Product Regulations and Circular Economy: which interactions?

Milan, 31 January 2024

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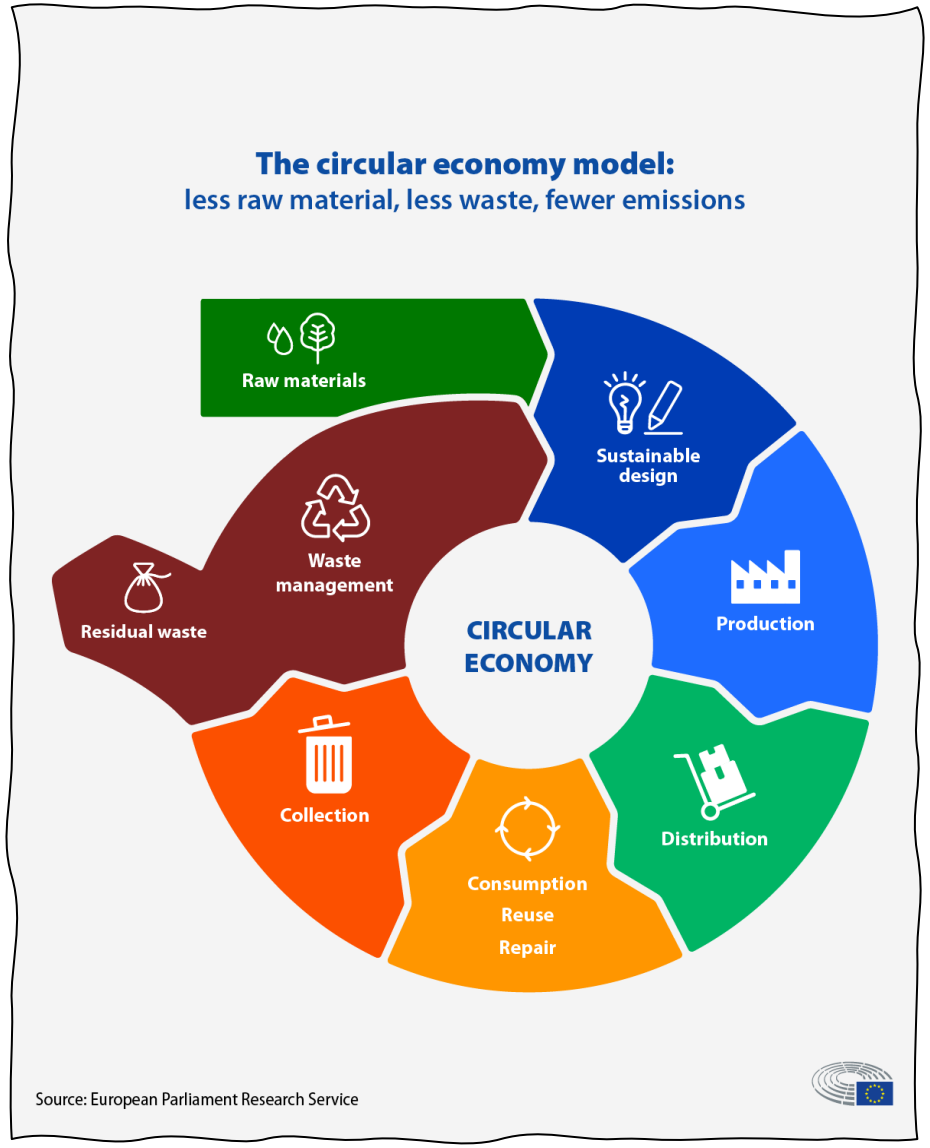
Circular Economy

- ✓ **More than 2.2 billion tones of waste are produced annually** in the EU;
- ✓ Circular economy: **new production and consumption** model involving sharing, lending, reusing, repairing, reconditioning and recycling existing materials and products for as long as possible.
- ✓ **Extending the life cycle of products**, helping to minimize waste.



https://ec.europa.eu/commission/presscorner/detail/it/ip_20_420

https://environment.ec.europa.eu/strategy/circular-economy-action-plan_en

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Product Regulations

- ✓ **REACH regulation:**
  - ➢ **Registration**
  - ➢ **Restrictions:**
    - ○ **Microparticles**
    - ○ **PFAS**
- ✓ CLP regulation
- ✓ Polymer registration
- ✓ SCIP Database (articles)
- ✓ …

REACH and recovered substances

Art. 2.2 REACH states that **waste** as defined in Directive 2006/12/EC of the European Parliament and of the Council (repealed by Directive 2008/98/EC, ed.) shall **not be considered to be a substance, mixture or article within the meaning of Article 3 of this Regulation**.

Therefore, the REACH provisions for substances, mixtures and articles do not apply to waste.

As soon as a material "**ceases to be waste**" (Art. 184-ter Legislative Decree 152/06 et seq.) the provisions of REACH apply in principle like any other substance.

By-products are exempt from registration according to Art. 2(7)(b), unless they are **imported or placed on the market** (All. V, pt. 5 REACH).

Art. 184-ter, paragraph 1 of Legislative Decree 152/06 et seq. (transposition of Art. 6 Directive 2008/98/EC and smi) states that

a waste ceases to be waste when it has undergone a recovery operation, including recycling, and meets specific criteria, to be adopted in accordance with the following conditions

a) the substance or object is intended to be used for specific purposes;

b) there is a market or demand for that substance or object;

c) the substance or object meets the technical requirements for the specific purposes and complies with existing legislation and standards applicable to products;

d) the use of the substance or object will not lead to overall adverse environmental or human health impacts.

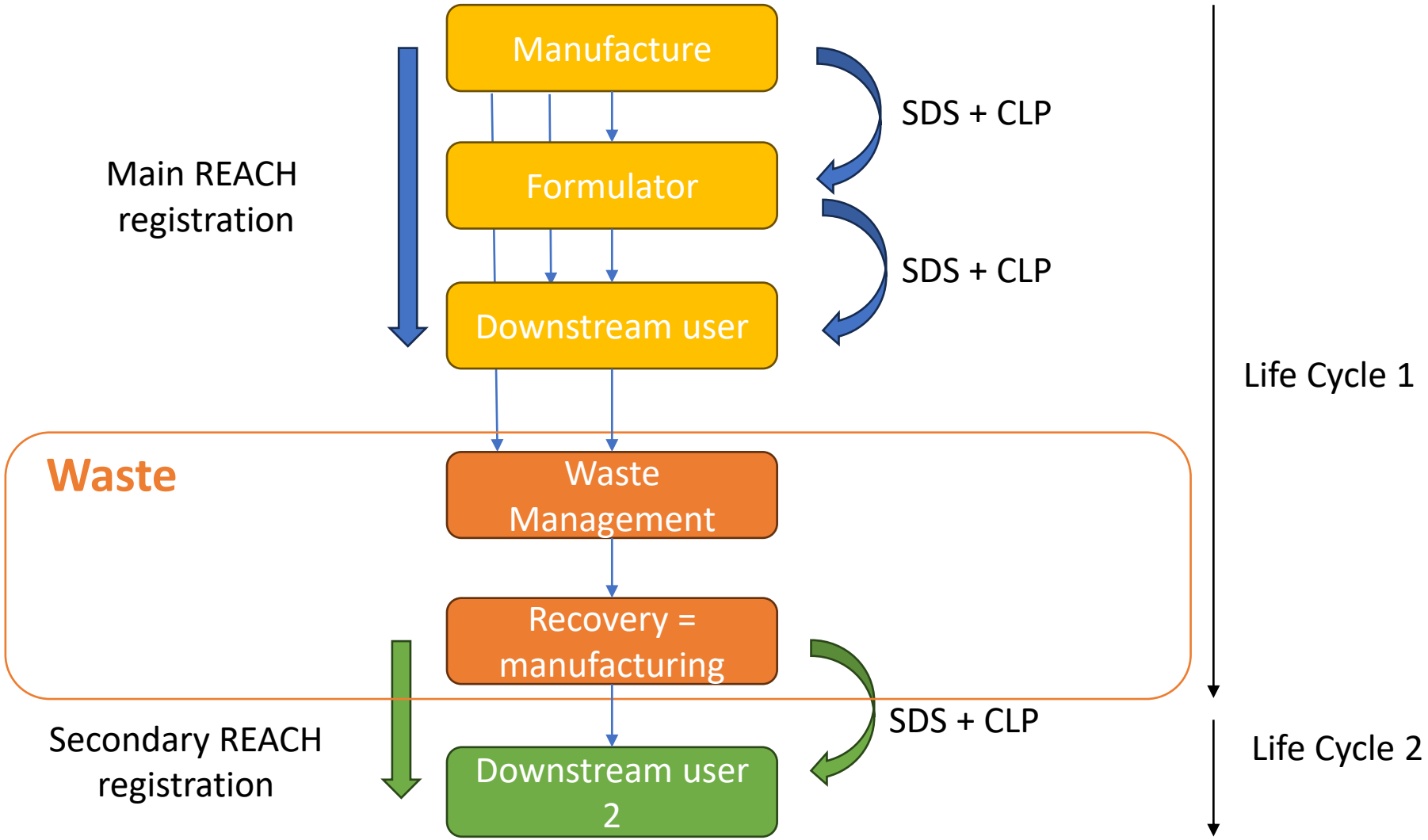
Manufacturing

All forms of recovery, including mechanical processing

are considered to be a **manufacturing** process **as a result in the production of one or more substances**, on their own, in a mixture or in an article,

which **have ceased to be waste after having undergone one or more recovery steps**.

REACH registration



REACH registration - exemption

Condition 1: "similarity" between a recovered substance and an already registered substance

The substance resulting from the recovery process is the same as the substance registered under Title II.

+

Condition 2: information required

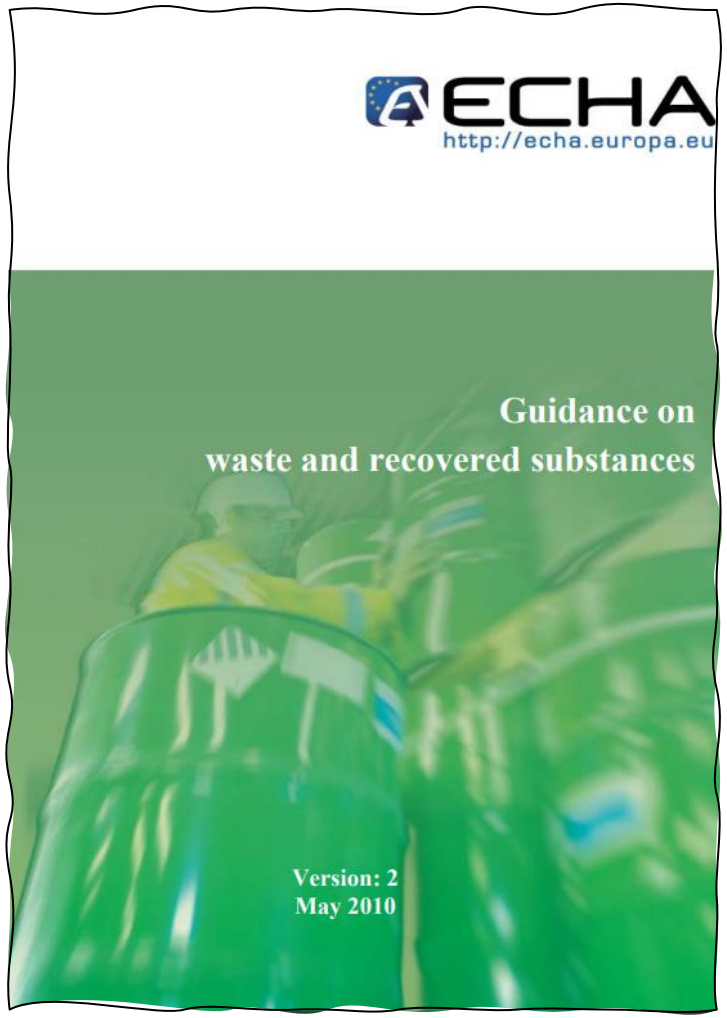
The information required by Articles 31 (SDS) or 32 (SIS) on the substance registered under Title II is available at the establishment carrying out the recovery.

Responsibility

It is the responsibility of the recoverer to determine whether the recovered substances fulfil the criteria for exemption.

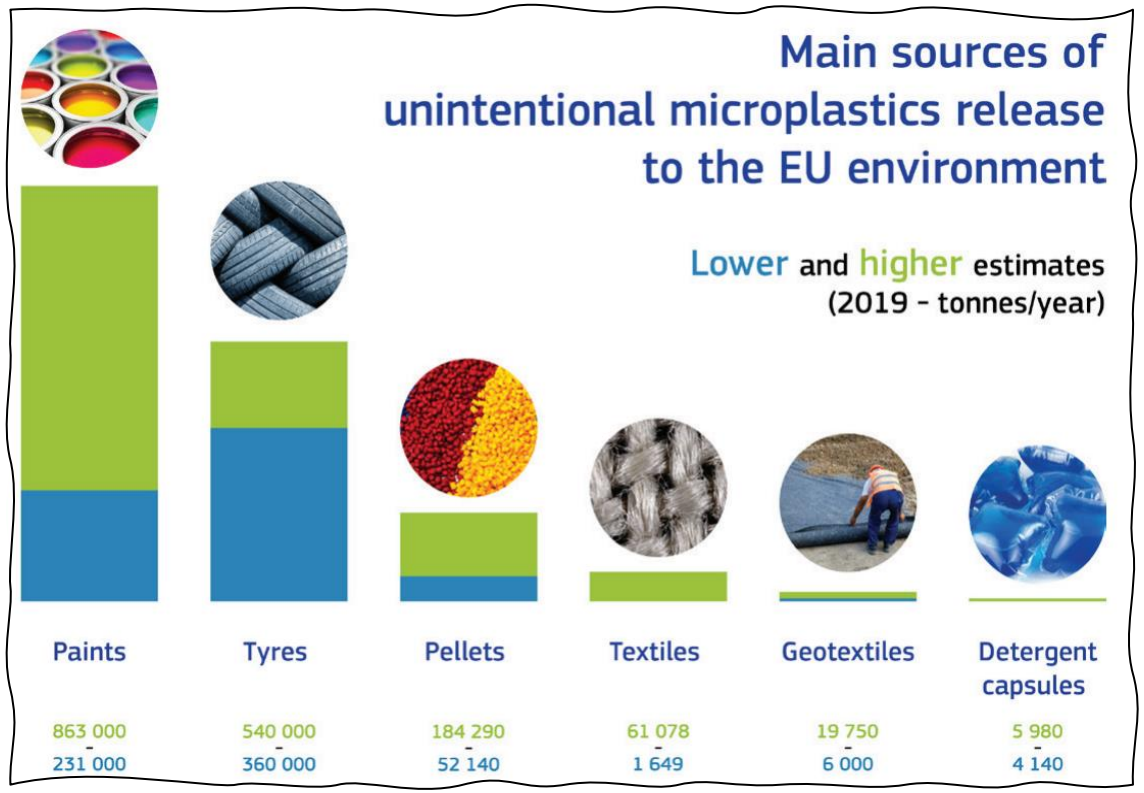
Information made available to users of recovered substances

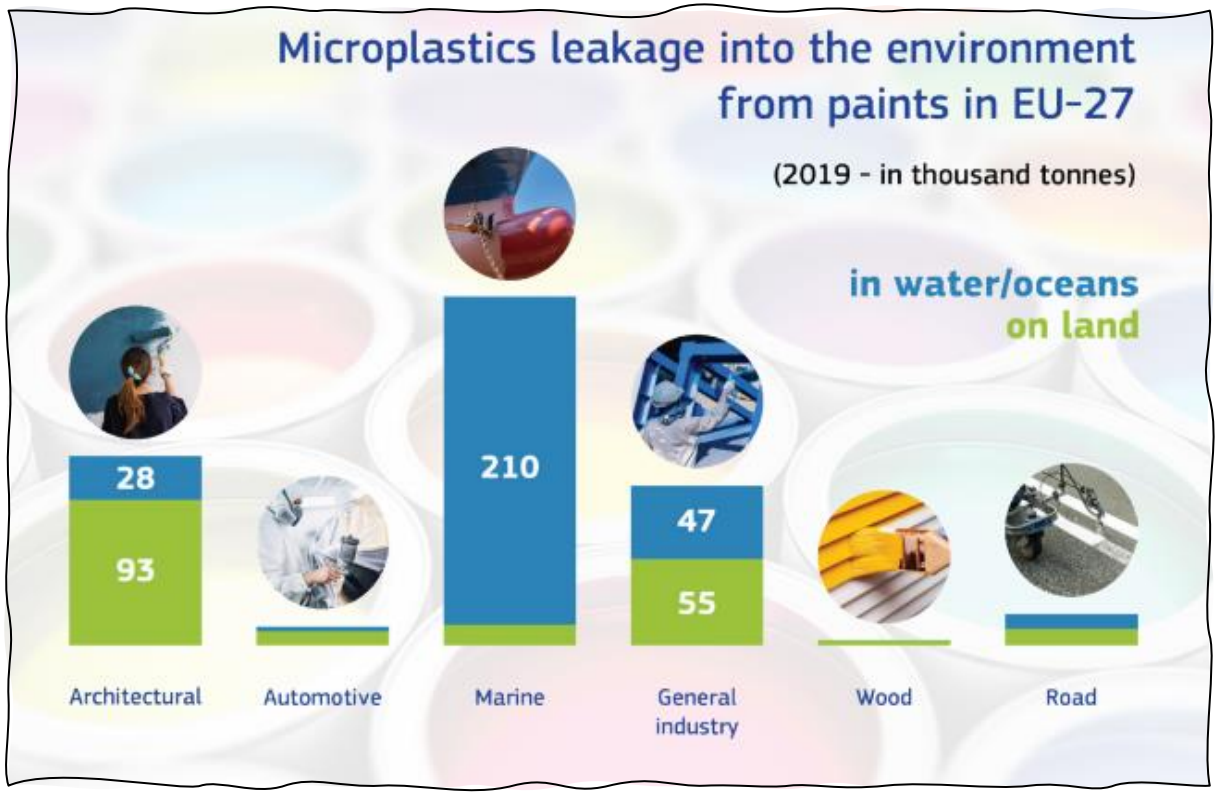
- ✓ Fraction of a recovered substance contained in a mixture
- ✓ Registration number
- ✓ Classification and Labelling Inventory (C&L Inventory)
- ✓ Safety Data Sheet (SDS) → EU Reg. 2020/878
- ✓ Exposure scenario
- ✓ Restrictions
- ✓ Authorizations



https://echa.europa.eu/documents/10162/2324906/waste_recovered_en.pdf/

Microplastics





https://op.europa.eu/en/publication-detail/-/publication/048dd075-6e47-11ee-9220-01aa75ed71a1

Synthetic polymer Microparticles

COMMISSION REGULATION (EU) 2023/2055

of 25 September 2023

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles

Synthetic polymer microparticles

polymers that are solid and which fulfil both of the following conditions:

a) are contained in particles and constitute at least 1 % by weight of those particles; or build a continuous surface coating on particles;

b) at least 1 % by weight of the particles referred to in point (a) fulfil either of the following conditions:

   i. all dimensions of the particles are equal to or less than 5 mm;

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

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R2055

Synthetic polymer Microparticles

Polymers excluded from this designation

a) **polymers which are the result of a polymerization process that took place in nature**, independently of the extraction process, and which are not chemically modified substances;

b) **degradable polymers** as demonstrated in accordance with the restriction;

c) **polymers having a solubility of more than 2 g/l** as demonstrated in accordance with the restriction;

d) **polymers that do not contain carbon** atoms in their chemical structure.

Synthetic polymer Microparticles

FORBIDDEN

Shall not be placed on the market as substances on their own or, where the synthetic polymer microparticles are present to confer a sought-after characteristic, in mixtures **in a concentration equal to or greater than 0,01 % by weight**.

The regulation, **for paints and varnishes**, applies from 17 October 2023, save exemptions.

Synthetic polymer Microparticles

…not apply…. p. 4 a)

Synthetic polymer microparticles, as substances on their own or in mixtures, for use at **industrial sites**.

p. 7 - Form 17 October 2025 suppliers shall provide the following information:

1. **instructions for use and disposal** explaining to industrial downstream users how to prevent releases of synthetic polymer microparticles to the environment;

2. the following **statement**: “The synthetic polymer microparticles supplied is subject to conditions laid down by entry 78 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council”;

3. the **information on quantity** or, as applicable, concentration of synthetic polymer microparticles in the substance or mixture;

4. **generic information on the identity of the polymers contained in the substance or mixture** that enables manufacturers, industrial downstream users and other suppliers to comply with their obligations […].

Synthetic polymer Microparticles

…not apply…. p. 5

a) synthetic polymer microparticles which are contained by technical means so that releases to the environment are prevented when used in accordance with the instructions for use during the intended end use;

b) 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;

c) synthetic polymer microparticles which are permanently incorporated into a solid matrix during intended end use.

From *17 October 2026* suppliers of products containing synthetic polymer microparticles […]shall provide **instructions for use and disposal** explaining to **professional users and the general public** how to prevent releases of synthetic polymer microparticles to the environment

Synthetic polymer Microparticles

For both cases explained …. *p. 10*

- ✓ The **information shall be provided in the form of clearly visible, legible and indelible text or, where appropriate, in the form of pictograms**.
- ✓ **The text or pictograms shall be placed on the label, the packaging, or the package leaflet of the products containing synthetic polymer microparticles or on the safety data sheet**.
- ✓ In addition to the text or pictograms, suppliers may provide a **digital tool that gives access to an electronic version of that information**.
- ✓ Where instructions for use and disposal are provided in the form of a text, they shall be in **the official languages of the Member States** where the substance or mixture is placed on the market, unless the Member States concerned provide otherwise.

Synthetic polymer Microparticles

For **synthetic polymer microparticles which are permanently incorporated into a solid matrix during intended end use** (p. 5 .c) …. *p. 12*

From *2027*, **suppliers of products containing synthetic polymer microparticles** […], **placed on the market for the first time to professional users and the general public**, **shall submit the following information to the Agency (ECHA) by 31 May of each year**:

a. a **description of the end uses** for which the **synthetic polymer microparticles** were **placed on the market** in the previous calendar year;

b. for each end use for which the synthetic polymer microparticles were placed on the market, **generic information on the identity of the polymers** placed on the market in the previous calendar year;

c. for each end use for which the synthetic polymer microparticles were placed on the market, an **estimate of the quantity of synthetic polymer microparticles released to the environment** in the previous calendar year, which shall include also the quantity of synthetic polymer microparticles released to the environment during transportation.

d. for each use of synthetic polymer microparticles, a reference **to the applicable derogation or derogations**.

PFAS

PFAS

Per- and polyfluoroalkyl substances (PFAS).
Any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it).

Persistent, Mobile, Bioaccumulation.
Various (eco)toxicological effects (e.g. endocrine disruptors, toxic for reproduction, can harm the unborn child, several may cause cancer, etc.).

Restriction

Date of intention: 15 July 2021
Expected date of submission: 13 January 2023
Final deadline for comments: 25 September 2023
Restriction entry into force: *expected 2024 or 2025*

Conditions of restriction (draft)

Shall not be manufactured, used or placed on the market as substance on their own.

Shall not be placed on the market in:
a. Another substance, as a constituent;
b. a mixture;
c. an article.

In a concentration of or above:
i. 25 ppb for any PFAS (excluded polymeric PFAS);
ii. 250 ppb for the sum of PFAS (excluded polymeric PFAS);
iii. 50 ppm per for PFAS (polymeric PFAS included).

A numbers of derogations have been also provided in the draft.

https://echa.europa.eu/en/hot-topics/perfluoroalkyl-chemicals-pfas

Thank you for your attention

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