



Keller and Heckman LLP Presents
REACH 30/30
a Webinar Series



Updates on PFAS and CLP

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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 Martínez 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. Update on PFAS



New Packaging and Packaging Waste Regulation – Prohibition of PFAS in Food Packaging

- ◆ Projected timeline for Publication in the Official Journal of the European Union: end 2024; will apply 18 months after (mid-2026 tentatively)
- ◆ **Food packaging** will be prohibited if it **contains PFAS** in a concentration of or above the following limit values:
 - ◇ **25 ppb** for any PFAS as measured with targeted PFAS analysis
 - ◇ **250 ppb** for the sum of PFAS measured as sum of targeted PFAS analysis
 - ◇ **50 ppm** for (i) fluoropolymers, and (ii) if targeted PFAS analysis not available
 - **Based on total fluorine content**

PFAS REACH Restriction: Timing

- ◆ **Public consultation:** March – September 2023
 - ◇ More than 5000 comments, mainly related to fluoropolymers
- ◆ ECHA's committees **RAC and SEAC** now working on their Opinion
 - ◇ Discussions organised sector by sector
 - ◇ E.g., food contact materials scheduled for September and November meetings: no specific outcome available as yet
- ◆ Fluoropolymers in general?

Second Public Consultation

- ◆ **(Draft) SEAC opinion crucial as it will be subject to second public consultation!** (likely mid-2025)
 - ◆ Focused on socio-economic aspects of bans and on derogations
 - ◆ Opportunity to request further derogations, or longer transition period
 - ◆ Opportunity to submit:
 - data on available and upcoming techniques to completely destroy fluoropolymers at the end of life
 - Existing best practices in the supply chain to ensure that fluoropolymers are disposed of properly, including recycling
 - recyclability limited because PFAS are typically used in mixtures?

European Commission Stage

- ◆ When RAC and SEAC finalise their opinion (mid 2026 likely), it will be **shifted to the European Commission for final decision**
 - ◇ Discussions at CARACAL, and at the Commission's REACH Committee
- ◆ No public consultation, but still **advocacy possibilities!** – either at CARACAL, 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 may be subject to legal challenge

General Statements Regarding PFAS



- ◆ **Chemicals Industry package** announced by the new Commission: incorporates 'Clean Industry Deal' goals; should bring **'clarity on PFAS'**
- ◆ Statement by Ursula Von Leyen:
 - ◇ EU intends to propose exemptions from PFAS restriction if they are needed to help industry meet green and digital transition goals
- ◆ September statement by German chancellor: Germany will advocate pragmatic approach to PFAS not hindering industrial competitiveness
- ◆ April 2024 BauA statement: *'dossier submitters could consider whether restrictions versus prohibitions would be appropriate to address the risks throughout lifecycle'*

Possible Outcome – Non-Polymeric PFAS



- ◆ **Non-polymeric PFAS for non-essential uses:** likely restricted, with more derogations if the use is essential and where no alternative
- ◆ November 20, 2024 progress update: batteries, fuel cells and electrolyzers mentioned specifically
 - ◆ Possibly also medical devices and semiconductors
- ◆ Packaging/FCM: not likely to receive derogations

Possible Outcome – Polymeric PFAS

◆ Polymeric PFAS:

- ◆ Either remain in the scope, with more derogations (especially for industrial uses)
- ◆ Or out of the scope, with alternative measures such as setting out waste management rules under waste legislation (prevent landfilling and/or require controlled incineration + recycling, coupled with EPR scheme)
- ◆ November 20, 2024 progress update: regarding fluoropolymers, information gathered in public consultation *'may form basis for alternative restriction options'*



II. Update on CLP





A. CLP Amendment



CLP Amendment



- ◆ [Amending Regulation 2024/2865](#) published on November 20, 2024
- ◆ Complete outline of changes: [K&H advisory of November 22, 2024](#)

Main Take-Away Message

- ◆ Incorporation of new hazard classes (ED, PBT/vPvM, PMT/vPvM)
 - Prioritized for Harmonized Classification and Labeling ('CLH')
 - ED/PBT/vPvB/PMT/vPvM in Candidate List + BP/PPP = will receive CLH
- ◆ Commission to initiate CLH procedure (EFSA indirectly)
- ◆ Grouping for CLH

- ◆ CLH is a cornerstone for generic restrictions (either under REACH, or under specific regulations)
 - ◇ Focus on ED (new REACH data requirement!)

Other Elements

- ◆ Changes in notification to ECHA Classification and Labelling Inventory
- ◆ Classification of specific forms or physical states of substances/mixtures
- ◆ Classification of multi-constituent substances
- ◆ Introduction of the new approach methodologies ('NAM')
- ◆ Digital labels, fold out labels, labeling formats



B. New ECHA Guidance on ED/PBT/vPvB/PMT/vPvM Criteria



New ECHA Guidance

- ◆ Long-awaited Guidance on the Application of CLP criteria, and in particular, its [Part 3 \(Health Hazards\)](#), which is related to ED for human health, and [Part 4 \(Environmental Hazards\)](#), which is related to ED for environment and to PBT/vPvP/PMT/vPvM

PBT/vPvB/PMT/vPvM

- ◆ PBT/vPvB: REACH Annex XIII criteria
- ◆ PMT/vPvM: carbon–water partition coefficient (log KOC) - rather straightforward

ED

- ◆ Criteria for ED:
 - ◇ ED activity
 - ◇ ED adversity
 - ◇ biologically plausible link
- ◆ Guidance based on 2018 Guidance documents for identifications of ED under biocides and plant protection products regulations and on OECD 150 test guidelines
- ◆ But: extends ED modalities (to non-EATS) and thus also the notion of ‘hormone’ and ‘ED activity’
 - ◇ + ‘any thyroid effect means ED effect’

ED Assessment Hurdles

- ◆ Based on blurred/strict criteria, companies may be facing the need to classify many substances as Cat. 2 ED ('suspected' ED)
- ◆ The Guidance shies away from giving specific borderline examples between ED Cat. 1, Cat. 2, and 'no classification.' As stated by ECHA during the [webinar held on November 21](#), the draft Guidelines did include such examples; however, they were removed because of the lack of consensus.
- ◆ But: we do not expect any strict enforcement until the criteria are clarified

Some Useful Principles for ED Assessment

- ◆ Self-classification based on assessment of available data
 - ◇ No requirement to generate new studies
 - ◇ Consider forms or physical states in which the substance or mixture is placed on the market or used
- ◆ No data = no classification
- ◆ Use of external experts
- ◆ In case of disagreement between registrants/in the supply chain: possibility to set up an expert panel (good contractual basis necessary!)

Consequences

- ◆ Rethink/reevaluate substance portfolio
- ◆ Seek external/legal help
- ◆ Opportunities
 - ◇ EU to push new hazard classes at GHS/UN level to give competitive advantage to EU Industry – ED first

Thank You

Any questions?

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