



# 2025 Highlights & What to Expect in 2026

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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.



# Agenda

## 2025 Highlights\*

- I. PFAS Restrictions
  1. REACH Restriction and
  2. PPWR restriction
- II. Transition period for new CLP hazard classes
- III. Microplastics
  1. Reporting obligations on microplastics and
  2. Preventing Plastic Pellet losses Regulation
- IV. REACH revision (update)
- V. OSOA Package
- VI. EUDR (update)
- VII. Remedies

## What to Expect in 2026

- I. Commission Work programme and Have your Say Initiatives
- II. Pending proposals
- III. Important deadlines to keep in mind

\*☹️ We are leaving out developments on CSRD, CSDDD, CBAM, ETS, Recycled Plastics, updates to the Battery Regulations on due diligence...

# 2025 Highlights



# I. PFAS Restrictions: The PFAS REACH Restriction





# Amended Background Document

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- ◆ On August 20, ECHA published amended PFAS proposal ('Background Document') incorporating feedback from the first public consultation; available [here](#)
- ◆ It will form the basis for future RAC and SEAC opinions
- ◆ RAC and SEAC will not evaluate the newly proposed exemptions
  - ◆ Left for the Commission

- ◆ **Draft SEAC opinion will be subject to second public consultation (60 days) (March/April 2026)**
  - ◇ In the form of questionnaire but free answers also possible
  - ◇ ECHA held a webinar on how to prepare on October 30, 2025 + issued a guidance [here](#)
  - ◇ November 2025: updated Mapping of PFAS uses evaluated in the SEAC draft opinion [here](#)
- ◆ ECHA's RAC and SEAC Opinions to be published by the end of 2026



# European Commission Stage

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- ◆ When RAC and SEAC finalize their opinion, they will be shifted to the European Commission for final decision
  - ◇ Many rounds of discussions at Commission's REACH Committee
- ◆ No public consultation, but still advocacy possibilities! – either directly with the Commission, or through MS representatives at REACH Committee
- ◆ **Final Restriction Regulation not likely before 2029/2030**
  - ◇ + transition period (18 months proposed)
- ◆ Final Regulation subject to legal challenge



## II. PFAS Restrictions: Article 5.5 of the PPWR



# Packaging and Packaging Waste Regulation – PFAS

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- ◆ [PPWR](#) Article 5.5. PFAS restriction will be applicable from August 12, 2026
- ◆ **Food** packaging will be prohibited if it contains PFAS in a concentration of or above:
  - ◇ 25 ppb for any PFAS targeted PFAS analysis
  - ◇ 250 ppb for the sum of PFAS measured as sum (targeted PFAS analysis)
  - ◇ 50 ppm for PFAS (polymeric PFAS included)
    - *Mirrors proposed REACH PFAS restriction. EC will conduct an evaluation to assess the need to amend or repeal within 4 years from EIF*
- ◆ ECHA current activities on PPWR re. PFAS:

Call for evidence to support the preparation of a study report under PPWR (due by 31 December 2026): [Mandate to ECHA](#) (such mandate includes the possibility to amend the PPWR PFAS restriction in order to avoid overlapping with REACH/POPs/FCM restrictions) and [Background Note](#).



# III. Transition Period for New CLP Hazard Classes



# New Hazard Classes

- ◆ Amendment of CLP Annexes by [Delegated Regulation 2023/707](#)
- ◆ New Hazard Classes:
  - ◆ PBT (persistent, bioaccumulative, toxic)
  - ◆ vPvB (very persistent, very bioaccumulative)
  - ◆ PMT (persistent, mobile, toxic)
  - ◆ vPvM (very persistent, very mobile)
  - ◆ Endocrine disruption for human health
  - ◆ Endocrine disruption for the environment
- ◆ Transitional periods (substances already on the market: 1 November 2026, new mixtures: 1 May 2026, mixtures already on the market: 1 May 2028)

# Some Useful Principles for ED Assessment

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- ◆ Self-classification based on assessment of available data
  - ◆ No requirement to generate new studies (but: new REACH data requirement?)
  - ◆ Existing studies: any ED effect? (thyroid...)
  - ◆ Check ED indications in literature review
- ◆ No data = no classification
- ◆ In case of disagreement between registrants/in the supply chain: possibility to set up an expert panel (good contractual basis necessary!)



## IV. Microplastics, Pellet Losses







# 1. Reporting Obligations on Microplastics



- ◆ **Downstream information obligation:**
  - ◇ SPM for use at industrial sites – the reporting obligation started October 17, 2025!
    - Use instructions, quantity (concentration), statement
  - ◇ Other derogated uses: longer reporting transition periods
- ◆ Yearly reporting requirements **to ECHA** related to plastic pellets for plastic manufacturing (from 2026) and other SPM at industrial setting (from 2027): identity, uses, releases



## 2. Preventing Plastic Pellet Losses Regulation



# Regulation on Preventing Plastic Pellet Losses to Reduce Microplastics Pollution (1)

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- ◆ Published on November 12 in the OJEU ([here](#))
- ◇ General application from 17 December 2027. However,
  - Some articles are already applicable from 16 December 2025. Examples include:
    - Article 3.1. re. obligation of economic operators to ensure that losses are avoided and that when they occur that they take immediate action to clean up/contain them
    - Article 5.6 second subparagraph re. keeping records of annually estimated quantities of losses and total quantities of plastic pellets handled
  - Some delayed application from 17 December 2028 for shippers and operators, agents, and masters of seagoing vessels

# Regulation on Preventing Plastic Pellet Losses to Reduce Microplastics Pollution (2)

- ◆ Main obligations for operators include:
  - ◆ Notify national authorities about each installation
  - ◆ Take immediate action to contain and clean up any pellet losses
  - ◆ Develop a risk management plan for each installation + DoC
    - Certification regime depending on company's size
  - ◆ New labelling obligations for plastic pellets that qualify as synthetic polymer microparticles under Annex XVII REACH
    - Image to add to the label, packaging, packaging leaflet, or safety data sheet





# V. REACH Revision: Update



# REACH Revision – Status

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- ◆ The Commission was aiming at REACH revision proposal for the end of 2025
- ◆ BUT: end of September, Commission's impact assessment for the REACH revision was struck down by Commission's Impact Assessment Board: Commission needs to rework it; delay + likely narrower scope



- ◆ Latest off-record statements by EU institutions:
  - ◆ REACH registration of polymers still under discussion (notification only?)
  - ◆ Generic Restrictions: likely only EDs and possibly PBTs (i.e., not STOT RE, Respiratory Sensitizers, PMTs...)
  - ◆ Mixture assessment factor off the table
  - ◆ New REACH data requirements for endocrine disruptors (and PMTs?): likely
  - ◆ Change in RMOAs: less power for MS, more power to ECHA



# VI. One Substance One Assessment (OSOA) Package



- ◆ OSOA Package:
  - ◆ October 21, 2025: final texts have been adopted by European Parliament
  - ◆ Publication: early 2026 likely



# 1. Regulation Establishing a Common Data Platform on Chemicals



- ◆ Regulation establishing a common data platform on chemicals + Annexes
- ◆ Creation of a common data platform centralizing and consolidating data generated by EU agencies (ECHA, EFSA, EMA, EPA)
- ◆ Including repository of limit values + new EU centralized framework for human biomonitoring data
- ◆ Database of study notifications
- ◆ Database of environmental sustainability-related data, a database on chemicals in articles or products, a database on alternatives to substances of concern, and a dashboard of indicators on chemicals
  - ◆ SCIP database deleted?



## 2. Re-attribution of Scientific and Technical Tasks Amongst Agencies



- ◆ Regulation on the re-attribution of scientific and technical tasks in the area of chemicals
  - ◇ Stronger role for ECHA: the Proposal refers to (future) specific legislation that will reattribute tasks from Commission services to ECHA regarding POPs, WFD, PPWD, cosmetics, observatory for nanomaterials, toy safety, medical devices
  - ◇ Scientific committees (SCCS, SCHEER) to gradually disappear
  - ◇ Reallocates to ECHA tasks under RoHS Directive



- ◆ Will keep its role
  - ◇ At least for exposure assessment; but limit values harmonized (?)
- ◆ Where there is a divergence between EFSA and another EU regulatory body in scientific opinions, the authorities shall prepare a report; the Commission may request ECHA to prepare a proposal for harmonized classification or amend an existing one
  - ◇ EFSA would in such case be required to cooperate with ECHA in developing the proposal



## VII. EUDR Update



# EUDR (Regulation (EU) 2023/1115) Update

- ◆ The EUDR is scheduled to enter into force by 30 December 2025. However:
  - ◆ On 21 October, the European Commission published a proposal to simplify the EUDR. On 19 November 2025, the Council adopted its negotiating mandate to **postpone the EUDR for medium large operators until 30 December 2026, and for micro/small operators until 30 June 2027**. On 26 November, the EU Parliament adopted its position confirming the 1-year delay.
  - ◆ **Next steps:** vote at the European Parliament on 16 December, and publication in the OJEU before 30 December 2025
  - ◆ Other Amendments include:
    - Commission mandated to review and assess the administrative burden of the EUDR by 30 April 2026, to be accompanied by a legislative proposal if needed.
    - The obligation and responsibility for submitting the due diligence statement (DDS) would fall exclusively on the operators who first place the product on the market; so downstream operators are no longer required to submit separate DDS
    - Proposed removal of wood-derived products under code ex 49: printed books, newspapers, pictures, other printed materials, manuscripts, typescripts, and plans



## VIII. Remedies



# Legal Remedies: TiO2 case

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- ◆ In general, EU legal acts can be challenged for annulment in the EU General Court
- ◆ Landmark TiO2 case (Case C-71/23)
- ◆ Hazard classifications must be based strictly on intrinsic properties of the substance
- ◆ EU institutions must verify that scientific evidence is reliable, relevant, and complete
  - ◇ Courts must verify whether the scientific assessment is manifestly incorrect
- ◆ Scientific uncertainty does not justify lowering evidentiary standards



# What to Expect in 2026



- ◆ Commission Communication from 21 October calling for simpler regulation and smoother implementation of EU rules to boost competitiveness: work focused on reducing administrative burdens and continuing with the omnibus legislative packages
- ◆ *New initiatives include:*
  - ◇ Circular Economy Act (legislative, Article 114 TFEU, Q3 2026) – Have your Say Public consultation (over)
  - ◇ European Product Act incl.
    - Update of the new legislative framework of product rules (Q3 2026) (Have your say public consultation), Update of rules on the market surveillance and compliance of products (Q3 2026) (Have your say public consultation) and Update of Rules on standardisation (Q3 2026)



◆ ***Evaluations and fitness checks scheduled:***

- ◆ Evaluation of the fertilising products Regulation (Q3 2026)
- ◆ Evaluation of the cosmetic products Regulation (Q4 2026)
- ◆ Evaluation of the European Food Safety Authority (Q2 2026)
- ◆ Evaluation of the biocidal products Regulation (Q4 2026)

◆ ***Pending proposals (not yet adopted but which have not been withdrawn):***

- ◆ Proposal for a Regulation amending Regulations (EC) No 1272/2008, (EC) No 1223/2009, and (EU) 2019/1009 as regards simplification of certain requirements and procedures for chemical products
- ◆ Proposal for a Regulation on the European Chemicals Agency and amending Regulations (EC) No 1907/2006, (EU) No 528/2012, (EU) No 649/2012, and (EU) 2019/1021
- ◆ Proposal for a Regulation amending Directives 2006/43/EC, 2013/34/EU, (EU) 2022/2464, and (EU) 2024/1760 as regards certain corporate sustainability reporting and due diligence requirements
- ◆ Proposal for a Directive on substantiation and communication of explicit environmental claims (**Green Claims Directive!**)

- ◆ [EC Communication](#) on 2030 Consumer Agenda and Action plan for consumers in the single market, 19 November
  - ◇ Transposition and implementation of existing rules
    - [Directive](#) on empowering consumers for the green transition: to be transposed by 27 March 2026 and applicable from 27 September 2026 ([FAQ DOCUMENT](#) PUBLISHED)
    - Harmonised label for the commercial guarantee of durability and Harmonised notice on the legal guarantee of conformity ([OJEU Publication](#)) – applicable from 27 September 2026

# Key 2026 Deadlines to Keep in Mind

- ◆ **14 June 2026:** Publication of Guidelines on compliance and due diligence on the Forced Labor Regulation (applicable as of 14 December 2027)
- ◆ **1 July 2026:** CLP Stop the Clock, some amendments introduced to Regulation 2024/2865 will apply from 1 July 2026\* while most provisions are deferred to 2028 (see [here](#))
- ◆ **12 August 2026:** PPWR PFAS Restriction (Art.5.5) – Also, on the PPWR:
  - FAQ Document (**Q1 2026**)
  - [Delegated Act](#) on the exemptions from reuse obligations for plastic wrappings and straps (**Q4 2025/Q1 2026**)
  - [Delegated Act](#) on rules on national registers of producers (**Q1 2026**)
- ◆ **27 September 2026:** Empowering consumers Directive and harmonized labels of legal and commercial guarantees
- ◆ **30 December 2026:** EUDR application date for medium and large operators (if delay is approved)
- ◆ **End of 2026:** Revision of the WEEE Directive

*\*Article 1, point (3)(b), Article 1, points (4) to (7), Article 1, point (12)(a), Article 1, point (13), Article 1, points (15)(a) and (b), Article 1, points (17), (18), (22) and (23), points (4), (8), (10) and (11) of Annex I and point (1) of Annex II*

# Thank You and see you in 2026!

Any questions?



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