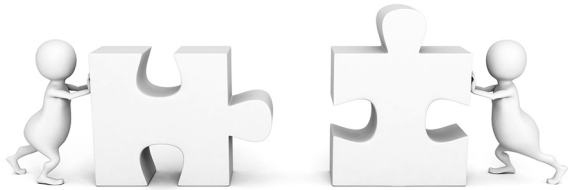
Online information session

Public consultation on the proposed restriction on the placing on the market of intentionally added microplastics

03 April 2019
11:00 – 13:00 Helsinki time

Objectives



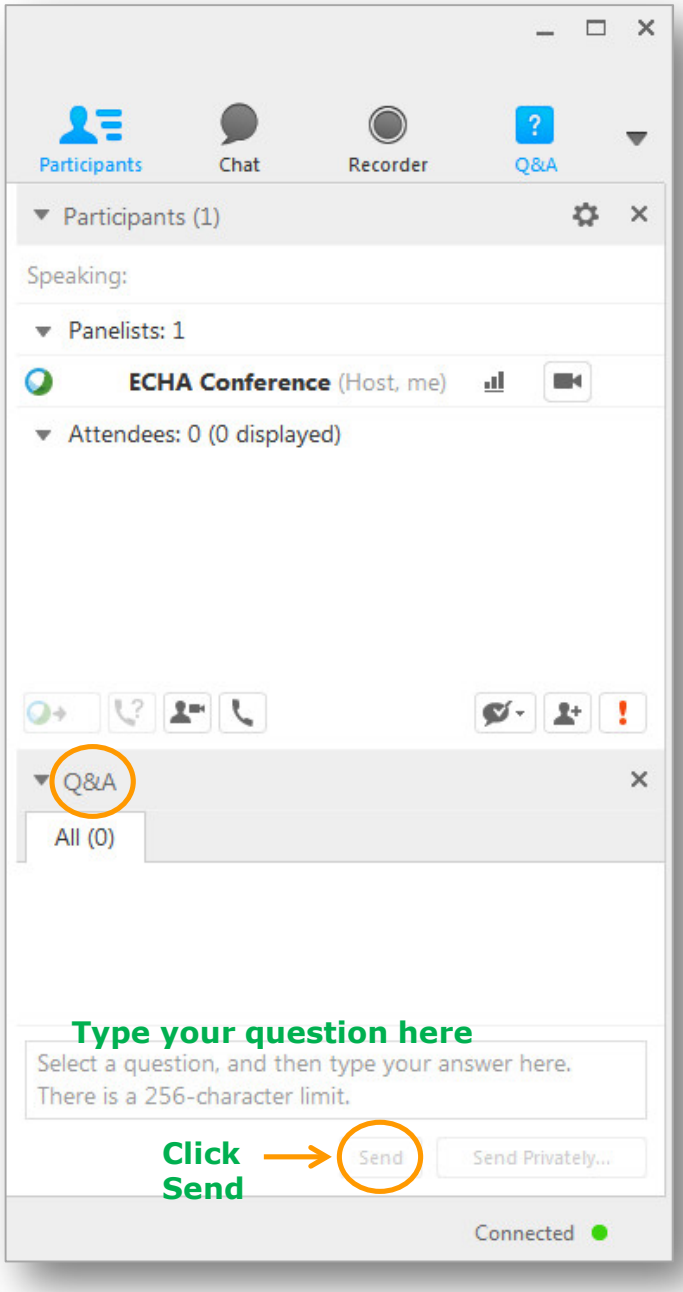
1. Introduce scope of proposed restriction on the placing on the market of 'intentionally-added' microplastics and the public consultation
2. Clarify questions on proposed scope and objectives of the public consultation
3. Help potential respondents decide if and what information to submit in the public consultation
4. Not a debate on the merits of the proposal

Agenda

- 11:00 – 11:10 Introduction
- 11:10 – 12:00 Proposed restriction
  - Summary of the scope
  - Q&A panel on scope/derogation topics
- 12:00 – 12:10 Break
- 12:10 – 13:00 Objectives of the public consultation
  - Technical points, general questions, specific questions
  - Q&A panel

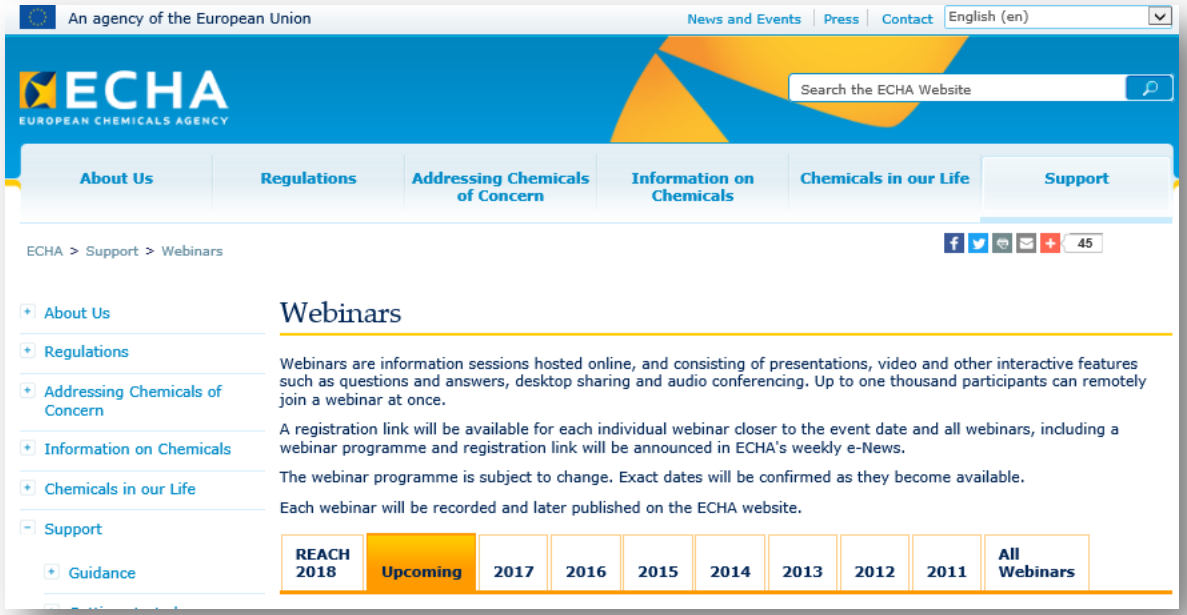
Asking a question

- Use the Q&A panel
- We will answer as many questions as we can
- Questions after the event: echa.europa.eu/contact
- Q&A published ASAP covering all main issues raised
- Press enquiries: press@echa.europa.eu



Material published

- On our YouTube channel: YouTube.com/EUchemicals
- Webinar material on our website
- Q&A and link to the recording on our hot topics page



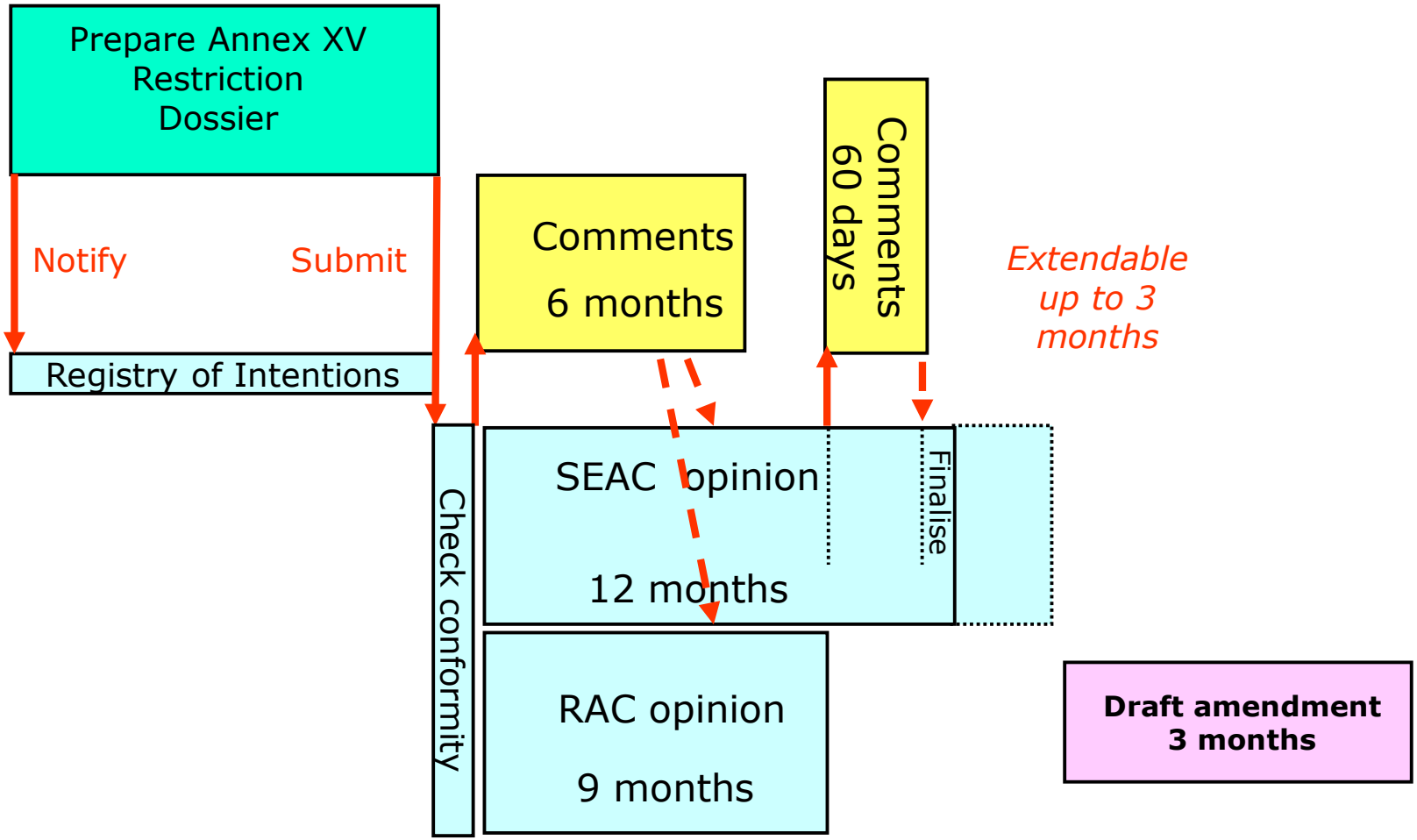
Introduction to REACH restriction

Mark Blainey

REACH restrictions

- Any condition on the manufacture/import/use of a substance (also in a mixture/article)
  - Address a risk that is not adequately controlled
  - Where action is required at Union level
- 'Safety net' for other REACH and EU processes
- Dossier submitter can be a Member State or ECHA
- Very few limitations to scope
  - No minimum tonnage
  - Can apply to medicinal products / polymers / cosmetics
- Certain uses can continue where no societal benefit from stopping them

Main steps and timelines



Proposed restriction on the placing on the market of intentionally added microplastics

Peter Simpson

Outline

- Focus on intended scope and implementation of the restriction
- Clarify misunderstandings

1. Four elements comprising the restriction
2. Microplastic definition
3. Derogations
4. Labelling
5. Reporting
6. Phased implementation
7. Analytical considerations

Elements of proposed restriction

Microplastic definition

Prohibition on 'placing on the market'

uses where MP releases to the environment are inevitable

Derogated uses

uses where MP are not released to the environment; uses already regulated

Mandatory 'labelling'

uses where MP release can be avoided / minimised with instructions for use

Mandatory 'reporting'

identity, description of use (function), tonnage, releases

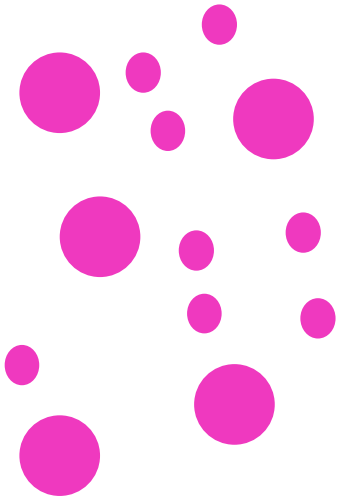
Phased implementation (up to 6 years)

Proposed restriction

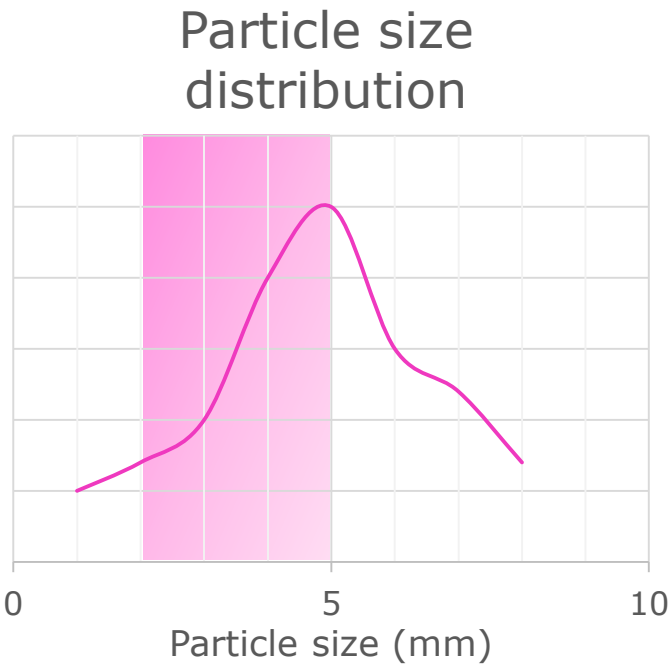
- Polymers shall not, from (approx. 2020), be placed on the market as a substance on its own or in a mixture *as a microplastic* in a concentration equal to or greater than 0.01% w/w (paragraph 1)
- Definitions (paragraph 2):
  - **Polymer:** as defined in Article 3(5) of REACH
  - **Microplastic:** 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



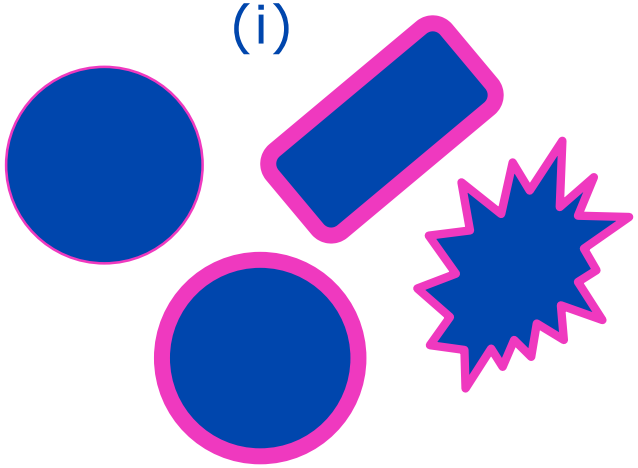
Size [1nm-5mm]
≥ 1% w/w ?



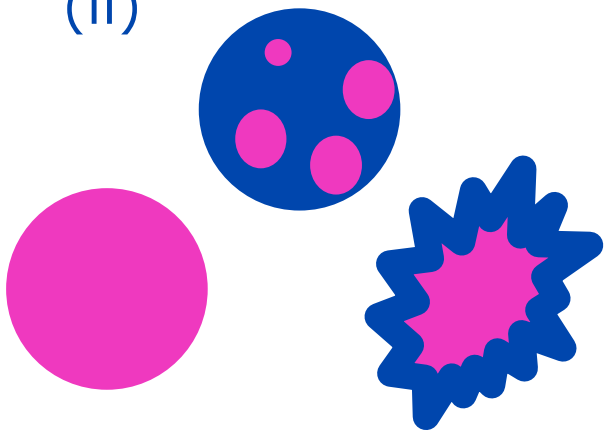
Definitions (I)

- **Particle:** minute piece of matter with defined physical boundaries; a defined physical boundary is an interface
- **Polymer-containing particle:** 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.

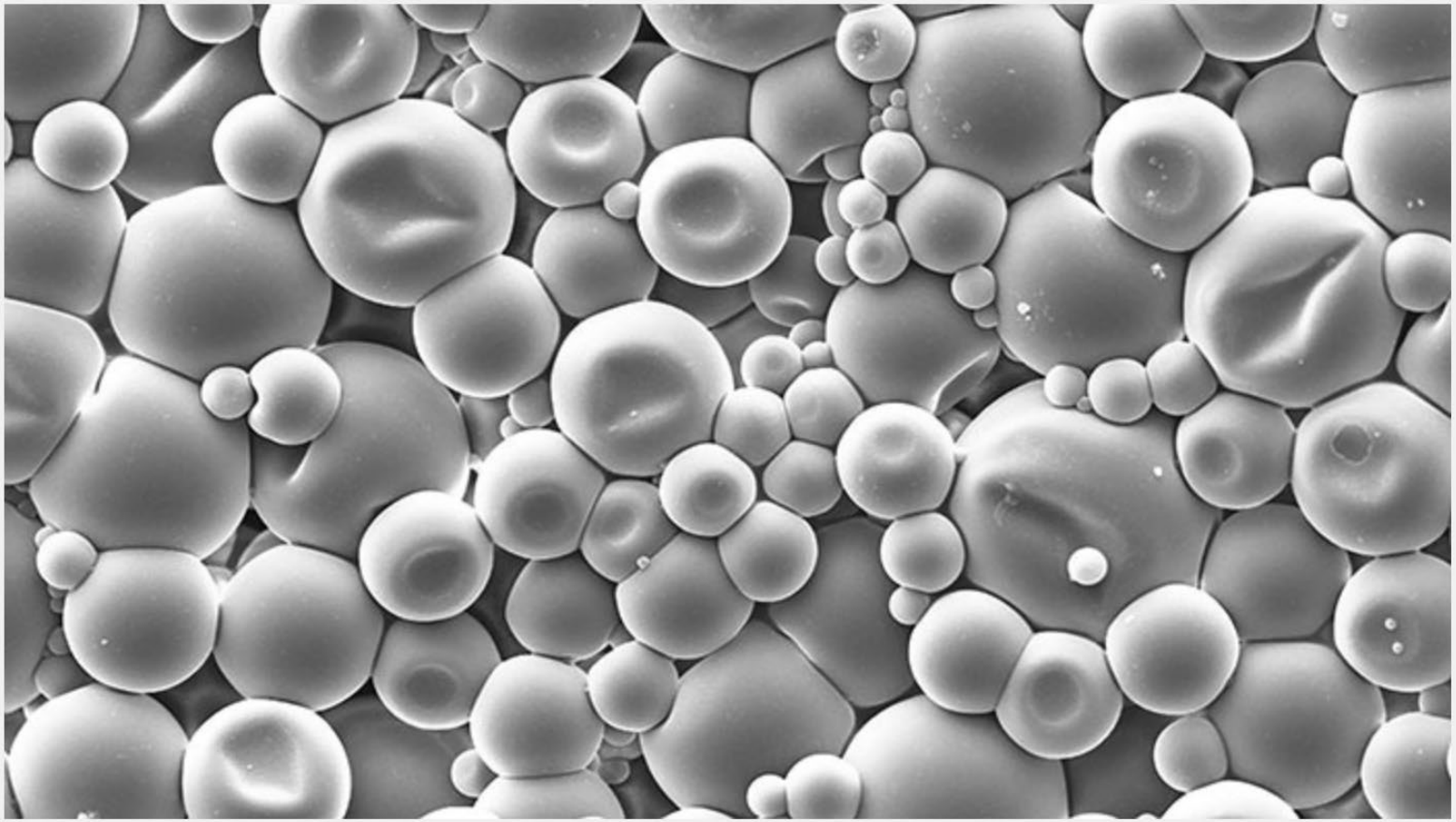
(i)



(ii)



Polymer ‘encapsulation’



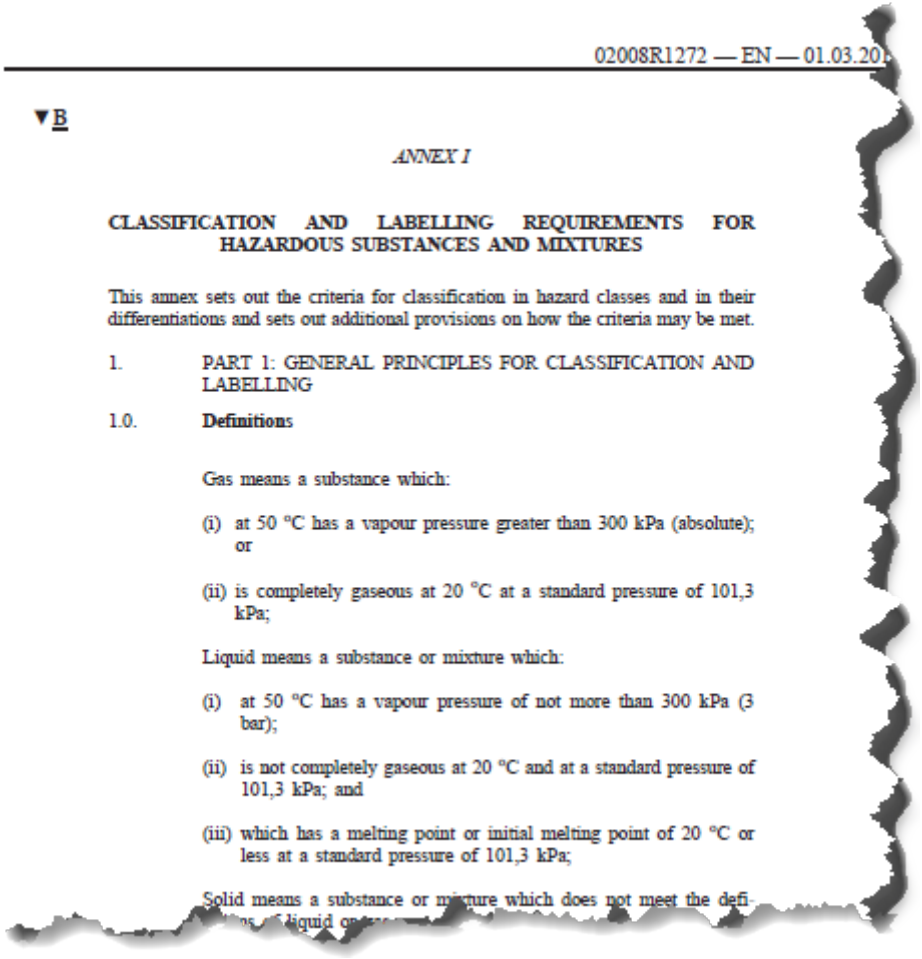
Microcapsules, which range in size from 5–30 µm, are used to deliver inks, fragrances, and more.

Credit: Encapsys

Source: https://cen.acs.org/articles/96/i5/encapsulation-taking-root-laundry-room.html

What is a solid?

- If it is not a gas
- If it is not a liquid
- …then it is solid
- CLP Regulation / GHS



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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 defi-

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
  Still subject to normal enforcement

(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

FAIL

PASS

PASS

PASS

PASS

Section 2.2.1.6 / Table 21 (Appendix X)

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

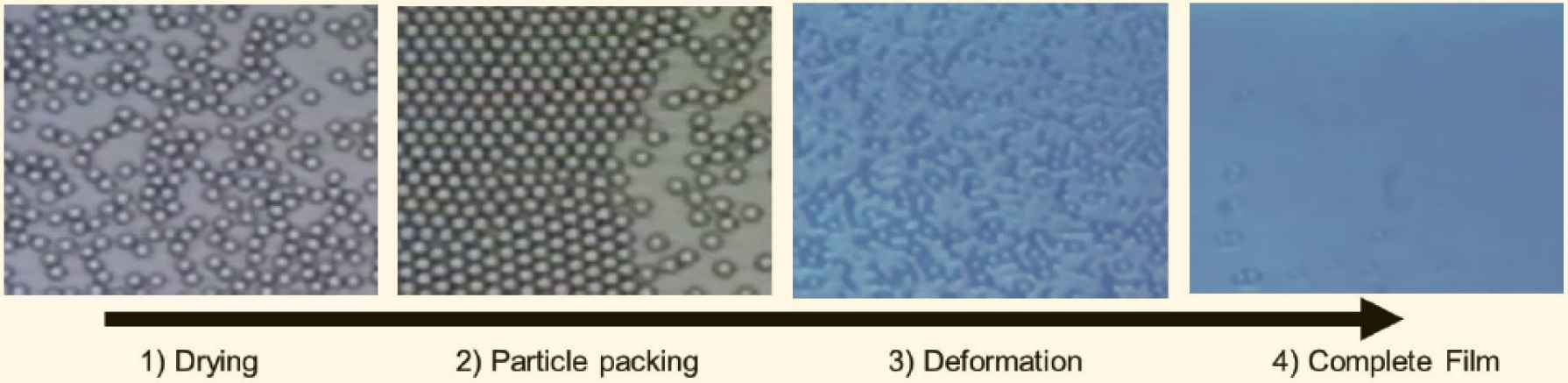
Labelling

- 5(a) Microplastics that are **contained by technical means** throughout life-cycle / hazardous waste disposal
  - *In vitro* diagnostic medical devices / or similar

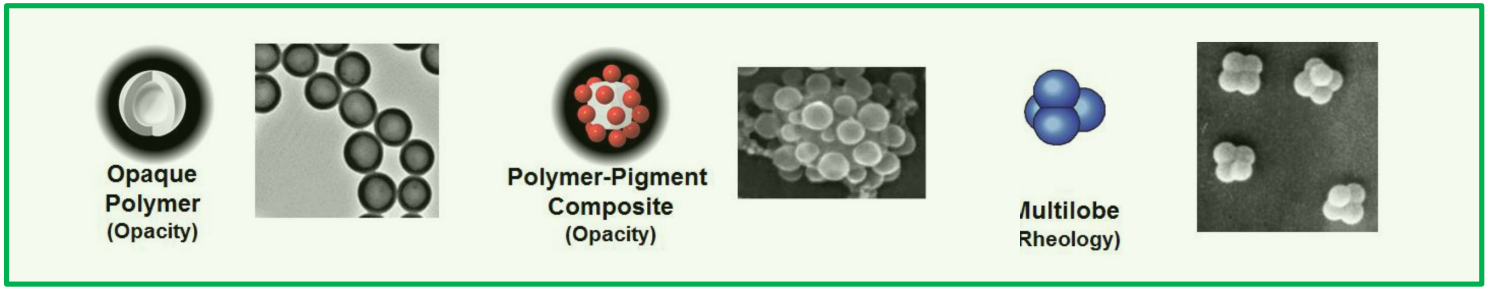
Labelling/reporting

- 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

Paints and coatings



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

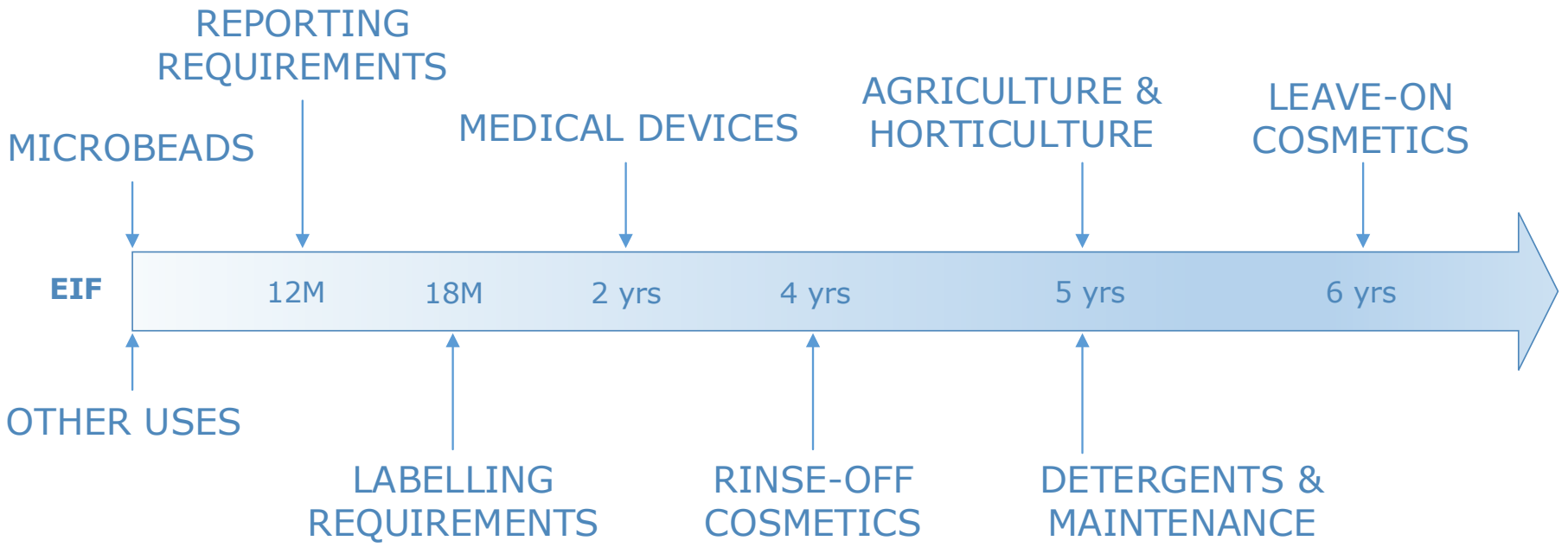
Labelling

- Required in certain cases when derogated from paragraph 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)*

Phased implementation



Analytical considerations

- Proposal outlines a tiered approach that could be used to determine presence of microplastics
  - Does the product contain polymer(s)?
    - Is the information readily available (e.g. from the label)?
  - Does the product contain particles with relevant particle size distribution?
    - If not known, standard sieving method(s) will be generally applicable for determining particle size distribution
    - Alternative methods, such as light scattering, can also be employed
  - If product contains particles with relevant particle size, but polymer content is unknown, a combination of analytical methods may be needed

Q&A panel

Mark Blainey (Moderator)

Peter Simpson

Risk Management I (D3)

Pertti Elo

Chemistry (B1)

Anu Kapanen

Hazard Assessment (C4)

Participating in the public consultation

Evgenia Stoyanova

- Objectives
- Specific information needs for the microplastics restriction proposal
- General public consultation questions for all restriction proposals

Objectives

Legal mandate

- Mandated in article 69.9 of REACH

  The Agency shall invite all interested parties to submit individually or jointly within six months of the date of publication:

  a) Comments on the dossier and the suggested restriction

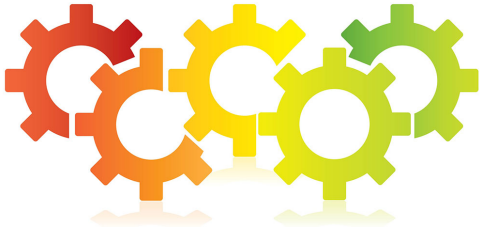
  b) A socio-economic analysis, or information which can contribute to one, of the suggested restrictions, examining the advantages and drawbacks of the proposed restriction. It shall conform to the requirements in Annex XVI.

  [Annex XVI of REACH: Socio-economic Analysis]

Objectives

- Gather relevant information for Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) to help evaluate the proposed restriction and conclude on whether it is the most appropriate community-wide measure to address the risks
- Engage stakeholders and the public at large in the evaluation of the restriction proposal
- Ensure transparency

General principles



- Supporting evidence is needed
  - Burden of proof on industry
- Comments accepted only via webform (public and confidential)
  by 20 September 2019
- Several comments can be submitted throughout consultation period
- Comments needed at key stages of opinion-development

Timing of comments

Plenary meeting	Risk Assessment Committee (RAC)	Socio-Economic Assessment Committee (SEAC)
1st meeting: Comments by **May 20, 2019**	Verify proposed scope. Conclude on **hazard** and hold preliminary discussion on exposure/risk.	Verify proposed scope. Conclude on **costs** of proposed restriction and hold preliminary discussions on benefits.
2nd meeting: Comments by **Aug 20, 2019**	Conclude on **exposure/risk** and hold preliminary discussion on derogations.	Conclude on **benefits** and hold preliminary discussions on proportionality and derogations.
3rd meeting: November 2019	Finalise **derogations**. Finalise opinion plus justification text and **adopt final opinion**.	Conclude on **proportionality** and **derogations**. Finalise opinion plus justification text and **agree on draft opinion**.
4th meeting: March 2020	Not relevant.	Conclude on issues raised during SEAC draft opinion public consultation. Adopt final opinion.

Specific questions to address information needs of microplastics dossier

Q1: (Bio)degradability criteria

- Paragraph 3(b) of the proposed restriction (Table 3 of restriction report)
  - 'polymers that are (bio)degradable' are not microplastics
  - tiered approach for establishing (bio)degradability (Appendix X/Table 21 in restriction report)
- Feedback on:
  - Test methods and pass/fail criteria that have been proposed:
    - Are they clear, appropriate and practical?
    - Any practical experience of applying the proposed criteria?
    - Any further modifications or adaptations, or alternative test methods, pass/fail criteria or guidance that should be considered?
    - Supporting justification should be provided

Q2: Infill material for synthetic turf

- Granular infill material meets the microplastic definition
- Further information needed to assess impacts, e.g.
  - Quantity used (per year) in Member States or EU/EEA
  - Quantity released (per year) to the environment
    - assessment of different emissions pathways
  - Best practice OCs and RMMs to prevent/minimise releases (and their costs)
  - Impacts to society of restricting this use, e.g.
    - availability of sports fields;
    - impacts on producers, installers and users;
    - impacts on releases from the management of waste tyres (e.g. incineration and resulting externalities)

Q3: Concentration limit

- For the CL of 0.01% w/w to be considered further:
  - What is the minimum concentration of microplastics in end products required to fulfil their intended technical function?
  - What proportion of products contain microplastics to achieve their intended function in concentrations: a) less than 0.001% w/w; b) between 0.001% w/w and 0.01% w/w; c) between 0.01% w/w and 0.1% w/w; d) between 0.1% w/w and 1% w/w; and e) greater than 1.0% w/w.
  - Are there analytical methods that could be used to detect and quantify microplastics in the end products?
  - Are you aware of microplastics corresponding to the definition proposed in the restriction being present in a substance or a mixture as an impurity? If so, at what concentrations (% w/w) do these occur?

Q3: Concentration limit

- When answering, please consider:
  - Paragraph 2d of the proposal (Table 3 in report), a '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
  - Please provide information separately:

Rinse-off cosmetic products	Agricultural & horticultural products
Leave-on cosmetic products	Waxes and polishes
3D printing	Detergents w/ fragrance encapsulates
Printing inks	Other detergents
Construction products	Medical devices, incl. *in vitro* diagnostic devices
Products used in oil & gas	Medicinal products (human & veterinary)
Paints and coatings	Food supplements & medical food

Q4: Medical devices and others

- Paragraph 5a: a derogation for substances or mixtures containing microplastics where the microplastics are both
  - contained by technical means throughout their whole lifecycle &
  - any microplastic containing wastes are incinerated or disposed of as though they are hazardous waste
- Please provide information on the feasibility and practicalities of implementing the containment by technical means and subsequent disposal for:
  - medical devices and in vitro diagnostic medical devices within a **2 year transitional period**
  - any similar uses that would also be permitted on the basis of this proposed derogation

Q5: Other uses and socio-economic impacts

- Substantial efforts to engage industry & other stakeholders to gather relevant information:
  - Call for evidence: Mar 1 – May 11, 2018
  - Stakeholder workshop: May 30-31, 2018
  - Contacted over 13 000 potential polymer producers & users :
    - At the stage of dossier preparation and submission
  - Press releases, social media & other outreach
- Conducted independent research

Q5: Other uses and socio-economic impacts

- Information on:
  - **other sectors or uses**, beyond those analysed that may be affected by the proposed restriction or
  - additional information to **refine the existing assessment**
- For example:
  - tonnages used, technical function, releases (including pathways)
  - actors that would be affected e.g. producers, formulators, professionals, consumers (including users of alternatives), with associated key economic information (e.g. profits, number of employees, etc.)
  - costs and benefits for actors in the supply chain
  - the number of products needing reformulation (with expected costs and timelines for transitioning to alternatives)
  - critical uses, for which no alternative currently exists and how long it would take to identify such alternatives
  - other potential impacts stemming from the use of alternatives, e.g., discontinuation of certain products, etc.

Q6: Cosmetics

- Call for Evidence:
  - Information on 19 polymers that could be impacted by the proposed scope in the call for evidence

Table 44 in Annex to restriction report

Microplastics by polymer material	Associated INCI name (for database queries)
Polyethylene	POLYETHYLENE
Polypropylene	POLYPROPYLENE
Polymethylmethacrylate	POLYMETHYL METHACRYLATE
Polytetrafluoroethylene	POLYTETRAFLUOROETHYLENE ACETOXYPROPYL BETAINE
Polyurethane crosspolymer – 1	POLYURETHANE CROSSPOLYMER-1
Polyurethane crosspolymer – 2	POLYURETHANE CROSSPOLYMER-2
Polyamide (nylon) 5	POLYAMIDE-5
Polyamide (nylon) 6	NYLON-6 NYLON 6/12
Polyamide (nylon) 12	NYLON-12 NYLON-12 FLUORESCENT BRIGHTENER 230 SALT NYLON 12 NYLON 6/12
Styrene acrylate copolymer	STYRENE/ACRYLATES COPOLYMER
Polyethylene terephthalate	POLYETHYLENE TEREPHTHALATE
Polyethylene isoterephthalate	POLYETHYLENE ISOTEREPHTHALATE
Polybutylene terephthalate	POLYBUTYLENE TEREPHTHALATE
Polyacrylates, acrylates copolymer	ACRYLATES COPOLYMER ACRYLATES CROSSPOLYMER
Ethylene/Acrylate copolymer	ETHYLENE/ACRYLIC ACID COPOLYMER
Polystyrene	POLYSTYRENE
Methyl methacrylate crosspolymer	METHYL METHACRYLATE CROSSPOLYMER
Polymethylsilsesquioxane	POLYMETHYLSILSESQUIOXANE
Poly lactic acid	POLYLACTIC ACID

Q6: Cosmetics

- Call for evidence:
  - Information on 19 polymers that could be impacted by the proposed scope in the call for evidence

  ⇒ Low scenario in restriction report
- Dossier development:
  - Information that as many as 520 polymers may be used in cosmetics
  - Not all uses likely in the scope of the proposed restriction
    - INCI name (International Nomenclature of Cosmetic Ingredients) not sufficient to determine whether in scope of proposed restriction

  ⇒ High scenario in restriction report

  ⇒ Public consultation to refine analysis

Table 88 in Annex to restriction report

INCI name	Estimated occurrence of INCI in leave-on cosmetics containing one of the 520 polymers [%]	Estimated occurrence of INCI in rinse-off cosmetics containing one of the 520 polymers [%]
CARBOMER	20-25%	20-25%
POLYETHYLENE	10-15%	5-10%
ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER	10-15%	10-15%
ACRYLATES COPOLYMER	10-15%	10-15%
NYLON-12	10-15%	< 0.5 %
STYRENE/ACRYLATES COPOLYMER	5%	15-20%
POLYBUTENE	5-10%	< 0.5 %
POLYQUATERNIUM-7	<1%	30-35%
TRIMETHYLSILOXYSILICATE	5-10%	< 0.5 %
POLYMETHYL METHACRYLATE	5%	< 0.5 %
SODIUM POLYACRYLATE	5-10%	<5%
POLYMETHYLSILSESQUIOXANE	5%	< 0.5 %
POLYETHYLENE TEREPHTHALATE	5%	< 0.5 %
PVP	<5%	<2%
METHYL METHACRYLATE CROSSPOLYMER	<5%	< 0.5 %
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER	5-10%	<5%
POLYACRYLAMIDE	3-5%	<2%
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER	<2%	< 0.05 %
OCTYLACRYLAMIDE/ACRYLATES/BUTYLAMINOETHYL METHACRYLATE COPOLYMER	<2%	< 0.5 %

Q6: Cosmetics

- For the polymers used in cosmetic products, consider if their use is impacted by the proposed restriction:
  - i) if the physical form of the polymer in the cosmetic mixture is consistent with the microplastic definition at point of release or use by end-users,
  - ii) that (bio)degradable or natural (not chemically modified) polymers are not considered to be microplastics (see Paragraph 3 in Table 3 in report)
  - iii) that certain uses are proposed to be derogated (e.g., film forming, see Paragraph 5b)

Q6: Cosmetics

- For those polymers that may be impacted by the scope of the proposed restriction, please specify their INCI name and provide:
  1) *Total number of formulations containing this INCI;*
  2) *Of the formulations reported in point 1), what is the total number of formulations containing this INCI meeting the microplastic definition?*
  3) *For the formulations reported in point 2), indicate the kilogrammes of this INCI used last year.*

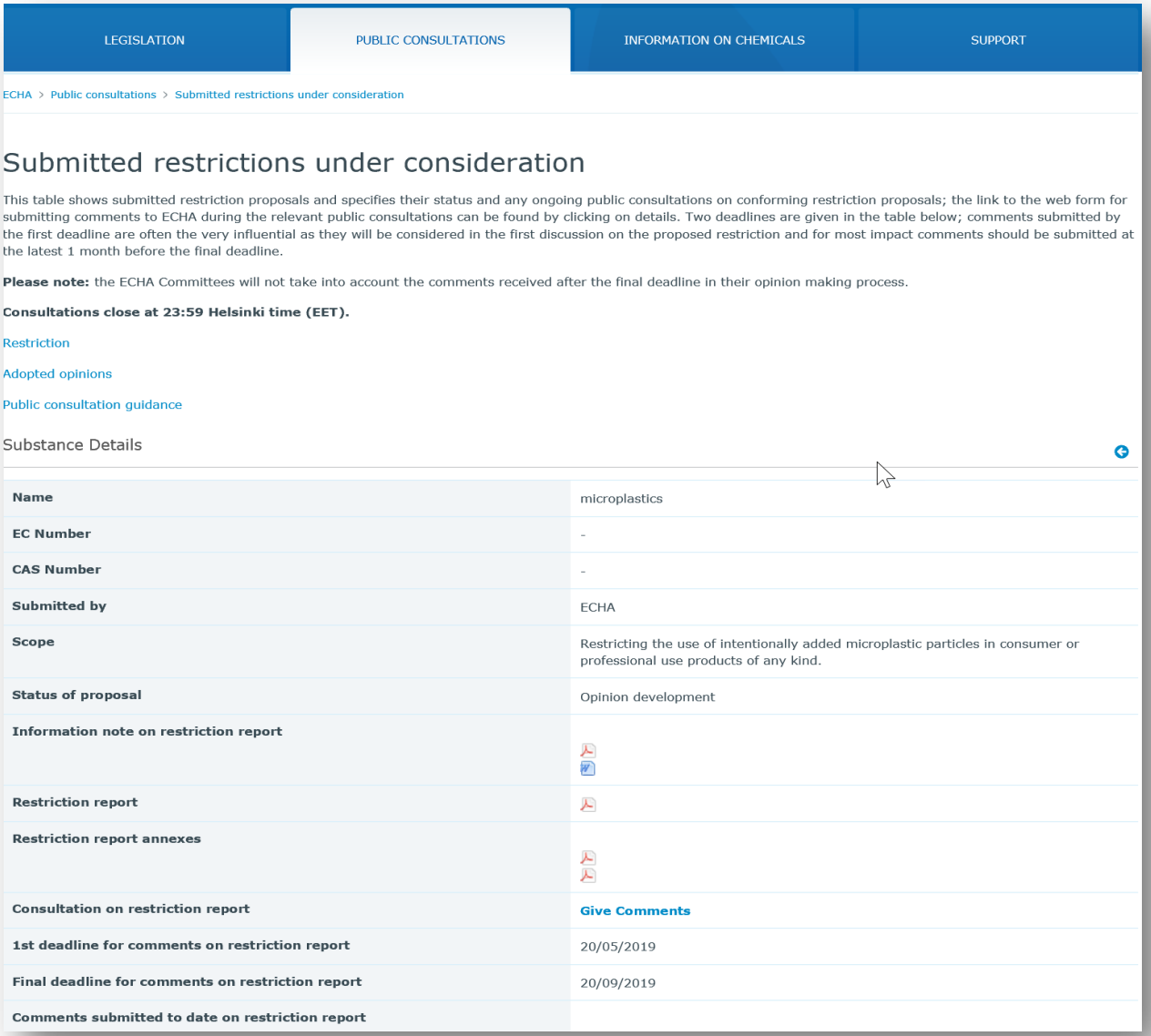
Q6: Cosmetics

- To be answered separately for:
  - Rinse-off cosmetics (combined)
  - Leave-on cosmetics: separately for
    - make-up,
    - nail varnish/remover,
    - skin care,
    - sun/self-tanning,
    - deodorant/antiperspirant,
    - hair styling & other

PUBLIC CONSULTATION

Intentionally added microplastics – Response template for Public Consultation question number six.

Polymer	Associated INCI name	Rinse-off products containing the INCI	Leave-on[2] products containing the INCI
Polyethylene	POLYETHYLENE	*Please provide:* *1) Total number of rinse-off formulations containing this INCI;* *2) Of the formulations reported in point 1), what is the total number of rinse-off formulations containing this INCI meeting the microplastic definition?* *3) For the formulations reported in point 2), indicate the kilogrammes of this INCI used last year.* *Example answer:* *1) 50* *2) 32* *3) 1 000 kg*	*Please provide:* *1) Total number of leave-on formulations in category 1 (e.g., make-up) containing this INCI;* *2) Of the formulations reported in point 1), what is the total number of leave-on formulations in category 1 (e.g., make-up) containing this INCI meeting the microplastic definition?;* *3) For the formulations reported in point 2), indicate the kilogrammes of this INCI used last year.* *Example answer:* *Make-up:* *1) 30* *2) 22* *3) 500 kg* *Skin care:* *1) 20* *2) 20* *3) 300 kg* *Nail varnish/remover:* *1) 2* *2) 2* *3) 5 kg* *Sun/self-tanning:* *1) 10* *2) 8* *3) 500 kg* *Deodorant/antiperspirant:* *1) 20* *2) 2* *3) 50 kg* *Hair styling & other:* *1) 10*



LEGISLATION | PUBLIC CONSULTATIONS | INFORMATION ON CHEMICALS | SUPPORT

ECHA > Public consultations > Submitted restrictions under consideration

Submitted restrictions under consideration

This table shows submitted restriction proposals and specifies their status and any ongoing public consultations on conforming restriction proposals; the link to the web form for submitting comments to ECHA during the relevant public consultations can be found by clicking on details. Two deadlines are given in the table below; comments submitted by the first deadline are often the very influential as they will be considered in the first discussion on the proposed restriction and for most impact comments should be submitted at the latest 1 month before the final deadline.

Please note: the ECHA Committees will not take into account the comments received after the final deadline in their opinion making process.

Consultations close at 23:59 Helsinki time (EET).

Restriction

Adopted opinions

Public consultation guidance

Substance Details

Name	microplastics
EC Number	-
CAS Number	-
Submitted by	ECHA
Scope	Restricting the use of intentionally added microplastic particles in consumer or professional use products of any kind.
Status of proposal	Opinion development
Information note on restriction report	
Restriction report	
Restriction report annexes	
Consultation on restriction report	**Give Comments**
1st deadline for comments on restriction report	20/05/2019
Final deadline for comments on restriction report	20/09/2019
Comments submitted to date on restriction report	

General comments for all restriction reports

General topics

- Scope or restriction options analysis
- Hazard or exposure
- Environmental emissions
- Baseline
- Description of analytical methods
- Information on alternatives
- Information on costs
- Information on benefits
- Transitional period/deferred entry into force
- Request for exemption (derogations/other RMOs)

Q&A panel 2

Mark Blainey (Moderator)

Evgenia Stoyanova
Risk Management II (D4)

Sanna Henrichson
Risk Management II (D4)

Peter Simpson
Risk Management I (D3)

Thank you!

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