Ongoing Public Consultations to Revise EU Chemicals and Sustainability Laws + PFAS Updates

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Ales Bartl

- Ales Bartl has a broad experience 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.

Alejandra Martinez Perea

- Alejandra Martínez Perea counsels clients on regulatory and compliance matters related to food and drug packaging, food and feed, medical devices, data sharing, and product safety. She also advises companies on REACH matters; the Classification, Labelling, and Packaging (CLP) Regulation; and the Biocidal Products Regulation (BPR).
- Alejandra also helps companies navigate the process of securing regulatory approvals for food contact materials within the European Union (EU) and at the level of individual Member States.

I. Summer Updates

A. Update on PFAS: Amended Background Document

Amended Background Document

- On August 20, ECHA published amended PFAS proposal ('Background Document') incorporating feedback from the first public consultation https://echa.europa.eu/documents/10162/17233/rest_pfas_bd_draft_240625_en.pdf/86488ab5-30c9-f7b9-547d-84db15535d9a?t=1755590462498
- It will form the basis for future RAC and SEAC opinions

Additional Sectors/Derogations

- Indefinite: spare parts, recycled materials (not FCM and toys)
- Time limited (mostly 13.5 years after EiF), all PFAS
  - Essential sectors (batteries, semiconductors…)
  - Lubricants, solvents, additional refrigerant uses, foam blowing agents, propellants, etc.
- Time limited (mostly 13.5 years after EiF), fluoropolymers
  - Machinery and sealing application in industrial uses
  - Cables, insulation materials for electronics
  - Technical textiles, Fuel Cells, photovoltaic…
  - Vehicle systems
  - Additional medical devices…
- “Contains intentionally added PFASs” statement for electronics and some PVC articles!

ECHA Update of August 27

- ECHA update on PFAS restriction process of August 27, 2025 (today)

https://echa.europa.eu/documents/10162/111425157/echa_update_pfas_en.pdf/6775e241-204e-af0a-a2d0-4c16ba2c138d?t=1756287349062

- ECHA's RAC and SEAC opinions to be published by the end of 2026
- *"RAC and SEAC have already made good progress on the 14 sectors covered by the original restriction proposal. However, including a further 8 sectors into the Committees' evaluations now would require significant time (…) Therefore, in the ongoing procedure, the Committees will not carry out a sector specific evaluation of these further eight sectors."*
  - Left for the Commission?

Second Public Consultation

- **Draft SEAC opinion crucial as it will be subject to second public consultation (60 days)** (likely early 2026)
  - Draft SEAC opinion will likely include all additional derogations from the Background Document
  - **Missing (or insufficient) derogation in the amended Background Document? Start preparing comments to be on time!**
    - Keller and Heckman has strong experience in helping companies filing comments in REACH restriction files
  - In parallel:
    - work on substitution plan (even derogated uses are time limited!)
    - inspect your products and supply chain (unintentional PFAS presence is covered by the restriction)

Lessons Learned from Second Consultation

- Lessons learned from first public consultation:
  - Gather your data well ahead of start of second consultation
    - Check questions asked in previous second consultations: likely to be similar (e.g., check PFCAs restriction file)
    - Check amended Background Document
    - Assume worst case
  - Avoid general two-pagers (generic statements not supported by data)
    - Submit specific data that can be referenced in the opinions to support the derogation
  - Request realistic derogations (scope/timing) based on a solid analysis of alternatives

B. Chemicals Industry Package

Content

- On July 8, the Commission issued:
  - A Communication from the Commission regarding the European Chemicals Industry Action Plan;
    - Legislative and non-legislative measures to boost competitiveness and decarbonization
  - A Sixth Omnibus simplification including; i) a proposal for a Regulation amending the recent CLP amendment (Regulation (EU) 2024/2865) as regards dates of application and transitional provisions; ii) a proposal for a Regulation amending the CLP Regulation, Cosmetics Regulation and Fertilizers Regulation as regards simplification of certain requirements and procedures for chemical products;
  - A proposal of a Regulation on the European Chemicals Agency.
  - **More detailed assessment: see our advisory available here:** Publication of an EU Action Plan for Chemicals and a Simplification Package | Keller and Heckman

REACH Revision

- The Commission has confirmed the timing of the REACH revision proposal for the end of 2025 (as part of the Chemicals Industry Package)
- Question marks remain whether it will go in the simplification way: recent communication from the EC has been mixed. For example, uncertainty pertains with regard to future REACH registration of polymers (notification only?)

II. Ongoing Public Consultations

1. The Circular Economy Act (CEA) (1)

- **Have your say:** **Call for Evidence for an Impact Assessment on the Circular Economy Act**
- **Type of act and timeline:** Proposal for a Regulation scheduled for Q4-2026
- **Feedback period**: 01 August 2025 - 06 November 2025 (midnight Brussels time)
- **Purpose of the consultation:** To inform the impact assessment and gather stakeholder feedback. In addition, targeted stakeholder feedback will be organized as well for certain players, such as SMEs.
- **Scope:** circular products, secondary raw materials and waste.
- **Goal of the CEA:** To facilitate the free movement of 'circular' products, secondary raw materials (including critical ones) and waste, and increase the supply and demand of recycled materials.
  - According to the Call for Evidence, may also tackle export of waste and secondary raw materials specifically.

1. The Circular Economy Act (CEA) (2)

- CEA will be structured on **2 pillars:**
  1. E-waste (electronic and electrical equipment) rules revision to ensure effective collection and recycling of the critical materials in the equipment.
  2. A “mix of interventions” on waste, secondary raw materials and their use in products. May include: reform of end-of-waste criteria, simplification and harmonization, and potential scope extension of EPR, reform of public procurement of circular goods criteria.
- **Regulatory Impact:** Introduction of changes to the Waste Framework Directive, the Ecodesign for Sustainable Products Regulation (ESPR), and the Packaging and Packaging Waste Regulation (PPWR) (as a minimum).
- **Next steps:** Closing of feedback on 06 November 2025; publication of a factual summary (8 weeks after 6 November) on the consultation; draft proposal by the EC by Q4-2026.

2. Omnibus Regulation on Environment (1)

- **Have your say:** Call for evidence for an initiative without Impact Assessment - Simplification of administrative burden in environmental legislation
- **Type of act and timeline:** Proposal for a Regulation planned for **Q4-2025**
- **Feedback period:** 22 July 2025 - 10 September 2025 (midnight Brussels time)
- **Scope:** environmental legislation in the areas of circular economy, industrial emissions and waste management.
- **Goal:** Reduce the administrative burden (reporting, monitoring, notifying, auditing obligations on the side of Industry and demands on the side of MS competent authorities for enforcement and implementation) without affecting the environmental objectives agreed under the existing legislation.

2. Omnibus Regulation on Environment (2)

- **Content may include:**
  - Rationalising reporting/notification obligations, for example, the discontinuation of the SCIP (substances of concern in products) database under the Waste Framework Directive;
  - Harmonisation of the provisions for authorised EPR representatives in each Member State and creation of one EU EPR competent authority/Registry;
  - Streamlining reporting obligations, removing double requirements to report, promoting further digitalisation of reporting in the area of circular economy, industrial emissions and waste management.
  - Any other?
- **Regulatory impact:** on the ESPR, WFD, PPWR.
- **Next steps:** Closing of feedback on 10 September 2025; stakeholder feedback will be summarized in the form of a staff working document and published with the proposal; draft proposal by the EC by Q4-2025.

3. Revision of the New Legislative Framework (1)

- **Have your say:** Call for Evidence for an Impact Assessment on Product legislation – ensuring futureproof rules (revision of the New Legislative Framework - NLF)
- **Type of act and timeline:** Proposal for a Regulation scheduled for **Q3 2026**
- **Feedback period:** 14 July 2025 - 02 September 2025 (midnight Brussels time)
- **Scope:** 30 legal acts which are under the scope of the NLF, icl. The Radio Equipment Directive, Medical Devices Regulation, Batteries Regulation, Machinery Regulation, Ecodesign requirements for sustainable products Regulation (ESPR), Cyber Resilience Act, and PPWR.
- **Goal:** Considering the previous evaluation of the NLF, the goal of this consultation is to revise and update the NLF to integrate digital solutions, simplify overall product framework increasing harmonization, market surveillance rules, and support the circular economy.

3. Revision of the New Legislative Framework (2)

- **Policy options:** Still to be decided between targeted amendments to a comprehensive revision of the NLF, which can include:
  - increasing digital integration through the mandatory Digital Product Passport*;
  - revising conformity assessment processes;
  - aligning the definitions with those set out in recent EU legislation, such as Regulation (EU) 2019/1020 on market surveillance;
  - improving clarity and efficiency in the way notified bodies function and strengthening their oversight; and
  - ensuring timely and consistent responses to non-compliant and dangerous products across Member States.
- **Regulatory impact:** Direct impact on the 30 legal acts covered by the NLF. There may be some transitional costs associated with the DPP, new tools & processes.

*Please see the complementary surveys to participate in the impact assessment on the Digital Product Passport (closing 27 August).

4. Single-Use Plastic Beverage Bottles – EU Rules for Calculating, Verifying, and Reporting on Recycled Plastic Content

- **Have your say:** Single-use plastic beverage bottles – EU rules for calculating, verifying and reporting on recycled plastic content
  - This implementing decision will repeal the previous one (Commission Implementing Decision (EU) 2023/2683 of 30 November 2023), which appears on the same Have Your Say consultation.
  - It enables chemical recycling in the EU, and it will help companies meet the recycled content targets under the Single-Use Plastics Directive (SUPD)
- **Status:** Feedback period to the draft implementing decision is already over (August 19).
- **Goal:** Lay down common rules for calculating, verifying and reporting on recycled plastic content in single-use plastic beverage bottles, increasing the use of recycled material in the EU
- **Next steps:** Vote in the technical committee (made of MS representatives); Commission adoption expected in the fall.

5. Other Ongoing Consultations

- **Have your say:** Toy Safety – amendment to the Toy Safety Directive as regards cobalt
  - Feedback period: 11 August 2025 - 08 September 2025 (midnight Brussels time)
  - Timeline: Commission adoption planned for Q4 2025.
  - Goal: The amendment proposes specific exemptions where cobalt use would be permitted, even though it's a CMR substance classified as 1B. The proposal outlines specific exemptions where cobalt use may be permitted under certain conditions, such as in stainless steel, electrical components, and certain neodymium-based magnets.

- **Have your say:** Biotech Act (specific consultation via questionnaire, available here)
  - Consultation period: 04 August 2025 - 10 November 2025 (midnight Brussels time)
  - Timeline: Planned for Q3-2026
  - Goal: Improve the size and competitiveness of the biotechnology sector in the EU while maintaining high safety standards.

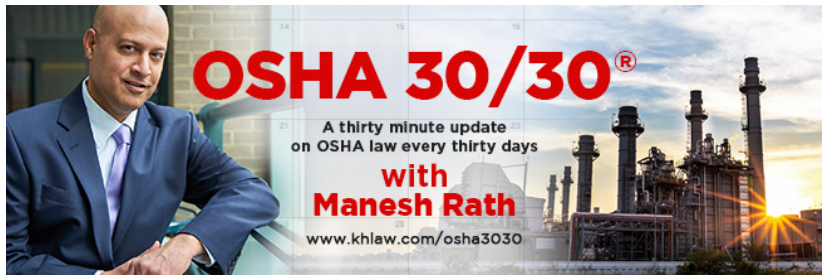
Practical Tips for a Successful Public Consultation

General Rules and Recommendations

- Feedback can be submitted in the form of a summary (comment in a box) or in an attachment as a separate file. Possibility to remain confidential.
- Recommendations:
  - general comments without specific data/request not very useful
  - submissions should elaborate on practical problems based on Industry experience and propose targeted and proportionate solutions in the form of key policy recommendations;
  - joint submissions by multiple companies may carry stronger impact (either submitted together in a sort of task force, or by Industry Associations)
  - Keller and Heckman has good experience in setting out ad-hoc task force for advocacy
- Ad-hoc advocacy (outside of public consultations) still possible, but impact uncertain (joint submissions are more impactful)

Upcoming Events

Please join us at 10:00 AM Eastern U.S.
Wednesday, 01 October 2025
www.khlaw.com/REACH-3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, September 17, 2025
www.khlaw.com/OSHA3030

Please join us at 1:00 PM Eastern U.S.
Wednesday, October 1, 2025
www.khlaw.com/TSCA-3030

Thank You

Any questions?

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