



# Product Liability Litigation in the EU

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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.





## A. New EU Product Liability Directive



# New Product Liability Directive (1)

- ◆ New Directive on consumer product liability 2024/2853 (Applicable to products placed on the EU market on or after 9 December 2026, with some exceptions)
- ◆ Wide definition of ‘product’: includes software and products such as drinking water
- ◆ The producer (defined broadly) must compensate damages caused by the defective product to individuals and private property
- ◆ Defective product: lack of the safety that a person is entitled to expect or that is required under Union or national law



# New Product Liability Directive (2)

- ◆ The victims must prove that (i) they have suffered damage, (ii) the product was defective, and (iii) the product caused the damage (unless proof is ‘excessively difficult’, and the causality is at least ‘probable’)
- ◆ Introduces disclosure obligation: Courts can oblige defendants to disclose relevant evidence if the injured party has made a sufficiently plausible claim for damages
  - ◆ New concept in many EU Member States



## B. Class Actions in the EU



# EU Class Actions Directive

- ◆ Not widely used in the EU as yet (unlike in the US)
- ◆ [Representative Actions Directive \(EU\) 2020/1828](#)
- ◆ Encourages consumer organizations designated by MS authorities to file class actions (financial incentives)
- ◆ Facilitates cross-border class actions
- ◆ Result: it is expected to lead to broader use of class actions (not currently used widely)
- ◆ Not yet: the system not fully implemented





## C. PFAS Litigation



# Relevance of PFAS litigation



- ◆ May serve as a precedent for product liability litigation in general

# Civil claims related to PFAS environmental pollution/workplace exposure



- ◆ 3M ordered by the Court to pay a family in Zwijndrecht (near 3M PFAS plant) a compensation of 2000 EUR for elevated PFAS in blood: case equivalent to 'excessive neighbor nuisance'
- ◆ Arkema: a group of residents and associations have filed an environmental criminal complaint, demanding damage compensation
  - ◇ In November, the Lyon judicial court dismissed the case. The plaintiffs are in the process of appealing the decision
- ◆ Three Dutch municipalities filed a lawsuit against Chemours and its predecessor, DuPont, in 2023 for contamination of PFAS in the soil, water and food.
  - ◇ The Rotterdam District Court ruled partially in favor for the municipalities, opening the door for compensation
  - ◇ Over 3,000 local residents have filed criminal charges against Chemours executives for knowingly endangering public health
  - ◇ A former employee has also sued Chemours, holding the company responsible for his health issues

# PFAS product liability claims

- ◆ Landmark case: Ronneby case in Sweden (2024)
  - ◇ PFAS-contaminated drinking water: dangerous product under EU Product Liability Regulation
  - ◇ 150 residents had high PFAS levels in their blood due to drinking water contaminated with PFAS because of a nearby manufacturing site
  - ◇ Swedish Courts: the risk of future damage does not constitute personal injury.
  - ◇ Supreme Court: physical harm occurring in the future could not in principle be regarded as personal injury. However, due to the elevated PFAS levels in blood, sufficiently proven as a substance leading to an increased risk of illness, there is a significant physical impairment that constitutes personal injury
  - ◇ Compensation claims still ongoing
- ◆ May open door for other similar cases

# PFAS claim against governments

- ◆ Ongoing case in the Netherlands (started August 2024):
  - ◆ First civil collective action against a government for its failure to take adequate measures in the short term to stop damage to the environment and public health
  - ◆ Main argument is a breach of duty of care: interest groups (including firefighters) demanding stricter controls on the chemicals industry; and claiming that the Dutch State has *“failed in its duty of care for Dutch citizens, animals and the environment by showing major shortcomings in protecting them against PFAS pollution”*.



## D. Climate Change Litigation





# Climate change litigation in the EU (1)

- ◆ **Overview:** around 75% of the EU climate cases have been filed against governments with a smaller proportion against private actors (16%) ([Climate Litigation in Europe, 2022](#)). Both to delay climate action or to advance it.
- ◆ Climate litigation is more and more linked to human rights and State responsibility (i.e. link between environmental degradation and human rights)
- ◆ The main reason for dismissal by the Courts is the lack of standing/procedural requirements
- ◆ Inadmissibility in the case ***Duarte Agostinho and Others v. Portugal*** before the ECHR because domestic remedies in Portugal were not exhausted and because of lack of jurisdiction (territoriality principle)

# Climate change litigation in the EU (2)

- ◆ **Government accountability cases** : recognition of legal duties of care regarding climate change
  - ◆ **Urgenda v. Netherlands** (2015 – 2019) : Supreme Court ordered 25% emissions reductions by 2020. Landmark case based on ECHR rights (Art. 2 & 8)
  - ◆ **Klimaatzaak v. Belgium** (2015 – 2021): Court found breach of the duty of care and the Appeal Court ordered reduction targets to be upheld
  - ◆ **KlimaSeniorinnen v. Switzerland** (April 2024): EUCJ ruled that Switzerland had failed to act in time and in an appropriate and consistent manner to develop and implement relevant legislation and measures to mitigate the effects of climate change.
    - However, it also ruled that States should be accorded a wide margin of discretion regarding the choice of means to meet climate related goals and targets
    - Likely to lead to the filing of further cases

# Climate change litigation in the EU (3)

## ◆ Against companies

- ◆ Climate litigation against companies on the rise since 2023, mainly related to the “polluter pays” principle and holding companies accountable for GHG emissions
- ◆ “Corporate framework cases” against companies to ensure alignment of group-level policies and governance processes with climate goals
  - **Milieudefensie et al. v. Royal Dutch Shell plc. (2019)** – duty of care of Shell under Dutch law and the European Convention of Human Rights
- ◆ “Transition risk cases” against corporate directors and officers for their management of climate risks
  - ClientEarth v. Enea (2018) and Enea’s decision to sue Enea’s former directors and their insurers for lack of due diligence over a coal power plant investment
  - Board directors’ potential liability for ongoing fossil fuel investments

# Climate change litigation in the EU (4)

## ◆ Against companies

### ◆ ClientEarth, Surfrider Foundation Europe, and Zero Waste France v. Danone (2023-2025)

- Claimed that the company does not adequately address the risks related to the plastic pollution it produces – asks to map, assess and potentially mitigate its impact
- After mediation was ordered by the Judge in France, an agreement was reached which included Danone's commitment to update its risk and vigilance plans related to plastic use, publishing its plastic footprint and implementing reuse solutions.

## ◆ Others

- ◆ Focus on implementation rather than on meeting climate targets per se
- ◆ Green vs. Green cases (trade-offs between climate and biodiversity claims)
- ◆ Just transition cases (distributional impacts of climate change policies)



## E. CLP Liability



# CLP issues

- ◆ New CLP hazard classes: ED, PBT/vPvB/PMT/vPvM
  - ◇ ED assessment difficult – new Guidance not helpful
- ◆ Self-classification based on assessment of available data
  - ◇ Using expert judgment – not objective
  - ◇ No requirement to generate new studies
  - ◇ No data = no classification
- ◆ Risk of NGO challenge!
  - ◇ Use of expert panel



# CLP enforcement

- ◆ Compliance check: in principle also C&L in the REACH dossier – not common
- ◆ But: enforcement also for national authorities! (rare)
- ◆ Liability consequences: potential liability claims towards downstream users (objective damage required typically)
- ◆ Contractual liabilities: check your contract with suppliers/customers
- ◆ C&L inventory: inconsistencies are common; amendment of CLP
  - ◆ Publicity of C&L notifiers
  - ◆ Obligation to provide reasons in case of divergence from existing entries

- ◆ Procedure for Harmonized Classification and Labeling driven by overconservative application of CLP criteria by RAC
  - ◇ e.g. many substances proposed to be CMR Cat. 1 despite limited evidence
- ◆ Appeal in TiO<sub>2</sub> case: Advocate General: *‘RAC and the Commission are always right, unless their assessment is ‘scientifically impossible’*

# Interim period in CLH procedure; advocacy



- ◆ In principle, not necessary to apply proposed classification immediately
- ◆ It is ok to communicate disagreement with proposed classification publicly, if based on facts and not include misrepresentations

# CLP: Downstream Liability

## ◆ **Consentino vs Stonemasons in Spain:**

- ◆ Initial case in Spain for failure to label adequately the 95% silica content of quartz agglomerate, despite being aware of the safety and health risks its manipulation entailed
- ◆ Initial penalty of 1.1 million euros in compensation to the stonemasons who sued Consentino for failing to warn about the risks of Silicosis linked to cutting and polishing Silestone, in addition to a jail penalty of 6 months and 3 days
- ◆ Many workers affected are still suing Consentino for damages



## F. Other Emerging Litigation Areas?



# Microplastics?

- ◆ All sorts of polymers
- ◆ Found in food chain, human blood and tissues
- ◆ Main direct sources: abrasion of tyres, washing-off textiles
- ◆ But also degradation of littered plastics; plastic pellet losses
- ◆ Litigation risk?
  - ◇ *Some issues: microplastics ubiquitous, not possible to identify specific polluter(s); health effect still uncertain*
  - ◇ *Possible mid-term solution: extended producer responsibility for (selected) plastics*
    - EPR for textiles in California
    - EPR for pharmaceuticals in the EU (Urban Wastewater Treatment Directive)



# Final thoughts



- ◆ Important recent precedent cases for civil liability claims
- ◆ Product liability litigation as an emerging risk?
  - ◇ More difficult (PFAS are ubiquitous so no obvious defendant)
  - ◇ Difficult to prove objective damage – but Ronneby case!
    - Similar to potential future claims regarding microplastics pollution



## G. Product Safety



# Product safety: General Product Safety Regulation



- ◆ New General Product Safety Regulation 2023/988
- ◆ Principle: Producers must only place safe products on the market
- ◆ New requirement: online marketplaces have to register with the Safety Gate Rapid Alert System

# Non-compliance involving safety issue; product withdrawal



- ◆ Where the product is deemed dangerous: obligation to self-disclose immediately to national authorities (applicable to manufacturers, importers and distributors)
  - ◇ Via Safety Business Gateway portal
- ◆ For products on the market, economic operators must take necessary measures, including a recall, when necessary

# Other non-compliance (formal)

- ◆ Formal non-compliance (*e.g.*, no or inappropriate CE marking or declaration of conformity, incomplete technical documentation, incomplete labeling...):
  - ◆ There is no self-disclosure requirement
  - ◆ Withdrawal or recall ordered only where the non-compliance persists

# Thank You

Any questions?

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