What is Left of the REACH Revision?

10 June 2026

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Ales Bartl

- Ales Bartl has a broad experience in European Union (EU) product regulatory law, including Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) regulation, the Classification, Labelling, and Packaging (CLP) regulation, Biocidal Products Regulation (BPR), medical devices, electronic products, and general product compliance and product safety. He advises on regulatory compliance of a broad range of products marketed in the EU and represents clients before EU and national competent authorities on compliance and enforcement issues, including product withdrawals and recalls.

- Ales also represents clients before the Court of Justice of the European Union and the Board of Appeal of European Chemicals Agency.

Agenda

- Update on PFAS
- REACH revision: what is left?

I. Update on PFAS

Update on PFAS

- Second public consultation ended May 25, 2026
  - 3,511 comments received (less than expected)
- ECHA/Commission to publish a summary of comments in next weeks
- Final RAC and SEAC Opinion will be published before year-end
- The Commission is already working on draft Regulation
  - It may be published as early as 1Q 2027!
  - Followed by discussions at CARACAL and REACH Committee (2 years at least)
    - Still advocacy possibilities
  - Meaning: the final Regulation may be published in 2029 already (+18 months transition period)

Commission's Position?

- Commission will have to:
  - Evaluate 8 new sectors not evaluated by SEAC
  - Make a decision on unlimited derogations for some uses (with some kind of review period) – RO3 option
- Commission driven by pro-competitiveness approach
- Previous statements: PFAS bans should be targeted on consumer uses
  - But this is complex: e.g., is engine sealing in passenger car a consumer use?

PFAS under PPWR

PFAS ban in food packaging will apply from August 12

Current PPWR Guidelines: Stepwise approach for enforcement of PFAS in food packaging:

- 1. Total Fluorine (TF) quantification (step 1): If TF is below 50 mg/kg, sample could be considered compliant.
- 2. If TF is above 50 mg/kg, methods such as pyrolysis-GC/MS can be used to confirm whether the fluorine is organic (PFAS) or inorganic in step 2. If the organic fluorine is below 50 mg/kg, the sample could be considered compliant.
- 3. Direct TOP (total oxidizable precursors) analysis is recommended to check compliance with the 25 µg/kg and 250 µg/kg concentration limit in step 3

On the basis of the evidence currently available to the Commission, all samples compliant with test (1) are also compliant with tests (2) and (3)

New Development

- France has been opposing to the approach in PPWR Guidance
- COM's PFAS task force: presentation of May 20, 2026: proposal to change the step wise approach: if TF between 10-50 ppm: go to targeted PFAS analysis
- Should be finalized in June

II. REACH Revision

REACH Revision – Status

- ‘Big’ REACH revision by way of full legislative procedure off the table
- Commission exploring possibilities to amend Annexes to REACH via comitology (by implementing acts)
- Which means:
  - Neither REACH registration, nor notification of polymers
  - No mixture assessment factor
  - No generic restrictions (amendment of Article 68 REACH would be necessary)

Generic Restrictions: Alternative Solutions

- Alternative solutions to extension of generic restrictions:
  - Recent draft Commission Regulation introducing REACH restriction of CMRs 1 in childcare products (based on existing Article 68(2) REACH); this procedure may be used as a backdoor to restrict CMRs in sensitive consumer uses (but only CMRs!)
  - Restrictions in specific product regulations (e.g., new Toys Regulation for EDs, future eco-design regulations, digital product passport…)
  - April: ECHA launched call for evidence on evaluation of the appropriateness of including endocrine disruptors in the Carcinogens, Mutagens or Reprotoxic substances Directive (CMRD) (until July 1)

Focus on EDs and PBTs

- CLP as a tool for sector-specific restrictions
  - New Toys Regulation restricting EDs
- Some EDs and PBTs in upcoming ATP already
- Importantly: the Commission is working on a regulation that will carry over all substances into CLP that have been identified as ED/PBTs/PMTs:
  - In Candidate List of SVHC
  - Under Biocidal + Plant Protection evaluations

Grouping!

- Grouping for harmonized classification and labeling (CLH) and restriction remains a priority and a threat to industry
- Typical candidates for grouping: EDs and PBT
  - phthalates and bisphenols
- April 2026: German intention to restrict bisphenols that are ED ENV in some articles (proposal by March 2027)
- The grouping approach in the upcoming PFAS REACH restriction may be challenged in the EU Court

New REACH Data Requirements?

- Can be done by Commission by implementing act
- But: only ED endpoint remains on the table
  - Not likely in near future

REACH Authorisation

- REACH authorisation will only be used for substances with limited uses

Changes to RMOA

- The Commission is considering changes to Risk Management Option Analyzis ('RMOA').
- RMOA would become a mandatory step before launching regulatory scrutiny on a substance
- Outcome would be binding
- RMOA should (more) systematically consider other routes than REACH routes: such as workers protection regulations, product level restrictions, eco-design, etc.

Focus on Enforcement

- Large quantities of non-compliant products in the EU, especially imported articles
  - Lack of level-playing field
- Boosting enforcement of imported articles/mixtures as one of the priorities of the Commission to boost competitiveness
  - Enforcement authorities understaffed/not performing = Commission's audit power
  - Stronger customs control

Revocation of Registration Numbers

- Non-compliant registration dossiers subject to registration number revocation?
  - Still under consideration
- But: can it be done without amending REACH (no data = no market)?

Thank You

Any questions?

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