



Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin

Risk assessment of polymers - the perspective of EU REACH

Dr. Oliver Peters

Federal Institute for Occupational Safety and Health (BAuA)

Division 5 – Federal Office for Chemicals

Baseline: Polymers have a ‚special status‘ in REACH

Article 2 (9): The provisions of Titles II and VI shall not apply to polymers.

Polymers are exempted from Registration and Evaluation under REACH.

→ Polymers are kind of a ‚blind spot‘ in REACH.

Restrictions (Annex XVII) and Authorisation (Annex XIV) however can still be applied to polymers.

Basic Problem: (non)availability of data

- **There is no obligation for registration of polymers, their additives that are necessary to preserve their stability and impurities deriving from the manufacturing process.**
 - see ECHA Guidance on monomers & Polymers for more details:
https://echa.europa.eu/documents/10162/23036412/polymers_en.pdf/9a74545f-05be-4e10-8555-4d7cf051bbed
- **Registration data only available for monomers and few oligomers that do not fulfil the polymer definition of Art. 3 (5) REACH**
 - ➔ To facilitate risk assessment and risk management of polymers: registration data is needed

Review mechanism in REACH: Article 138 (2)

2. The Commission may present legislative proposals as soon as a practicable and cost-efficient way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established, and after publishing a report on the following:

- (a) the risks posed by polymers in comparison with other substances;
- (b) the need, if any, to register certain types of polymer, taking account of competitiveness and innovation on the one hand and the protection of human health and the environment on the other.

Review mechanism in REACH: Article 138 (2)

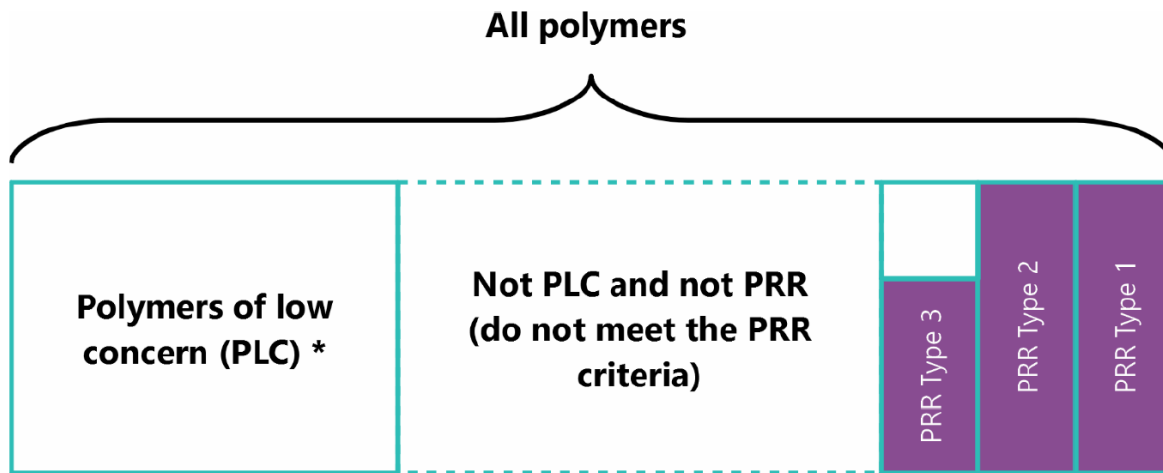
Three studies were commissioned by EU COM:

- **2012:** Review of REACH with regards to the registration requirements on polymers, Part A: Polymers (Final report)
- **2015:** Technical assistance related to the review of REACH with regard to the registration requirements on polymer
- **2020:** Scientific and technical support for the development of criteria to identify and group polymers for Registration/ Evaluation under REACH and their impact assessment

→ 2020 report (by Wood/PFA) was the basis for discussions in the CARACAL subgroup on polymers (CASG Polymers)

EU COM approach: Polymers Requiring Registration (PRR)

From 'Polymers of Concern' (PoC) to 'Polymers Requiring Registration' (PRR)



Source: <https://op.europa.eu/en/publication-detail/-/publication/1cc811ff-d5fc-11ea-adf7-01aa75ed71a1>

Polymers of Low Concern (PLC)

- **i.a. Australian Government Definition:** „A 'polymer of low concern' (PLC) is a polymer that we consider to be of low concern to human health and the environment because it meets all the criteria we have set.”

<https://www.industrialchemicals.gov.au/help-and-guides/polymer-low-concern-plc-criteria>

- **Australian PLC criteria (I):** PLCs must
 - have a number average molecular weight greater than or equal to 1,000 g/mol as well as meet **the low molecular weight species and reactive functional group requirements**
 - or
 - be a polyester manufactured solely from prescribed reactants

Polymers of Low Concern (PLC)

- **Australian PLC criteria (II): A PLC must also meet the following criteria:**
 - have a low cationic density
 - contain approved elements only
 - not contain any difluoromethylene (CF_2) or trifluoromethyl (CF_3) groups
 - be stable under the conditions in which it is used
 - not be a high molecular weight (greater than or equal to 10,000 g/mol) water absorbing polymer
 - not have any known hazard classification

EU COM approach: Polymers Requiring Registration (PRR)

Currently foreseen main steps of registration of PRRs

(Work in progress!):

1. Assessment of PRR/non-PRR/Polymeric precursor status of all polymers put on the market
2. Notification of polymers
3. Grouping of polymers for registration and formation of joint submissions
4. Registration of polymers meeting PRR criteria
5. Regulatory work by ECHA/MS CAs

EU COM approach: Polymers Requiring Registration (PRR)

➤ PRR-Criteria (flowchart) to check if polymer is a PRR, a non-PRR or a Polymeric Precursor

<https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/8715513d-67f9-4886-8798-e153de035b42/details>

1. Is the Polymer solely a precursor handled like intermediates under SCC to produce other polymers or articles? Yes = Polymeric Precursor
2. Polyester from monomers from EU-list? Yes = non-PRR
3. Polymer fluorinated? Yes = PRR
4. Polymer meeting cationic criterion? Yes = PRR
5. Polymer meeting MW criterion MW1 or MW2? Yes = PRR
6. Polymer classified as hazardous? Yes = PRR
7. Polymer having reactive functional Groups? Yes = PRR
8. Polymer surface active? Yes = PRR
9. Polymer suspected to degrade to substance(s) of concern? Yes = PRR

All 'No' =
non-PRR

EU COM approach: Polymers Requiring Registration (PRR)

- **Criteria similar to the ‘inverted PLC’ criteria (MW, oligomer content, RFG, etc.), but differ in detail:**
 - Cut-off values are different
 - e.g. all fluorinated polymers are envisaged to be PRR.
 - Polymers that are suspected to degrade to “substances of concern” are envisaged as PRR
 - Surface active polymers

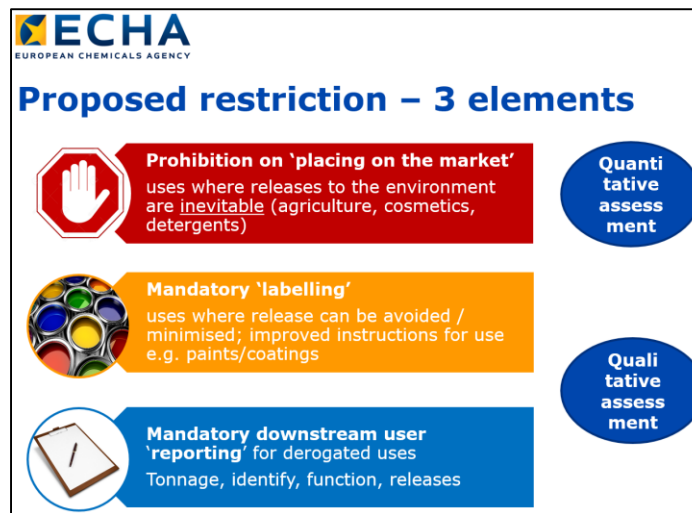
- **All CASG Polymers documents are publically available:**
<https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/806e87e4-1236-4b2b-a768-de1ac2ba15c4>

EU COM approach: Polymers Requiring Registration (PRR)

- **Discussions started in 2020 (CASG Polymers)**
- **Still work in progress (outcome and timeline???)**
 - Current delay in the Revision of REACH under the CSS
 - Outcome of Impact Assessment yet unknown
- **Up to date details might still be amended, i.a.:**
 - Substance identity of polymers + Grouping approach
 - SIR incl. Bioavailability Assessment
 - etc.

Restriction proposal for 'intentionally added microplastics'

- One of several actions of the 'EU Plastics Strategy'
- Restriction Dossier was prepared by ECHA; RAC and SEAC supported the restriction proposal
- Quite complex restriction proposal for 'synthetic polymer microparticles' currently in the political discussion in the REACH Committee



Restriction proposal for ‘intentionally added microplastics’

➤ ECHAs risk assessment conclusions:

- Inevitable release of microplastics to the environment, despite RMMs
- Widespread evidence of exposure/ingestion
- Evidence of adverse ecotoxicological effects and trophic transfer
- Degradation pathway via ‘nanoplastics’; very limited information on the risks of these transformation products
- “Extreme persistence” in the environment leads to an increasing and irreversible environmental stock
- Effect thresholds in literature not sufficient to demonstrate ‘adequate control’ of risk even with assessment factors
- Considered as ‘non-threshold’. Risk management to minimise releases

Thank you for your kind attention!

Dr. Oliver Peters
Federal Office for Chemicals
Unit 5.2 "Evaluation of Chemicals and Risk Management"

Federal Institute for Occupational Safety and Health
Friedrich-Henkel-Weg 1-25
D-44149 Dortmund

ChemG@baua.bund.de

www.baua.de and <https://www.reach-clp-biozid-helpdesk.de>