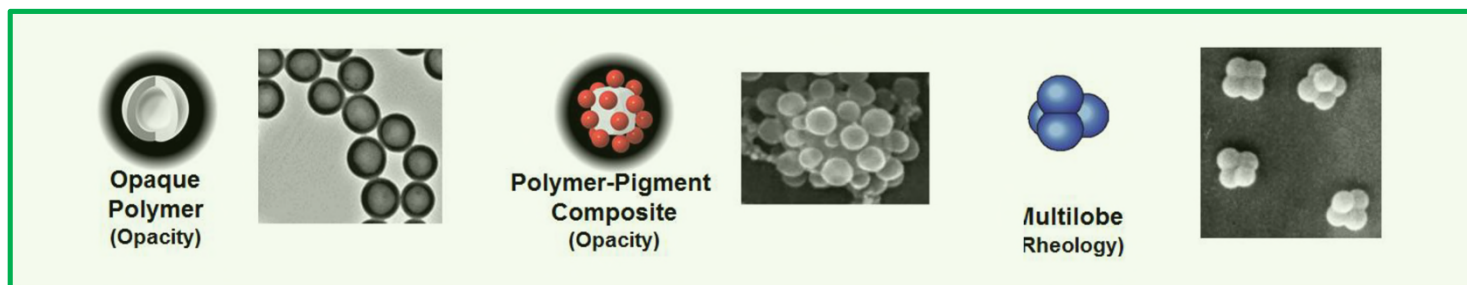
- e.g. film-forming in paints, coatings, cosmetics
 - 'soluble' polymers

- 5(c) Microplastics that are **permanently incorporated** into a solid matrix when used

- Intended for building/construction applications



Film-forming derogated – para 5(b)



Other microplastics derogated – para 5(c)

Sources:

<https://insights.basf.com/home/article/read/coalescents-in-low-voc-paint>

<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)*