

International Trade & the Critical Chemicals Alliance + Update on POPs Regulation

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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.





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- 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. General Updates



General Updates



- Updated PFAS Restriction timelines:
 - Second public consultation will start in March 2026
 - ♦ ECHA will hold a webinar on how to prepare data; on October 30, 2025 Events ECHA
- COM is considering postponement of date of applicability of the **Deforestation** Regulation for 1 year (30 December 2026 for large operators and 30 June 2027, for micro- and small enterprises)
- European Commission's Regulatory Scrutiny Board has issued a negative opinion on the impact assessment for the REACH revision – proposal likely to be delayed
- Chemical Package (Omnibus VI, published in July 2025): Council approves <u>proposal</u> to postpone certain application dates of the CLP Regulation to 1 January 2028 for mandatory formatting requirements, provisions on advertisements and distance sales regarding chemical products





II. International Trade & the Critical Chemicals Alliance



Background



- Context: challenges which the EU chemicals industry is facing incl. high energy costs and competition from non-EU countries
 - Trade deficit specially in the production of critical molecules (e.g., sodium carbonates)
 - ♦ EU global market share has declined by over 50% since 2003 (EC estimation)
 - Estimated 200.000 direct jobs at risk (<u>CEFIC Report estimation</u>)
 - Pressure to the European Commission to establish trade defence mechanisms against unfair practices and to protect EU production of strategic molecules
- See, e.g. Parliamentary question to EC on EU Critical Chemicals Act initiative (E-002039/2025)

Call for an EU Critical Chemicals Act (1)



• Call for EU Critical Chemicals Act (12 March 2025) by some EU Member States (incl. France, Italy, Spain) while Germany opposes, to designate key chemical compounds as "strategic" (i.e., building-block molecules that are upstream to all the European strategic value chains).

List includes:

- Olefins (petrochemistry & organic chemistry): Ethylene, Propylene, Butadiene
- Aromatics (key platforms for multiple industries): Benzene, Toluene, Xylene, Phenol,
 Styrene (Pharma, adhesives, construction, automotive, electronics, plastics, detergents)
- Agriculture & Energy / Advanced Materials: Ammonia, Methanol
- Health, Hygiene & Construction: Chlorine, Sodium Hydroxide (PVC)
- Mobility, Electronics & Food: Sulfur, Silicon, Sodium Carbonates
- Advanced & High-Tech Materials: Hydrofluoric Acid (batteries, electronics, flame retardants)
- ♦ Food & Health Industries: Methionine, Lysine

Call for an EU Critical Chemicals Act (2)



- Also branded as "strategic": Low-carbon footprint molecules can substitute existing strategic molecules (i.e., alternative bio-based molecules).
- MS calls for measures:
 - Investments in industrial transformation to develop sustainable production platforms and advance technology (biofuels, plastic recycling, bioplastics, and downstream chemical chains) and modernization of existing plants
 - « EU strategic project » labels for strategic projects
 - To adapt/expand state aid schemes to support strategic chemicals
 - ♦ Agile monitoring of production capacities → targeted incentives
 - Use trade defense mechanisms (anti-dumping, anti-subsidies, safeguards) to protect EU producers from unfair trade practices

European Chemicals Industry Action Plan



- Response to this Call by the EC in the <u>European Chemicals Industry Action Plan</u> (8 July 2025) to focus on 4 intervention areas:
 - 1) strengthening resilience: maintaining critical production in EU and opening new
 markets and protecting the EU industry
 - 2) securing energy supply, supporting decarbonisation and shift towards clean and circular economy
 - 3) creating lead markets and promoting innovation; and
 - 4) simplifying the regulatory framework.
- What about critical/strategic molecules and trade measures? What happened with the initiative for an EU Critical Chemicals Act?

The Critical Chemicals Alliance (1)



- ◆ EU Chemicals Industry Action plan introduces Critical Chemicals Alliance "as a strategic umbrella that enables cooperation with Member States and stakeholders, so that the risks of production capacity closures in the sector can be mapped and addressed."
 - Alliance will facilitate discussions on key trade challenges, supply chain dependencies, and intellectual property rights issues
 - Tasks include:
 - Developing criteria for identifying chemical sites and molecules that are critical for the EU's strategic objectives
 - Mapping critical molecules which would benefit from enhanced monitoring under the Customs Surveillance System and could serve as a basis for a potential legislative proposal (so, proposal not dead yet!)
 - Coordinating between EU and MS to align investment priorities and allocate funds incl.
 Important Projects of Common European Interest (IPCEIs)

The Critical Chemicals Alliance (2)



- Potential Projects of Common European Interest (IPCEIs) for the chemicals sector (e.g., 1. Joint European Forum for IPCEI (JEF-IPCEI) to identify potential strategic projects in biotech chemicals; 2. Circular Advanced Materials Project (design currently ongoing))
 - MS may design of aid measures for clean transition technologies and infrastructure projects, but IPCEI realization depends on fiscal capacity of participating Member States
- In addition, EC to assist MS to designate EU Critical Chemical Sites
 - ♦ To modernise sites at risk of closure and to facilitate their green transition, in line with State aid rules where applicable
 - Investments to be made via co-creation of regional plans for EU Critical Chemical Sites and via funding tools in place already

The Critical Chemicals Alliance (3)



Timeline for action:

- Establish a Critical Chemicals Alliance at EU level (Q4 2025)
 - Set up support for MS and stakeholders to develop criteria to identify critical production sites and molecules in the EU (Q4 2025)
 - Assist MS and stakeholders in mapping critical molecules, which will serve as a basis for enhanced monitoring under the Customs Surveillance System, supply diversification, as well as a possible legislative proposal on critical molecules (2026)
 - Assist Member States and Regions in setting up EU Critical Chemicals Sites, to facilitate investments, innovation, improve access to funding and assist the modernisation of critical production capacities (2026).

International Trade (1)



From Action Plan:

- ♦ EC to expand EU network of free trade agreements and review existing ones to promote trade in chemicals incl. access to raw materials
- Trade defence measures (e.g., anti-dumping, anti-subsidy, or safeguard measures where needed)
 - 30 June 2025: 46 measures in force which concern chemicals mainly concerning imports from China
 - Update of EU trade defence toolbox to respond to unfair pricing practices in the chemical sector
- Monitoring import of chemicals via Import Surveillance Task Force + specific monitoring for certain industrial chemicals (March 2025)

International Trade (2)



- Stronger enforcement of EU chemicals legislation for non-compliant imports: role of the Digital Product Passport to increase transparency and targeted risk-based checks as part of customs reform and market surveillance
- Summary of trade actions:
 - Strengthen the monitoring of chemicals under the Import Surveillance Task Force including for trade defence (Q3 2025)
 - ♦ Support the development of harmonised risk-based controls for chemicals (Q4 2025).
 - Coordinate a package of enforcement and market surveillance actions, including through the integration of REACH through the EU Single Window Environment for Customs, as well as by prioritising chemicals in national market surveillance work plans (Q4 2025)

What to Expect?



- More opportunities for EU based industry and investments for innovative projects
- Increased enforcement activities and import monitoring
- Would it be enough to enhance competitiveness and protect critical/strategic chemicals?





III. POPs Regulation



1. Stockholm Convention



- Stockholm Convention (SC) on Persistent Organic Pollutants (POPs): <u>Annexes</u>
 with restricted substances
- Applicable worldwide (few exceptions: US)
- ♦ EU is often submitter of the proposal for a new POPs
- ♦ 2-5 years procedure

2. EU Regulation on POPs



- SC not applicable directly: need for national implementation
- ♦ EU: <u>POPs Regulation</u> (EU 2019/1021)
- Restricts substances in the Stockholm Convention
- Sometimes even before SC listing (e.g., PFOA)

3. Scope of Restrictions in POPs Regulation



- Annex I: prohibition on manufacturing, placing on the market and use (with specific exemptions)
- Annex III: release reduction provisions (stockpiles, articles in use); and
- Annex IV: waste management provisions
- ♦ 33 substances currently (<u>List of substances subject to POPs Regulation ECHA</u>)

4. Recent Additions to EU POPs Regulation



- UV-328 UV stabilizer in plastics and inks (OJ July 15, entry into force August
 4)
- Dechlorane flame retardant (e.g., in electronic products OJ imminent, entry into force within 20 days after OJ)
- No transition period: importance of early warning!

5. Other Substances in the Pipeline



- Updated list <u>here</u>
- Long-chain PFCAs and their salts CnF2n+1CO2H (where 8 ≤ n ≤ 20) recently listed in SC (2025)
- Chlorpyrifos (insecticide) recently listed in SC (2025)
- Chlorinated paraffins C14-17 recently listed in SC (2025)
- bis(2-ethylhexyl) tetrabromophthalate (TBPH) (flame retardant) proposal for SC listing: public consultation ended in August
- polyhalogenated dibenzo-p-dioxins and dibenzofurans early stage
- D4/D5/D6 were set aside

6. General Exemptions



- Substance present as an unintentional trace contaminant (specific thresholds in the Annex)
- 6-months sell-off period for articles produced before the entry into force of the restriction
- Indefinite exemption for articles already in use before the entry into force of the restriction
- Commission's guidance document on the Implementation of Article 4(2) of the POPs Regulation

Upcoming Events





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



Please join us at 1:00 PM Eastern U.S. Wednesday, October 22, 2025
www.khlaw.com/OSHA3030



Please join us at 1:00 PM Eastern U.S. Wednesday, December 10, 2025 www.khlaw.com/TSCA-3030





Any questions?

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