



# Update on PFAS + New Toys Regulation, its Horizontal Relevance

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# Ales Bartl

- ◆ Ales Bartl has a broad experience in European Union (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, including tobacco products, novel products, modern oral nicotine products, and electronic cigarettes, 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.





# I. Update on PFAS REACH Restriction





# A. Restriction Limits



# PPWR PFAS Limits Mirror REACH

- ◆ PPWR 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 as measured with targeted PFAS analysis (250 ppb for their sum)
  - ◇ 50 ppm for PFAS measured as total fluorine
    - ◇ If total fluorine above 50 ppm, source must be investigated
    - ***Mirrors proposed REACH PFAS restriction.***

# Commission Draft Guidance on PPWR PFAS Restriction (1)

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- ◆ Commission Notice interpreting some provisions of the PPWR (PPWR Guidance) to be published soon (non-official version leaked)
- ◆ FAQ Document also scheduled to be published (not available yet)

# Commission Draft Guidance on PPWR PFAS Restriction (2)

- ◆ **Stepwise approach for enforcement of PFAS in food packaging:**
  - ◇ **Step 1:** total fluorine <50 mg/kg – sample considered compliant *so no need to test the other two limits!*
  - ◇ **Step 2:** TF >50 mg/kg, methods such as pyrolysis-GC/MS can be used to confirm whether fluorine is organic (PFAS) or inorganic – sample considered compliant if organic fluorine < 50 mg/kg – *no need to test the other two limits*
  - ◇ **Step 3:** Direct total oxidizable precursors (TOP) analysis is recommended to check compliance with 25 µg/kg (individual PFAS measured by targeted analysis) and 250 µg/kg (sum of PFAS measured as the sum of targeted PFAS analysis) limits.

# Limitations

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- ◆ Guidance not yet final
- ◆ Commission Guidance in general not binding
  - ◆ E.g., French authorities informed that they will enforce the 25 ppb limit even if org. fluorine below 50 ppm



# B. Second Public Consultation



# Second Public Consultation

- ◆ Second public consultation still scheduled for end-March 2026 (SEAC meeting on March 10-13, 2026) – will last 60 days
- ◆ Format for PC will be different: questionnaire; focus on socio-economic impact + alternatives
- ◆ ECHA held a webinar on how to prepare data on October 30, 2025 + issued a guidance [here](#)
- ◆ November 2025: updated Mapping of PFAS uses evaluated in the SEAC draft opinion [here](#)
- ◆ **Missing (or insufficient) exemption in the amended Background Document (August 2025)? Start preparing comments to be on time!**



## C. PFAS in UK



- ◆ Not on board for universal PFAS restriction (yet)
- ◆ February 3, 2026: DEFRA's [paper](#) 'PFAS Plan: building a safer future together'
  - ◆ Focus on understanding PFAS sources and ad-hoc reducing emissions
  - ◆ More PFAS on UK Candidate List of SVHC (publication + consultation summer 2026)
  - ◆ By December 2028: proposal towards UK REACH restrictions (that will be 'aligned' with EU)



# D. Commission Study on PFAS Costs



# Commission's Study on Costs of PFAS Pollution

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- ◆ January 29, 2026: Commission's [report](#)
- ◆ If no action on PFAS: costs of €440 billion until 2050
  - ◆ But: data limited to PFOS, PFOA, PFHxS, and PFNA only!
- ◆ Expected to be used by SEAC



## II. New Toys Regulation



# Status

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- ◆ New [Toys Regulation 2025/2509](#) published on December 12, 2025
- ◆ Generally applicable from August 1, 2030

# Chemicals Restrictions

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- ◆ Previous Toys Directive: only CMRs (1 and 2)
- ◆ New: endocrine disruption for human health category 1 or 2, STOT SE/RE 1, respiratory and skin sensitizers cat. 1
- ◆ Intentional use of PFAS
- ◆ Presence of bisphenols listed in Annex II, Part D
- ◆ Obligation to consider ‘cocktail effect’ of chemicals in the safety assessment
- ◆ A ban on treatment with biocides (except for toys with permanent outdoor use)

# Harmonized Classification Only

- ◆ Restrictions applicable to substances ‘Classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008’  
= harmonized C&L
- ◆ In contrast: Regulation 10/2011 (‘Plastics Regulation’):  
monomers/additives ‘classified as’ CMR category 1 and 2 cannot benefit from the functional barrier exemption  
= self-classification
- ◆ **Regarding ED: revision of REACH (pending):** new data requirements for ED endpoint
  - ◆ Idea: push Industry to generate data, then harmonized classification => generic restriction (such as in toys)

# Digital Product Passport (DPP)

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- ◆ Part I of Annex VI Toys Regulation, including:
  - ◇ a list of allergenic fragrances that are present in the toy
- ◆ i.e., not a comprehensive list of all ‘substances of concern’
  - ◇ Because Toys Regulation not an ecodesign regulation

# Regulation Establishing a Framework for Ecodesign Requirements for Sustainable Products ('ESPR')

- ◆ Presence of **substances of concern** in products is one of the eco-design criterion to be set by the Commission by delegated acts
- ◆ **Article 2(27):**
  - ◇ 'substance of concern' means a substance that:
    - (a) is an SVHC; or
    - (b) is classified in Part 3 of Annex VI to CLP Regulation as:
      - CMR, cat. 1 and 2
      - PBT/vPvB/PMT/vPvM/ED
      - respiratory and skin sensitisation category 1
      - chronic hazard to the aquatic environment categories 1 to 4
      - hazardous to the ozone layer
      - specific target organ toxicity (repeated and single); or
    - (c) negatively affects the re-use and recycling of materials in the product in which it is present

# Regulation Establishing a Framework for Ecodesign Requirements for Sustainable Products ('ESPR')

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- ◆ Information obligations relating to the presence of substances of concern in products:
  - ◇ Information requirements by digital product passport: should enable the tracking of all substances of concern throughout the life cycle and at least:
    - Name of the substances of concern; location of the substances; concentration/maximum concentration or range in the product; its components or spare parts; relevant instructions for safe use; information relevant for disassembly

# Cybersecurity requirements

- ◆ Toys which include artificial intelligence are to comply with Regulation (EU) 2024/1689 (AI Act)
- ◆ Connected toys: Regulation (EU) 2024/2847 on horizontal cybersecurity requirements for products with digital elements (Cyber Resilience Act)
  - ◇ Products for which ‘intended or reasonably foreseeable use includes a direct or indirect, physical or logical data connection to another device or a network’
  - ◇ Full entry into force December 2027
- ◆ Regulation (EU) 2022/30 (Radio Equipment Directive) already applicable to internet-connected toys



# Thank You

Any questions?

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