Understanding the Packaging and Packaging Waste Regulation (PPWR)

Focus on Substances of Concern

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Understanding the Packaging and Packaging Waste Regulation (PPWR): Focus on Substances of Concern

The PPWR establishes a comprehensive substances-of-concern regime applicable to all packaging placed on the EU market from 12 August 2026. This presentation provides a detailed technical and legal analysis of Article 5 obligations, concentration limits, PFAS restrictions, information requirements, and the evolving landscape of delegated and implementing acts.

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Three-layer obligations, minimisation duty & compliance evidence

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1. The Regulatory Framework

1.1. The Three-Layer Substances Regime

PPWR Article 5 establishes three overlapping layers governing substances of concern in packaging. The numerical restrictions do not replace the general minimisation obligation — packaging that meets the heavy-metal and PFAS limits must still satisfy Article 5(1) for all other substances of concern.

1

Layer 1 — General Minimisation

A general obligation to minimise substances of concern in all packaging, covering materials, components, emissions, and waste-management outcomes including microplastics.

2

Layer 2 — Heavy-Metal Limit

A combined concentration limit of 100 mg/kg for the sum of lead, cadmium, mercury and hexavalent chromium present in packaging or packaging components.

3

Layer 3 — PFAS Thresholds

Specific concentration limits for per- and polyfluorinated alkyl substances (PFAS) in food-contact packaging, applicable from 12 August 2026.

The Commission summarises: *"Presence of SoC to be minimised, including considering adverse effects due to microplastics."* — European Commission, stakeholder material, 10 December 2024.

1.2. General Minimisation Obligation

Article 5(1) of Regulation (EU) 2025/40 provides: *"Packaging placed on the market shall be so manufactured that the presence and concentration of substances of concern as constituents of the packaging material or of any of the packaging components is minimised, including with regard to their presence in emissions and any outcomes of waste management, such as secondary raw materials, ashes or other material for final disposal, and to the adverse impact on the environment due to microplastics."*

What "*Minimised*" Means

Not necessarily elimination. Manufacturers must identify relevant substances of concern and consider all technically feasible means of reducing their presence and concentration throughout the packaging lifecycle.

Scope of the Obligation

- Packaging materials and components
- Coatings, inks, varnishes, glues and adhesives
- Emissions generated during waste treatment
- Substances transferred into secondary raw materials
- Ash, leachate and other final-disposal outcomes
- Environmental effects associated with microplastics

1.3. Application Date and Concentration Limits

12 August 2026 — General Minimisation Obligation Applies

Application date for the general obligation to minimise substances of concern content — confirmed by the Commission FAQ, 2nd edition, Section III, Q7.

3 PFAS Thresholds for Food-Contact Packaging

Distinct concentration limits at 25 ppb (individual PFAS), 250 ppb (sum of PFAS), and 50 ppm (including polymeric PFAS).

100 mg/kg Combined Heavy-Metal Limit

Specific combined concentration limit for Pb, Cd, Hg and Cr(VI). No universal threshold applies to all other SoC under Article 5(1).

The absence of a general concentration threshold does not postpone Article 5(1). Manufacturers can already identify relevant substances using the existing PPWR definition: *"Substances meeting the substances of concern (SoC) criteria can already be identified by the manufacturer based on the existing definition of SoC."* — PPWR FAQ, Section III, Q6.

1.4. Demonstrating Compliance

The Commission recommends using the existing harmonised standard as an interim compliance framework, whilst acknowledging that the PPWR's requirements are broader than the previous directive. EN 13428:2004 provides an interim method for documenting a minimisation assessment.

1

Apply EN 13428:2004 (Interim)

Use Annex C — Minimisation of Dangerous Substances or Preparations and Demonstration of Conformity — as the interim assessment methodology until an updated harmonised standard is available.

2

Extend Beyond the Standard's Original Scope

Account for the PPWR's broader requirements: reuse and recycling impacts, chemical safety, microplastics, and secondary raw materials — areas not fully addressed in the 2004 standard.

3

Await Updated Harmonised Standard

The Commission has confirmed that an updated standard is forthcoming. Interim use of EN 13428:2004 must be revisited once the updated standard is published and referenced.

1.5. Scope and Responsibilities

The obligation applies to all packaging placed on the market. Responsibility lies principally with the manufacturer, though suppliers play an essential role in enabling compliance through information provision.

Who Is Responsible?

The manufacturer placing packaging on the market — or, where the manufacturer is a microenterprise, a supplier — must ensure compliance. Source: PPWR FAQ, 2nd edition, Section III, Q11.

Supplier Information Requirements

Suppliers must provide manufacturers with all information and documentation necessary to demonstrate conformity, including:

- Substance identity and concentration
- Function in the packaging material
- Harmonised CLP classification
- REACH Candidate List status
- POPs status and intentional use or contamination
- Analytical results and declarations

2. Definition of "*Substance of Concern*" and Connection with Chemicals Legislation

2.1. Definition of a "*Substance of Concern*"

The PPWR's definition of a substance of concern draws directly from the Ecodesign for Sustainable Products Regulation (ESPR), ensuring conceptual alignment across EU product regulation. The definition is deliberately broad and captures substances on multiple, alternative grounds — chemical hazard, regulatory status, or functional interference with circular economy objectives.

REACH SVHC

Meets Article 57 criteria and identified under Article 59(1) of REACH as a Substance of Very High Concern.

Harmonised CLP Classification

Listed in Part 3 of Annex VI to the CLP Regulation in specified hazard classes.

POPs Regulation

Regulated as a persistent organic pollutant under Regulation (EU) 2019/1021.

Recycling Interference

Negatively affects the reuse and recycling of materials in the product, undermining circular economy objectives.

2.1. Definition of a "*Substance of Concern*"

PPWR applies the definition in Article 2(27) of Regulation (EU) 2024/1781 (ESPR). The conditions are **not cumulative** — fulfilment of any single criterion qualifies a substance as an SoC. The Commission confirms: *"The definition of substances of concern (SoC) refers to the ESPR, which means that substances of concern are defined in the same manner in the PPWR and the ESPR."* — PPWR FAQ, Section III, Q2.

REACH SVHC (Art. 57 + 59(1))

Substances of very high concern identified on the Candidate List. Identification triggers SoC status without automatically prohibiting use in packaging.

CLP Harmonised Classification

Substances classified in Part 3 of Annex VI to CLP in specified hazard classes — including CMRs, EDs, PBT/vPvB, PMT/vPvM, and aquatic hazards.

POPs Regulation

Substances regulated under Regulation (EU) 2019/1021, independently of REACH or CLP status.

Recycling Interference

Substances that negatively affect reuse or recycling, even without a chemical-safety risk — e.g., interference with sorting or secondary-material quality.

2.2. Link with the CLP Regulation

The CLP limb of the SoC definition captures substances with a harmonised classification in **Part 3 of Annex VI** to **CLP**. A new or amended harmonised classification can therefore affect PPWR SoC status without any amendment to Article 5 PPWR itself.

Carcinogenicity Cat. 1 & 2	Mutagenicity Cat. 1 & 2	Reproductive Toxicity Cat. 1 & 2	ED — Human Health Cat. 1 & 2
ED — Environment Cat. 1 & 2	PBT / vPvB	PMT / vPvM	Respiratory Sensitisation Cat. 1
Skin Sensitisation Cat. 1	Aquatic Hazard — Chronic 1–4	Hazardous to the Ozone Layer	STOT RE Cat. 1 & 2; STOT SE Cat. 1 & 2

Source: PPWR FAQ, Section III, Q2, reproducing ESPR Article 2(27)(b). The reference is specifically to harmonised classifications in Part 3 of Annex VI CLP — Annex I establishes classification criteria; Annex VI brings the substance within this limb of the definition.

2.3. Endocrine Disruptors

CLP Definition

An endocrine disruptor is *"a substance or a mixture that alters one or more functions of the endocrine system and consequently causes adverse effects in an intact organism, its progeny, populations or subpopulations."*

Source: CLP Regulation, consolidated text at 1 July 2026, Annex I, Section 3.11.1.1(a).

PPWR Relevance

For the purposes of the PPWR SoC definition, the ESPR captures harmonised CLP classifications in **categories 1 and 2** for:

- Endocrine disruption for human health
- Endocrine disruption for the environment

Two separate categories are established for human health classification.
Source: CLP Regulation, Annex I, Section 3.11.2.1.

2.4. PBT and vPvB Substances

PBT — Persistent, Bioaccumulative and Toxic

A substance is PBT when it fulfils the persistence, bioaccumulation and toxicity criteria set out in CLP Annex I, Sections 4.3.2.1.1 to 4.3.2.1.3.

Source: CLP Regulation, Annex I, Section 4.3.2.1.

vPvB — Very Persistent and Very Bioaccumulative

A substance is vPvB when it meets the classification criteria in CLP Annex I, Section 4.3.2.2 — applying stricter persistence and bioaccumulation thresholds.

Source: CLP Regulation, Annex I, Section 4.3.1.1.

Both PBT and vPvB substances are captured by the harmonised CLP classification limb of the PPWR SoC definition. A substance need not separately satisfy the REACH SVHC limb to qualify.

2.5. PMT and vPvM Substances

CLP introduces PMT (Persistent, Mobile and Toxic) and vPvM (Very Persistent and Very Mobile) as distinct hazard profiles, addressing substances that persist in and migrate through the water environment.

PMT — Persistent, Mobile and Toxic

A substance meets the PMT criteria when it fulfils the persistence, mobility and toxicity criteria in CLP Annex I, Sections 4.4.2.1.1, 4.4.2.1.2 and 4.4.2.1.3. Mobility criterion: **log Koc < 3**.

CLP Annex I, Section 4.4.2.1.2.

vPvM — Very Persistent and Very Mobile

Applies stricter thresholds than PMT. Very mobile criterion: **log Koc < 2**. Source: CLP Annex I, Section 4.4.2.2.2. A substance is vPvM when it meets the classification criteria in Section 4.4.2.2.

Source: CLP Regulation, Annex I, Section 4.4.1.1. These classifications are captured by the PPWR SoC definition through the CLP harmonised classification limb.

2.6. Interaction with REACH

REACH performs three distinct functions within the PPWR substances framework, operating as a definitional trigger, a follow-up route, and a preserved baseline.

1

Definitional Trigger — SVHC Candidate List

A substance that meets REACH Article 57 criteria and is identified under Article 59(1) qualifies as an SoC. Candidate List identification alone does not prohibit the substance in packaging — a separate restriction measure is required.

2

Follow-Up Route — Chemical Safety

Article 5(2)(a) provides that the Commission may use REACH Article 68(1) and (2) procedures to adopt new restrictions for SoC that *primarily* affect human health or the environment.

3

Preservation of Existing Restrictions

Article 5(4) operates without prejudice to existing restrictions under REACH Annex XVII. These baseline restrictions continue to apply independently of the PPWR framework.

2.7. Interaction with the POPs Regulation

Independent Qualification

The ESPR definition captures any substance *"regulated under Regulation (EU) 2019/1021"* — the POPs (Persistent Organic Pollutants) Regulation. Source: ESPR Article 2(27)(c), as reproduced in PPWR FAQ, Section III, Q2.

The POPs limb is entirely separate from the REACH and CLP limbs. A substance regulated under the POPs Regulation qualifies as an SoC without also needing to satisfy the other definitional conditions.

Practical Significance

Packaging manufacturers must therefore screen substances not only against the REACH Candidate List and CLP Annex VI, but also against the POPs Regulation's Annexes, as an independent qualification route for SoC status.

3. Mapping Substances and Future Restrictions

3.1. The Commission's Monitoring Role

Article 5(2) establishes a permanent monitoring and reporting framework, administered by the Commission with the assistance of ECHA. The monitoring obligation does not have a fixed end date — it is a continuing duty that will shape the future restrictions and design-for-recycling criteria applicable to packaging under the PPWR.

Monitoring

Continuous observation and data collection by the Commission, assisted by ECHA, on the presence of substances of concern in packaging and packaging components. A permanent, ongoing obligation under Article 5(2).

Report

By 31 December 2026, the Commission must deliver a report on the presence of SoC in packaging and packaging components, identifying substances that negatively affect reuse and recycling.

Follow-up

Based on the report's findings, the Commission takes appropriate measures: either initiating a REACH restriction procedure (chemical-safety route) or adopting delegated acts under Article 5(7) or 6(4) (reuse and recycling route).

Evaluation

By 12 August 2033, the Commission evaluates the overall effectiveness of Article 5 and, where appropriate, proposes legislative amendments.

3.1. The Commission's Monitoring Role

> *"The monitoring of SoC is a permanent task for the Commission."*
>
> — PPWR FAQ, Section III, Q13

Article 5(2), first subparagraph, provides: *"The Commission shall monitor the presence of substances of concern in packaging and packaging components and shall take, where appropriate, the relevant follow-up measures."* Source: Regulation (EU) 2025/40, Article 5(2).

This is a continuing obligation rather than a task ending with the 2026 report. Manufacturers and suppliers should expect the Commission's monitoring activity to generate further regulatory action over time, including potential REACH restrictions and design-for-recycling criteria restricting specific substances in specific packaging formats.

3.2. Commission–ECHA Report

Statutory Deadline

31 December 2026 — the Commission, assisted by ECHA, must deliver a report on the presence of SoC in packaging and packaging components. Source: Article 5(2), second subparagraph.

ECHA's evidence-gathering covers: packaging materials and uses, tonnages, substances used, manufacturing, downstream processing, recycling and waste management technologies.

Study Scope and Output

The report may list SoC present in packaging and indicate the extent to which they could present an unacceptable risk to human health and the environment. The Commission confirms there is currently no definite list of SoC in packaging.

The study must distinguish between:

- Substances primarily affecting health or environment
- Substances primarily interfering with reuse or recycling
- Substances presenting both types of concern

3.3. Chemical-Safety and Recycling Interference

Article 5(2) creates two distinct follow-up routes depending on the nature of the concern identified in the Commission–ECHA report.

Chemical Safety → REACH Restrictions

Article 5(2)(a): For SoC *"primarily affecting human health or the environment"*, the Commission may initiate REACH Article 68(1) or (2) restriction procedures. The Article 5 report does not itself prohibit a substance — a separate REACH measure is required.

Recycling Interference → Design for Recycling

Article 5(2)(b): For SoC *"that negatively affect the re-use and recycling of materials"*, restrictions may be established as part of design-for-recycling criteria under Article 6(4). Source: Regulation (EU) 2025/40, Article 5(2)(b).

3.4. Member States' Role

Information Submission (Deadline: 31 Dec 2025)

Article 5(2), final subparagraph: Where a Member State considers that a substance negatively affects reuse or recycling, it must supply that information — along with any relevant risk assessments or data — to the Commission and ECHA. This information feeds the general mapping exercise. Source: PPWR FAQ, 2nd edition, Section III, Q13.

Specific Restriction Requests

Article 5(3): Member States may request the Commission to restrict — via Article 6(4)(a) — specific substances that potentially negatively affect reuse or recycling, *for reasons other than chemical safety*. A request must be accompanied by a report documenting substance identity, uses, and how use in packaging hinders recycling. The Commission must evaluate and present results to the Article 65 committee.

3.5. Design-for-Recycling Delegated Acts

Article 6(4) requires the Commission to adopt delegated acts by **1 January 2028** establishing design-for-recycling criteria and recyclability-performance grades. In relation to SoC, these acts may both identify and restrict relevant substances.

1

Identify SoC

Criteria must, where appropriate, identify substances of concern that negatively affect re-use and recycling in the packaging in which they are present. Source: Article 6(4)(a)(iv).

2

Impose Restrictions

Criteria may, where appropriate, impose restrictions on SoC — or groups of SoC — in packaging for reasons not relating primarily to chemical safety. Source: Article 6(4)(a)(v).

3

Take Account of Article 5 Study

When adopting delegated acts, the Commission must take into account the results of the Article 5(2) assessment. The Article 5 report and delegated acts are therefore expressly linked.

Restrictions imposed through design-for-recycling criteria may also serve to reduce unacceptable risks to human health or the environment, without prejudice to REACH Annex XVII or FCM legislation.

4. Who's who under the PPWR

Manufacturer

- Subject to various crucial sustainability and labelling obligations before 'placing on the EU market'
  - Must prove conformity

- Only **one** 'manufacturer' within the meaning of the PPWR
  - Legal manufacturer vs. actual fabricating manufacturer
  - In practice, various scenarios:

Key question: *who wishes to assume the PPWR's manufacturers' (conformity) obligations?*

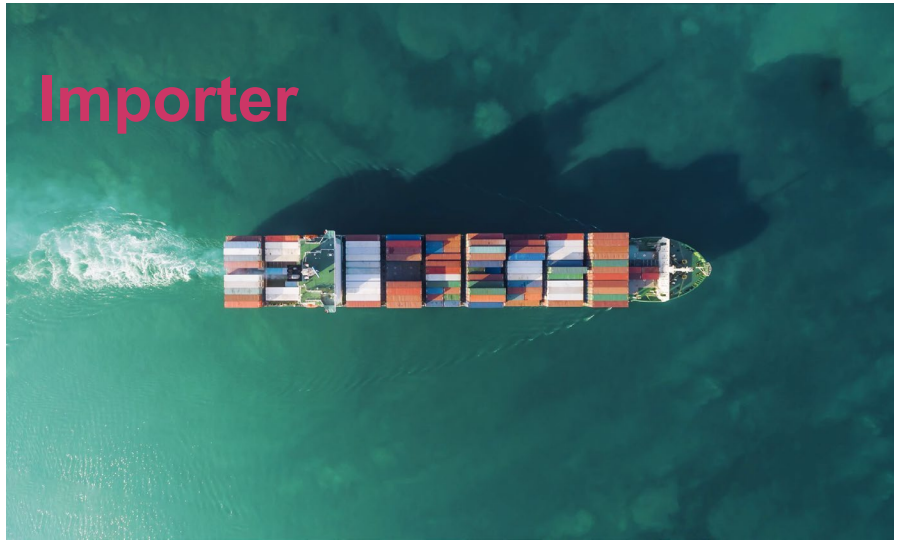
EU-based

- On behalf of an EU-based entity (i.e. branded with the name / trademark of this entity)
- Under its own name / trademark

Assembly outside the EU

- On behalf of an EU entity (i.e. branded with the name / trademark of this entity), or:
  - Under its own name / trademark;
  - On behalf of a non-EU entity (i.e. branded with name / trademark of this entity)
- AR required or otherwise 'importer' may be considered to act as a 'manufacturer

Importer or Distributer?



- Must be established in the EU / importing from outside the EU
  - Definitions in the PPWR differ from commercial supply chain concepts or EU customs law
- Various entities within a group may qualify as 'importer' under the PPWR
  - Ensure correct labelling obligations

- Make the packaging / packaged product in the EU further available in the supply chain
- Less obligations in contrast to the 'importer', but…
  - Act with due care
  - Remain subject to cooperate with the authorities

Producer Perils

PRODUCER(S)? → ***How many?***

↓

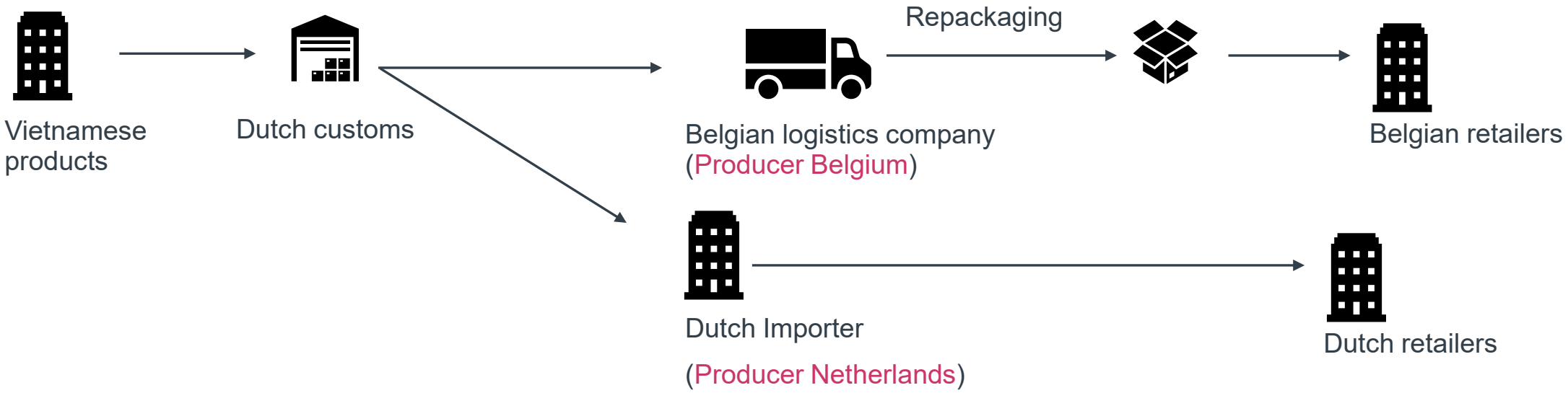
Where and when does the packaging becomes waste?

- Various economic operators could qualify as 'producer'
- No waste = no producer

Examples – I


UK Company
(Producer)
Appoint AR in Belgium
Waste occurs in Belgium
Sells directly online to Belgian customers

Examples – II


Repackaging
Vietnamese products
Dutch customs
Belgian logistics company (Producer Belgium)
Belgian retailers
Dutch Importer
(Producer Netherlands)
Dutch retailers

Examples – III

UK Company

(Producer)

Selling via online platform

Belgian customers

- PPWR prevents free-riding
- Role online platforms?
  - Various verification obligations

5. Information, Documentation and Digital Marking

Information, Documentation and Digital Marking

Article 5(6) and Article 12 of the PPWR establish the information and documentation architecture required to demonstrate and communicate compliance with the substances regime. Technical documentation must be drawn up in accordance with Annex VII, and packaging containing substances of concern must ultimately carry digital markings identifying those substances by name and concentration.

Technical Documentation

Annex VII files proving compliance with Art. 5(4) (heavy-metal limit) and Art. 5(5) (PFAS thresholds). Must be drawn up and kept available for market surveillance authorities.

Digital Marking *(from 1 January 2030)*

Under Article 12, packaging containing substances of concern must carry a digital marking identifying those substances by name and concentration. Methodology implementing act due by 1 January 2030.

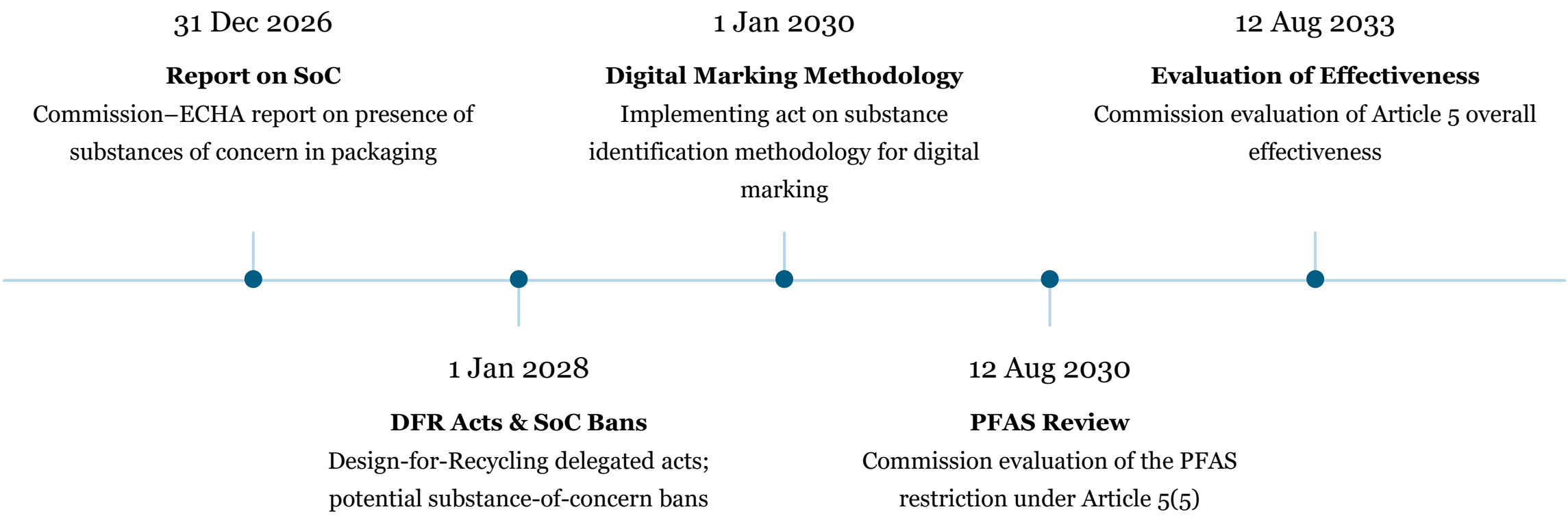
Supplier Declarations

Analytical results and supporting evidence provided by suppliers to manufacturers, covering substance identity, concentration, CLP classification, REACH Candidate List status, and POPs status.

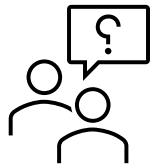
6. Delegated and Implementing Acts

Delegated and Implementing Acts

Article 64(2) confers delegated powers on the Commission for a period of ten years from 11 February 2025. The substances-related delegated powers cover the principal mechanisms through which the PPWR's substances regime will evolve — including lowering the heavy-metal limit, amending derogations, and establishing design-for-recycling restrictions.



Questions and Answers



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