

Speakers





Kimberley de Miguel
Regulatory and
Compliance Managing Analyst,
EMEA

Kim joined Enhesa in 2023 to oversee and develop analytical and regulatory content for Europe. With a background in materials engineering, she built expertise in R&D on coatings and performance technology products. Over the past five years, she has supported non-governmental organizations in the Mediterranean region to apply circular economy principles, and in ensuring compliance with the Stockholm and Minamata Conventions.



Francesca Santacatterina
Regulatory and Compliance Analyst,
EMEA

Francesca joined Enhesa earlier this year. As part of the analyst team, she analyses and interprets regulatory changes and trends concerning chemicals and chemical products, with a focus on EMEA. She believes that sharing knowledge is key to safer markets and better businesses. her prior experience includes working with cosmetics and medical devices manufacturers as a regulatory consultant to ensure compliance.



Speakers





Fourat MuzielRegulatory and
Compliance Analyst, EMEA

Based in Ottawa, Canada, Fourat is a hazard communication professional with extensive expertise in GHS, WHMIS, and CLP. He has worked in industry as a regulatory consultant, where he helped clients in the EU, North America, and APAC regions author compliant Safety Data Sheets (SDS) to meet the specific requirements of each region. Additionally, Fourat has experience in performing compliance audits and holds certification in dangerous goods transport.



Webinar chair: Ryan McErlean, GTM Lead for Enhesa Product Intelligence



Looking for



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- Beyond chemicals coverage
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2024 Global product intelligence

On the agenda

European elections and the REACH restriction roadmap;

Updates into Chromium VI, PFAS & F-gases in the EU;

The EU's global commitments on mercury and POPs;

EPR for Packaging and packaging waste in the UK;

CLP's upcoming 22nd ATP changes;

Cosmetics insights across the EU and UK;

Key developments in Ukraine, Lithuania and Russia;

Updates on product safety and environmental protection laws in Saudi Arabia, Israel, and Mauritius; and

EPR implementation in Jordan.

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During the webinar:

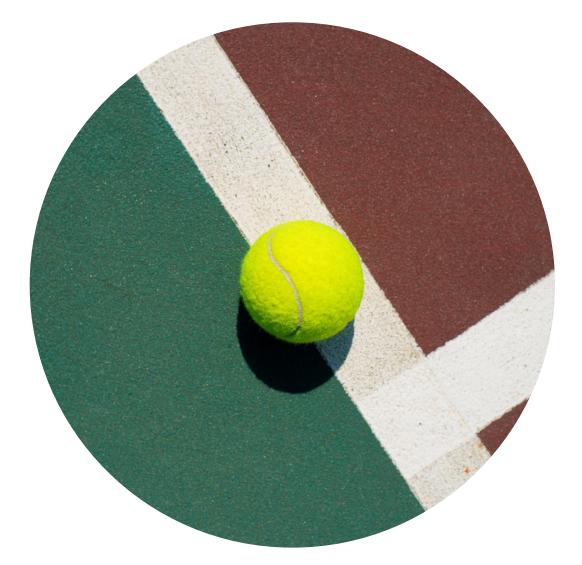
- let us know of any technical issues
- ask questions via the chat

Following today's webinar we will share:

- the webinar recording
- slides
- key takeaways summary







European elections

Election results determine the direction the bloc takes towards environmental policy all the way up to 2030!

- Election Outcome: Far-right parties gained fewer seats than expected.
- Impact on Environmental Policies: Could hinder the rollout of the EU Green Deal, the revision of REACH and the 'one substance, one assessment' package?
- Chemicals Safety Outlook: Despite concerns, some experts believe that Parliament members will remain committed to chemical safety, though a more pragmatic approach is expected, recognizing the role of chemicals in achieving goals like net-zero emissions.

Overall, while traditional parties retained a majority, the results raise concerns about the future direction of EU environmental policy, with the potential for more conservative approaches influencing key legislative developments.



REACH restrictions roadmap

CMR Substances in Childcare Articles:

Discussions in the REACH committee planned for **October 2024**.

Brominated Flame Retardants:

Restriction dossier by end 2024 - Q1 2025, following an ECHA investigation report due in December Organophosphate Flame Retardants?

Chromium VI - April 11, 2025 expanded restriction proposal

Q3 2024

Q4 2024

Q1 2025

2025

PVC and Additives:

A registry of intention (RoI) is expected in Q3

Lead Chromates: Further restrictions are under review, with a proposal expected by late 2024

D4, D5, and D6, are expected to be added to the authorization list under REACH by late 2024

Octocrylene: Submission of the Annex XV restriction dossier is delayed to January 10, 2025 from October 2024.

Hydrocarbyl Siloxanes: Formal restriction processes not expected before 2025

Bisphenol S (BPS): Ongoing assessments, with potential restriction proposals expected by mid-2025

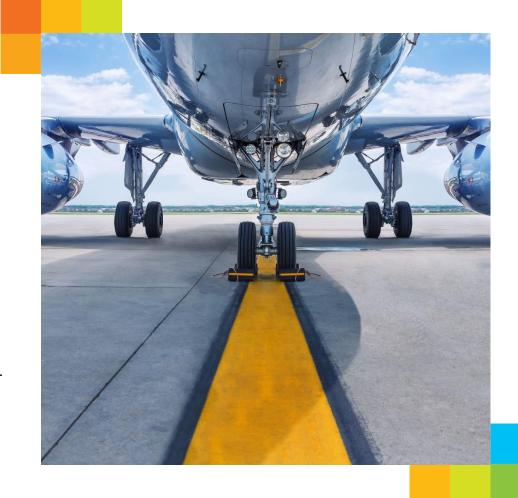
1,4-dioxane: Dossier submission planned for October 2025



Restriction proposal chromium (VI)

In May the European Commission requested ECHA to broaden the scope of the REACH restriction proposal to cover at **least 12 chromium (VI) substances.** Second call for evidence to support the <u>preparation of the proposal in June 2024</u>.

- Now includes the chromium (VI) substances specified in entries of the REACH Authorisation List
- Extended mandate does not include the 3 <u>lead chromate</u> entries, which are pigments used in paints.
- Decorative plating to reduce volumes by at least 50% to extend their authorisation beyond 2028
- ECHA will submit the restriction proposal by 11 April 2025





The latest on PFAS



The EU proposal to **restrict up to 10,000 per- and polyfluoroalkyl substances (PFAS)**. <u>DG announced</u> the restriction proposal will not be out in 2025.

A <u>sector-by-sector</u> approach. Its risk (RAC) and socio-economic (SEAC) assessment committees will focus on

- Consumer mixtures (cleaners, polishes and waxes), cosmetics and ski wax; metal plating and manufacture of metal products.
- Textiles, food contact materials, and petroleum and mining sectors
- Applications in <u>fluorinated gases</u>, transport and construction products.

The recently published EU essential use criteria will not affect the ongoing PFAS restriction process.



The latest on PFAS

PFAS litigation is on the rise in Europe with actions in Belgium, the Netherlands and in France. The adoption of the restriction proposal on PFAS could trigger further litigation in Europe. EU member states, are pressing ahead with PFAS bans at a national level:



Denmark

The ban is part of a wider PFAS action, which was first <u>announced</u> in April. A draft will be submitted for consultation, after which the government expects to adopt the measure in July next year.



- Clothing, shoes and waterproofing agents
- Binding limit for Unintentional trace contamination

Includes a fund of 404m Danish kroner (€54m) to prevent, contain and clean up the pollution between 2024 and 2027.



France

In May, the Senate <u>adopted</u> a bill restricting the manufacture and sale of clothing, cosmetics and other products containing PFAS

From 2026, the bill would restrict the persistent substances in:

- cosmetic products
- wax products
- consumer textile clothing, shoes and waterproofing products, except products that are designed to protect people.

From 2030, all clothing – not just those for consumers – would be restricted, with the exception of protective clothing for safety and civil security professionals.

F-gas labels

The <u>new F-Gas Regulation (EU) 2024/573 entered into force on 11 March 2024</u> (amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014)



Entered into force 11 March 2024



- Production rights phased down to a minimum (15%) as of 2036
- Consumption of HFCs will be completely phased out by 2050
- A full ban on placing products and equipment containing HFCs on the market for several categories
- Specific dates (2030 to 2035) for the complete phase-out of the use of Fgases in air conditioning, heat pumps and switchgears



Feedback period ended in June 2024



1 January 2025

- Extended obligations for leak checks
- New recovery and destruction requirements
- Expanded annual reporting obligations
- Prohibition of additional products



Commission adoption 2 September 2024

Commission Implementing Regulation: Repeals and updates the previous labeling rules to include new categories of products, such as metered dose inhalers



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EU's Global commitments - Minamata Convention



30 May 2024 The Council of the EU adopted a regulation to completely ban the use of dental amalgams and prohibit the manufacture, import, and export of mercury-added products to make the EU mercury-free. Current rules already ban the use of dental amalgam for treating teeth in children under 15 years old, and pregnant or breastfeeding women. The new rules will extend the prohibition to include everybody in the EU.

1 January 2025

Use and export of dental amalgam will be prohibited



31 December 2025 Export, import and manufacturing ban

- Compact fluorescent lamps (CFLs)
- Halophosphate phosphor lamps
- Non-linear halophosphate phosphor lamps

31 December 2026 Export, import and manufacturing ban

- Tri-band phosphor lamps
- Non-linear tri-band phosphor lamps



Before December 2025

Guidance on abatement technologies for mercury emissions from crematoria will be published



1 July 2026 Ban on manufacturing and import in the EU





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EU's Global commitments - Stockholm Convention

In May 2023 three substances listed in Annex A (elimination) (SC-11/11) with specific exemptions, 11th meeting of the Conference of the Parties to the Stockholm Convention. EU adopted Annex I to Regulation (EU) 2019/1021 on persistent organic pollutants (POP Recast Regulation)

Dechlorane plus

Applicability: February 26, 2025

Specific exemption ≤ 1 mg/kg (0.0001%) as unintentional trace contaminant (UTC)

Aerospace, space, defense applications, medical imaging and radiotherapy devices until **26 February 2030**

Spare parts for various applications allowed until the end of their service life or **31 December 2043** whichever comes earlier

Methoxyclor

Applicability: 20th day following publication in the Official Journal of the EU

Specific exemption ≤ **0.01 mg/kg** (0.00001%) as UTC

No derogations

UV-328

Aplicability: February 26, 2025

Specific exemption $\leq 1 \text{ mg/kg} (0.0001\%)$ as UTC

Recycling Industry: Ongoing discussions about adjusting the UTC limit to better accommodate the recycling process

Land-based motor vehicles, Mechanical separators in blood collection tubes, Photographic paper until **February 26, 2030**

Spare parts for various applications allowed until the end of their service life or **2044**, whichever comes earlier



United Kingdom's latest developments in EPR



In **February 2023** The UK Packaging Regulations came into effect, introduced new requirements for packaging producers to collect and report data on the amount and type of packaging they place on the market.



The government published draft EPR (Packaging and Packaging Waste) Regulations 2024, ahead of the new requirements **coming into effect from January 2025**.

It will be brought before parliament later this year.

Payments for waste deposited in street bins and litter will now be addressed in later legislation, as will plans for a mandatory cup takeback scheme.

The draft regulations include:	
Coming into force of labelling obligations by	April 2027
Packaging producers will be subject to EPR obligations should a DRS not be introduced by	January 2028
Recycling targets for	2025-2030
- Plastic expected	65%
- Glass, paper and steel	85%
- Wood	50%
- Aluminium	67%
'Household packaging' definition narrowed to allow material sold through 3rd parties exemption from disposal costs if they meet 'business use only' criteria	



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United Kingdom's latest developments in EPR

In April, UK government, DAERA NI, Scottish & Welsh Govs published a joint policy statement on plans for Deposit Return Scheme (DRS) for drinks containers. Announced a revised go-live date of October 2027 across the whole of the UK.

Legislation will set out to establish a Deposit Return Scheme (DRS) for drinks containers where:

- Deposit Management Organisations (DMOs) will be established, funded by producer fees, unredeemed deposits, and revenue from the sale of recycling.
- Initially target only single use drinks containers and support voluntary trials for reusable and refillable drinks containers.
- Include all single-use drinks containers from 150ml up to 3 litres in PET bottles, steel and aluminium cans
 (excluded from disposal cost fees and labelling obligations under Extended Producer Responsibility for Packaging)

Phase I

Regulations in place in all administrations
DMOs appointed
by Spring 2025

Phase II
DMOs set-up
Spring 2025 to
Spring 2026

Phase III

Roll out

Businesses adapt

Spring 2026 to

Autumn 2027

Launch
Deposit Return Schemes
across the UK are
operational
October 2027



Targeted revision of the EU Cosmetics Regulation

Original timeline: EU Commission proposal expected in Q4 2022(!)

Current status: the proposal is delayed due to ongoing political discussions on certain matters.

Topics to be addressed in the revision:

- Digital labelling
- General ban on endocrine disruptors category 1
- Introduction of specific provisions on respiratory sensitizers of category 1 and Specific Target Organ Toxicity (STOTS)
- Reallocation of the Scientific Committee on Consumer Safety (SCCS) within **ECHA**
- Introduction of horizontal definition of nanomaterials
- Strengthened customs enforcement CPNP linked to customs IT systems



EU Cosmetics Regulation revision in 2027, 2028, or beyond?



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EU Cosmetics: Upcoming bans and restrictions

The EU Commission has published two laws establishing new bans and restrictions for substances used in cosmetic products:

- <u>Commission Regulation (EU) 2024/858</u> banning the use of certain nanomaterials and restricting the use of Hydroxyapatite (nano)
- <u>Commission Regulation (EU) 2024/996</u> regulating the use of the following substances:
 - 4-Methylbenzylidene Camphor banned
 - Genistein, Daidzein, Kojic acid, Alpha-Arbutin, Arbutin
 - Retinol, Retinyl Acetate, Retinyl Palmitate
 - Preservatives Triclocarban, Triclosan



	Concentration limits	Mandatory warning
Retinol		Contains Vitamin A. Consider your daily intake before use.
Retinyl Acetate	 Up to 0.05% Retinol Equivalent (RE) in body lotion Up to 0.3% RE in other cosmetic products 	
Retinyl Palmitate		



EU Cosmetics: Omnibus Act VII

June 2024 – The EU notified to the WTO the <u>draft of Omnibus Act VII</u> banning the cosmetic substances newly classified as CMR in the 21st ATP to the CLP Regulation.

Application date: 1 September 2025

(!) Important (!) No different transitional periods for placing on the market and making available on the market. On 1 Sep 2025, non-compliant cosmetics must be sold already or recalled.

The full list of substances is available <u>here</u>.













Identify products containing soon-to-be banned substances



Inform the supply chain

Find alternatives and reformulate products

Update PIF and safety assessment

Re-labelling

Update CPNP notification and ensure old products are sold or recalled by the deadline

EU Cosmetics: Upcoming bans and restrictions

31 December 2024:

Restrictions for POM Triclocarban, Triclosan

1 February 2025:

Applicability of restrictions and ban on POM nanomaterials restrictions on POM on Genistein, Daidzein, Kojic Acid, Alpha-arbutin, Arbutin

1 May 2025: Ban on POM 4-MBC <u>1 September 2025:</u> Omnibus Act VII applies – both POM and MA

1 May 2027: applicability of restrictions on MA Retinol, Retinyl Acetate, Retinyl Palmitate 1 May 2026: Ban on MA 4-MBC 1 November 2025:
applicability of
restrictions and ban on MA nanomaterials
restrictions on POM Retinol, Retinyl Acetate,
Retinyl Palmitate

31 October 2025: applicability of restrictions on MA Triclocarban and Triclosan



Cosmetics: REACH restrictions on D4, D5, D6

May 2024 – Commission Regulation (EU) 2024/1328 amends REACH.

D4, D5, and D6 shall not be placed on the market in a concentration ≥ 0.1% by weight of the respective substance after 6 June 2026.

Extended transitional period for

- Cosmetics see table below
- Medical devices and in-vitro diagnostic medical devices (IVDs) 6 June 2031
- Medicinal products and veterinary medicinal products 6 June 2031
- As a solvent in the dry cleaning of textiles, leather and fur 6 June 2034

	REACH before the update of 2024	Commission Regulation (EU) 2024/1328 amending REACH	EU Cosmetics Regulation
		From 6 June 2027	
Cyclotetrasiloxane, D4	Up to 0.1% in rinse-off cosmetics	Up to 0.1% in leave-on cosmetic products	Banned for use
Cyclopentasiloxane, D5	Up to 0.1% in rinse-off cosmetics	Up to 0.1% in leave-on cosmetic products	Not regulated
Clohexasiloxane, D6	Not regulated	Up to 0.1% in all cosmetic products	Not regulated



The law establishes also some exclusions.

Cosmetics insights in the UK

On 1 April 2024, the UK issued a <u>new regulation</u> restricting the use of **Butylated hydroxytoluene (BHT)** in cosmetic products. Timeline: <u>24 February 2025</u> for placing on the market (POM) new cosmetic products and <u>24 June 2025</u> for making available on the market (MA).

In April, the UK also notified the WTO a <u>draft regulation</u> restricting the use of **Kojic acid** in cosmetic products and prohibiting the use of **52 CMR substances**.

Proposed timeline for application: <u>20 April 2025</u> for POM and <u>20 August 2025</u> for MA.

Passive divergences with the EU The UK adopts the same requirements as the EU with some delay	Active divergences with the EU The UK adopts different requirements compared to the EU
Restrictions on Kojic acid Ban on CMR substances already banned in the EU through Omnibus Acts V and VI	 Pentasodium Pentate Pentetic Acid Pentapotassium salt Have not been classified as CMR under GB CLP Regulation. Hence, these substances are allowed for use in the UK but not in the EU.
Restrictions on BHT for the following uses: Toothpaste Mouthwash Other cosmetic products	Restriction on BHT in <u>leave-on oral care products</u> : In the EU: Up to 0.8% In the UK: Up to 0.001%



Scotland: Ban on wet-wipes containing plastic

On 23 July 2024, Scotland notified the WTO of a <u>draft regulation</u> banning the supply and sale of wet wipes containing plastic - **Environmental Protection (Wet Wipes Containing Plastic) (Scotland) Regulations 2024**

Proposed date of adoption: 31 October 2024

Proposed date of entry into force: 30 April 2026

Definitions	
Wet wipes	Non-woven piece of fabric which has been soaked and stored in liquid and which is not designed or intended to be re-used, including but not limited to <u>baby wipes</u> , <u>cosmetic wipes</u> , <u>moist toilet tissues</u> , <u>personal hygiene wipes and wipe-based cleaning products</u> .
Plastic	A material consisting of polymer as defined in Article 3(5) of REACH to which additives or other substances may have been added, and which can function as a main structural component of final products, with the exception of natural polymers that have not been chemically modified.

Exemptions:

- Wet wipes supplied by retail pharmacies
- Medical purpose wet wipes supplied by health care professionals or under their direction
- Wet wipes for use in the course of a support service which provides personal care or personal support
- Wet wipes supplied to businesses or local authorities



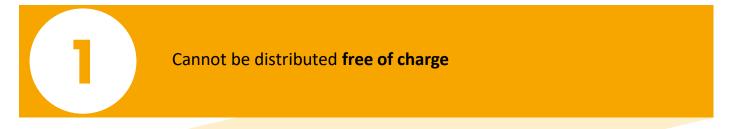
England, Wales, and Northern Ireland are committed to introduce their own legislation on the same intent and scope.

Lithuania: Single-use plastic food containers and cups

July 2024 – Lithuania amends the Packaging and Packaging Wast Act

Scope: single-use plastic food containers and beverage cups filled at the time of sale and distributed by catering activities

Effective date: 1 May 2025



Catering activities shall provide consumers with a plastic-free or reusable **alternative**





At mass events and beaches: can be provided if there is a deposit system in place



Ukraine: Technical Regulation on the classification, labeling and packaging of substances and mixtures

On 10 May 2024, Ukraine adopted the <u>Technical Regulations on Hazard Classification</u>, <u>Labeling and Packaging of Chemical Products</u> based on the EU CLP Regulation.

15 November 2024 – Entry into force of the technical regulation



Chemical products not complying with the technical regulation, but which were placed onto the market before 15 November 2024, may remain on the market until **10 November 2025**

Application as of 1 January 2025:

- Section 3 Labelling of chemical products with information about hazards
- Section 6 Authorized bodies in the field of ensuring chemical safety and management of chemical products



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Ukraine: Technical Regulation on the safety of chemical products

On 23 July 2024, Ukraine adopted the Technical Regulation on the Safety of Chemical Products based on the EU REACH

Key requirements:

- Registration of all chemicals produced, imported and placed on the market in Ukraine in volumes exceeding one ton per year
- Simplified procedure for substances already registered under EU REACH
- Candidate list for substances of very high concern (SVHC) and relevant communication requirements
- Authorization list of substances

26 January 2025 Entry into force

1 October 2026

Deadline for the registration of substances produced/made available in more than 1`000 tonnes per year, CMR 1A and 1B in more than 1 tonne/year, and sub. very toxic to acquatic organisms more than 100 tonnes/year

1 June 2028

Deadline for the registration of substances produced/made available between 100 and 1`000 tonnes per year

1 March 2030

Deadline for the registration of substances produced/made available between 1 and 100 tonnes per year

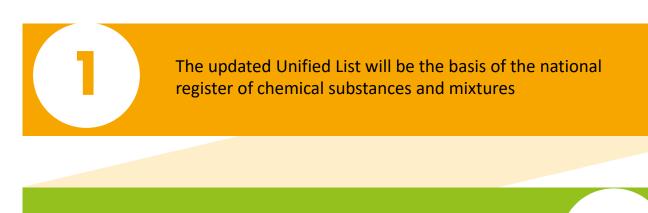


Russia: Unified List of Chemical Substances

August 2024 - <u>Call to action</u>: Companies are invited to <u>provide the information</u> on the substances and mixtures they place or plan to place on the market in Russia in concentration above 0.1%.

Deadline: 20 January 2025

Goal: update the <u>Unified List of Chemical</u>
<u>Substances</u> in the context of the new **Technical Regulation on the safety of chemical products**



Inventory is voluntary

Substances not included in the Unified List will be considered "new" and require more complex notification procedure



CLP — upcoming 22 ATP

On January 18th, 2024, the European Commission published a draft document through a <u>WTO notification</u> for the 22nd adaptation to technical progress (ATP) of Regulation (EC) 1272/2008 on the classification, labeling, and packaging of substances and mixtures, commonly known as the CLP Regulation. This draft proposal aims to amend Table 3 of Part 3 of Annex VI of the CLP by introducing new and revised entries for the harmonized classification and labeling of 42 substances and by deleting one entry.

Background:

- CARACAL supports EU in adopting delegated acts for CLP.
- Substances in Annex VI require classification and labeling by manufacturers/importers.

Changes:

- Based on Risk Assessment Committee (RAC) conclusions (March - December 2024)
- 27 new classifications
- 16 updated classifications

Impact on Cosmetics:

- Example: Helional classified as Skin Sens 1B: H317
- Affects products like perfumes, cosmetics, and cleaning agents.



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Saudi Arabia: The Product Safety Law

<u>The Product Safety Law</u>, issued under Royal Decree No. (M/36) (Aug 16th 2024), establishes regulations to ensure the safety of products marketed in Saudi Arabia. It applies to <u>all products</u>, including those sold electronically, except those under the jurisdiction of the Food and Drug General Authority.

Timeline: Takes effect 90 days after its publication date in the gazette.

All product must be safe

Conformity Assessment

Market Monitoring

Responsible parties

Penalties



Saudi Arabia: The Specifications and Quality Law

<u>The Specifications and Quality Law</u>, issued under Royal Decree No. (M/36) (Aug 16 2024), establishes a framework for standardization and quality in Saudi Arabia. The act sets out the roles and responsibilities of the Saudi Standards, Metrology and Quality Organization (Authority) and regulates the preparation, adoption, and implementation of standards and quality marks.

Timeline: Takes effect 90 days after its publication date in the gazette.

Unified regulatory framework replacing the fragmented system

Emphasis on pre-market controls and proactive market surveillance

Updated technical standards with significant penalties for non-compliance

Quality Mark

Penalties



Israel's Environmental Protection Law Amendments 2024

Israel - The Environmental Protection Law (streamlining environmental licensing procedures) (legislative amendments) 2024, published on 16 April 2024, implements the permit consolidation policy, which has been widely discussed in recent years.



Implemented as of 1 January 2027. Other amended provisions will be implemented as soon as 1 September 2024.

Activity subject to a Unified Emission Permit under the Clean Air Act is exempt from a Hazardous Materials Permit





Hazardous Materials Permit is required only when the chemical is classified as hazardous under CLP or activities specified in the law.

Jordan Implementation of Extended Producer Responsibility

On July 4th 2024, the Jordanian Ministry of Environment launched the Extended Producer Responsibility (EPR) initiative as part of the Jordan Bottle Recovery Project. The project involves the United Nations Human Settlements Programme, alongside various government and private sector entities. Revolutionize waste management by improving the collection and recycling of clean plastic and glass waste from major service sectors.

Key Changes

- Producer Accountability: Producers are now responsible for the entire lifecycle of their products, including take-back, recycling, and disposal.
- Incentivized Recycling: Installation of reverse vending machines equipped with scanners to sort waste. Participants are rewarded with points and vouchers for recycling.
- Focus on Recyclability: Encourages the production of environmentally friendly and easily recyclable products.



There will be a greater emphasis on creating products that are more easily recyclable, potentially requiring changes in material selection and manufacturing processes.



Mauritius: The Enviornmental Bill (No.1 of 2024)

Introduction of the Environment Bill (No. I of 2024) replacing the Environment Protection Act. To establish a modern legislative framework for enhanced environmental protection, management, and conservation within Mauritius.

Key Changes

- Policy Integration: National Policy on Sustainable Development & Circular Economy every 5 years.
- New Committees: Establishment of National Environmental Laboratory, Observatoire de L'Environnement, and National Oil Spill Coordination Committee.
- Regulatory Enhancements: Stricter Environmental Impact Assessment (EIA) and Stratgic Environmental Assessment (SEA) requirements.
- Plastic Management: Framework for sustainable plastic use and reduction.

Impact

- Compliance Requirements: More rigorous environmental assessments and reporting obligations.
- Operational Adjustments: Need for compliance with new plastic management and circular economy strategies.
- Risk Management: Enhanced penalties and stricter enforcement increase the risk of non-compliance.





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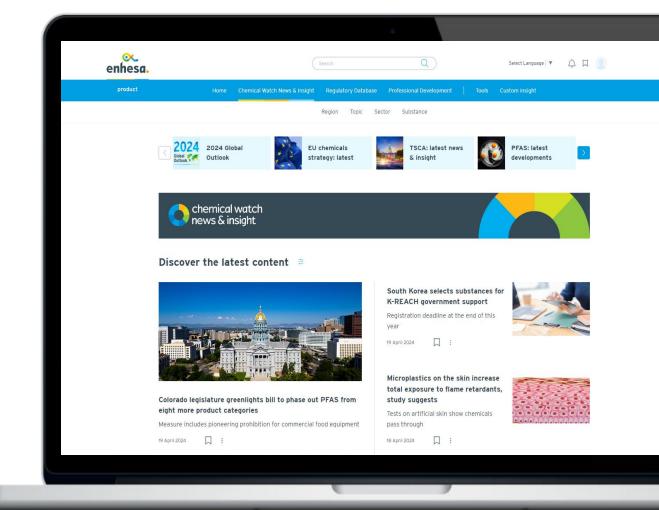




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Key Regulatory Updates Europe 2024

14-15 October | Conference

PFAS Updates Europe 2024

16 October | Conference







