



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



# Hot Topics for 2024 and Update on the PFAS Restriction

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# Ales Bartl

- ◆ Ales has a broad experience in EU product regulatory law, including REACH, CLP, POPs, biocidal legislation, food law, medical devices, electronic products, and product and food 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. Ales also advises on product recalls and withdrawals.
- ◆ Ales primarily focuses on EU regulation of chemicals and food, including representing clients in various procedures before the European Chemicals Agency (ECHA) and European Food Safety Authority (EFSA).



# Marie Escorneboueu

- ◆ Marie Escorneboueu counsels clients on regulatory and compliance matters related to food and drug law, with an emphasis on food and drug packaging, cosmetics, chemical control, and environmental issues.
- ◆ She assists companies in obtaining regulatory clearances for food-contact materials at the European Union (EU) and Member State level and advises clients with respect to mutual recognition. She also advises companies on sustainability initiatives; REACH matters; the Classification, Labelling, and Packaging (CLP) Regulation; and Biocidal Products Regulation (BPR).





# REACH



# REACH Revision

## ◆ REACH revision timeline modified

- ◆ Initially expected by end of 2022, delayed twice until end of 2023
  - No longer appearing in [Commission 2024 Work programme](#)
  - Left for the new Commission

## ◆ Guidance on essential uses

- ◆ COM officially announced horizontal guidance determining exemptions from group bans for certain essential uses
  - Based on [WSP report](#)
- ◆ Text ready at the technical level, awaiting final decision
- ◆ Published before the elections?

# One Substance One Assessment

- ◆ **Pilot project (ECHA/EFSA): butylated hydroxy toluene (BHT)**
  - ◇ Antioxidant, used in a range of consumer uses, including food additive, cosmetics...
  - ◇ CLH as a sole ground for determining hazard (BHT is under assessment for ED)
  - ◇ EFSA: only exposure assessment, no other determination of hazard and risk

# PFAS Restriction (1)

## ◆ End of consultation phase

- ◆ Consultation phase closed on 25 September 2023
- ◆ In principle:
  - RAC opinion and SEAC draft opinion to be issued by the end of 2023
  - SEAC to final opinion by March 2024, following a consultation
- ◆ However, special circumstances:
  - Unprecedented number of comments submitted
  - Unprecedented scope of the restriction
  - Contested aspects (e.g., fluoropolymers; exemptions)

# PFAS Restriction (2)

- ◆ **(draft) SEAC opinion crucial as it will be subject to second public consultation**
- ◆ **Status of discussions in RAC and SEAC (60<sup>th</sup> SEAC Meeting Minutes, 66<sup>th</sup> RAC Meeting Minutes)**
  - ◇ SEAC work plan for 2024 not yet publicly available
  - ◇ Likely outcome:
    - SEAC discussions organised sector by sector
    - SEAC opinion will be published in parts
    - First part: food contact materials (March 2024?)
    - Consumer mixtures, cosmetics, and ski wax (later)
    - Other applications (even later)
  - ◇ Our estimation: second public consultation on draft SEAC opinion: likely Q1 2025
  - ◇ Consequence: significant delays, final Regulation not likely before 2030
  - ◇ Question marks whether the wide scope will be kept (fluoropolymers?)



# Additives in PVC (1)

- ◆ **Investigation launched by COM in May 2022**
- ◇ Current status of PVC additives under REACH:
  - Existing restrictions: certain phthalates, organotins
  - Potential restrictions under investigation: medium-chain chlorinated paraffins, flame retardants, orthophthalates
- ◇ COM considering broader restriction:
  - Aim to target alternative substances used to replace banned additives
  - Focus on PVC microparticles
  - To define the scope of the potential restriction, COM requested ECHA to investigate

# Additives in PVC (2)

## ◆ ECHA Report, 22 November 2023:

### ◆ Additives concerned:

- List of 63 'prioritised' PVC additives (incl. 19 ortho-phthalates)
- Belonging to three main classes: heat stabilisers (organotin), plasticisers, flame retardants
- Focusing on additives which: 1) contain constituents already identified as ED or reprotox, 2) have data showing ED/reprotox effects; and/or 3) for which direct read-across/grouping can be applied

### ◆ Applications investigated:

- Pipes, flooring, cables, window frames, **packaging**, toys, medical applications, artificial leather

# Additives in PVC (3)

## ◆ Conclusions

- ◆ Priority additives grouped for concern
- ◆ Restrictions for some warranted without CLH or SVHC listing, coupled potentially with other measures
- ◆ Microparticles: ECHA recommends measures to minimise on-site releases, focusing on recycling (not under REACH likely)

## ◆ Next steps ([ECHA rolling action plan 2024](#))

- ◆ COM to issue mandate for ECHA restriction dossier preparation by Q3 2024
- ◆ ECHA report expected Q4 2025

# Bisphenols

- ◆ **German restriction proposal:** ([COM Rolling action plan](#))
  - ◇ Group restriction on bisphenols having **ED (env) properties**
  - ◇ Withdrawn on 31 August 2023, following receipt of information submitted during consultation
  - ◇ New report to be issued – **date unknown**
  
- ◆ **ECHA assessment of need for action:** ([COM Rolling action plan](#))
  - ◇ COM and ECHA assessing need for further regulatory action (incl. Restrictions, SVHC identification or CLH)
  - ◇ Hazards targeted: reprotox, ED (human health)

# Microplastics

- ◆ Restriction in force since October 2023 for non-exempted uses
- ◆ Commission announced comprehensive Q/A document by the end of 2023
- ◆ Some interpretational issues:
  - ◇ [Commission website](#): glittered decorative objects (with no intentional release of glitter) covered. Extensive interpretation of ECHA Guidance on Articles?

## ◆ **Proposal pending before the EP and the Council**

- ◆ Parliament adopted its position on 4 October 2023
- ◆ EP and Council reached provisional agreement on 5 December 2023:
  - Clarifies that the regulation also applies to online sales
  - Physical labels remain the principle, digital labels the exception
  - Alignment of provisions re: hazard classes with other ongoing legislative initiatives
- ◆ Agreement now needs to be endorsed by both institutions



# Pending Proposals



# Preventing Plastic Pellets Losses (1)

- ◆ Proposal for a Regulation on preventing plastic pellet losses to reduce microplastic pollution, 16 October 2023
- ◆ COM 2022 consultation:
  - COM identified at the time **three priority targets**: tyres, textiles, pellets
  - Decision not to pursue with tyres (covered by EURO 7) and textiles (remaining uncertainties and data gaps)
- ◆ Proposal exclusively focusing on pellets losses:
  - Ensure that losses are avoided and when they occur, take immediate action to remedy it
  - Targeting economic operators handling > 5 tonnes pellets per year in the EU and carriers transporting pellets in the EU



# Preventing Plastic Pellets Losses (2)

## ◆ General obligations

- ◆ Ensure that losses are avoided and when they occur, take immediate action
- ◆ Notify the competent authority each installation they operate

## ◆ Handling of plastic pellets

- ◆ Establishment of a risk assessment plan for each installation:
  - Content set out under Annex I: site map, identification of locations where spills may occur, equipment and measures in place to prevent, contain, and clean spills
  - Plan is notified to the MS where the installation is based
    - For SMEs and medium and large companies' installations handling < 1000 tonnes of pellets each year, plan and DoC updated every 5 years
    - For medium and large companies' installations handling > 1000 tonnes of pellets, update every year

# Preventing Plastic Pellets Losses (3)

## ◆ Certification

- ◆ Based on [Clean Sweep programme](#)
- ◆ Obligation for large companies (> 1000 tonnes of pellets) to obtain a certificate of compliance for each installation
- ◆ For others, self-declaration only

## ◆ Complaint mechanism

- ◆ MS to set complaint mechanism for natural and legal persons « having a sufficient interest » or « those who consider that their rights were impaired»

## ◆ Next steps:

- ◆ Pending before EP and Council
- ◆ [Consultation](#) running until 18 December 2023

# Ecodesign for Sustainable Products (1)

- ◆ Proposal for a Regulation establishing a framework for setting ecodesign requirements for sustainable products ('ESPR')
  - ◇ Current Ecodesign Directive limited to 'energy-related products'
  - ◇ ESPR requirements to be extended to broader range of products
    - COM identified potential sectors to be covered:
      - End-use products: **ceramic products**, lubricants, paints and varnishes, cosmetics ... packaging mentioned as well for aspects not covered by PPWR
      - Intermediary products: **chemicals, plastics and polymers**, paper, pulp paper and boards...
      - Horizontal measures: durability, recyclability ...
  - ◇ This is just a framework Regulation: specific measures for specific products defined via delegated acts

# Ecodesign for Sustainable Products (2)

- ◆ **Ecodesign requirements relate to the following aspects**
  - ◇ Durability, reliability, reusability, upgradability, reparability;
  - ◇ **Presence of substances of concern;**
  - ◇ Energy and resource efficiency, carbon and environmental footprint;
  - ◇ Expected waste generation, recyclability;
  
- ◆ **Criteria will include**
  - ◇ Performance criteria
  - ◇ Information: re: compliance, substances of concern, and Digital Product Passport ('DPP')

# Ecodesign for Sustainable Products (3)

- ◆ **Information on substances of concern**
  - ◆ Tracking of « *all substances of concern* » throughout the life cycle
  - ◆ 'Substance of concern': restricted substances **OR** belong to certain hazard classes (incl CMR) **OR** « *negatively affect the re-use and recycling* »
  - ◆ COM to define which substances are targeted in the sector-specific acts

# Ecodesign for Sustainable Products (4)

- ◆ **Digital Product Passport**

- ◆ See our [August REACH 30/30](#)

- ◆ **Next steps**

- ◆ Provisional agreement between EP and Council reached on 5 December
  - ◆ Adoption expected by end of 2024

# Detergents Regulation

- ◆ **Revision of sectoral chemicals legislation in the CSS**
  - ◇ Announces revision of the food contact materials, food additives, toys, detergents, and cosmetics legislation
  
- ◆ **First initiative issued is a Proposal revising the Detergents Regulation**
  - ◇ Mandatory conformity assessment (CE marking)
  - ◇ Creation of a digital product passport:
    - Ingredient data sheet including all intentionally added substances and preservatives listed under Annex V of the Proposal
    - Product identifier, manufacturer identity ...
    - Accessible to end-users and authorities through a data carrier
    - Uploaded in ESPR registry



# Upcoming Proposals





## ◆ Cosmetic Products Regulation revision Roadmap – October 2021

- ◆ Revision of Regulation (EC) No. 1223/2009, announced in the CSS, aiming to:
  - Align the Cosmetics Regulation with the goals set under the CSS
  - Extend the generic approach to risk management
    - CMRs, Eds, PBT first
    - In a second stage, chemicals affecting the immune, neurological, or respiratory system and chemicals toxic to a specific organ
  - Reattribute tasks of the SCCS to ECHA (in line with OSOA approach)
  - Review the definition of nanomaterials

## ◆ **Timeline**

- ◆ Proposal planned for Q4 2022, postponed since with no defined date

# Food Contact Legislation

## ◆ Pillars of the revision

- ◆ Shift focus onto final material: producers assess safety with full knowledge of substances that can migrate
- ◆ Prioritisation of substances of concern:
  - Tiered approach with direct prohibition of CMRs, EDs, PBTs and vPvBs
- ◆ Sustainability (e.g., ecodesign requirements)

## ◆ Next steps

- ◆ Proposal expected in 2024 at the earliest



# Thank You

Any questions?

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