





# Europe

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### **European Union**

The Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) regulation, Regulation (EC) No 1907/2006, is the legal framework for the regulation of chemicals in the European Union (EU). It was adopted to enhance the protection of human health and the environment from potential risks posed by chemicals, while promoting the competitiveness of the EU chemicals industry. REACH entered into force on June 1, 2007, and applies to all chemical substances, including those used in industrial processes, consumer products, and articles such as paints, cleaning products, furniture, and electronics. It requires manufacturers and importers to register substances produced or imported in quantities of one tonne per year or more, unless specifically exempted. Registered substances can then circulate freely within the EU market. The regulation also encourages alternative testing methods to reduce reliance on animal testing.

Under REACH, companies have the burden of proof to identify and manage the risks associated with their substances. They must demonstrate safe use to the European Chemicals Agency (ECHA) and communicate risk management measures to downstream users. If risks cannot be controlled, authorities can restrict or ban substances, with the long-term goal of substituting hazardous chemicals with safer alternatives. The registration process follows a "one substance, one registration" principle, requiring companies producing the same substance to share data through a joint registration dossier submitted to ECHA. The dossier consists of a Technical Dossier (covering identity, classification, test data, and use) and a Chemical Safety Report (CSR) (for substances exceeding 10 tonnes per year, detailing hazard assessments and exposure scenarios). Since the registration deadline of May 31, 2018, unregistered chemicals cannot be manufactured or marketed in the EU, ensuring strict compliance with REACH regulations.

### Key News from 2024

#### ECHA Expands SVHC Candidate List in 2024

In 2024, the European Chemicals Agency (ECHA) added seven substances to its Candidate List of Substances of Very High Concern (SVHC) on three occasions, bringing the total to 242 entries. Notable additions include  $bis(\alpha,\alpha-dimethylbenzyl)$  peroxide in June for its reproductive toxicity, and triphenyl phosphate in November for its endocrine disrupting properties. These updates aim to better protect human health and the environment by identifying and regulating hazardous chemicals. Companies are now required to manage the risks associated with these substances and provide safety information to customers and consumers. Read more <u>here</u>, <u>here</u> and here.

#### European Union Updates CLP Regulation and ECHA Issues Revised Guidance

The European Union has adopted Regulation (EU) 2024/2865, amending the Classification, Labelling, and Packaging (CLP) Regulation. It was published in the Official Journal on November 20, 2024, and entered into force on December 10, 2024. In conjunction, the European Chemicals Agency (ECHA) published updated guidance on November 13, 2024, detailing the application of new hazard classes, including criteria for endocrine disruptors and persistent, bioaccumulative, and toxic substances. Read more <a href="here">here</a>, here</a> and <a href="here">here</a>, here</a> and here.



# Key News from 2024

#### EU Adopts New Regulation to Combat Ozone Depletion

The European Union has adopted Regulation (EU) 2024/590 to limit emissions of ozone-depleting substances. The Regulation was published on February 20, 2024, and entered into force on March 11, 2024, repealing Regulation (EC) No 1005/2009. The Regulation prohibits the production, import, export, and sale of listed substances, with exemptions for specific uses such as feedstock, process agents, essential laboratory applications, critical halon uses, and emergency methyl bromide applications. This initiative is in line with the European Green Deal, which aims to protect the ozone layer and reduce greenhouse gas emissions. Read more here.

#### **ECHA Launches** ECHA CHEM Database

On January 30, 2024, the European Chemicals Agency (ECHA) launched ECHA CHEM, a user-friendly platform providing information on more than 100,000 chemicals registered under REACH. This initial release aims to enhance public access to chemical data, with future expansions planned to include the Classification and Labelling Inventory and Regulatory Lists. ECHA CHEM reflects ECHA's commitment to efficiently manage the growing volume of chemical data and to take advantage of technological advances. Read more <a href="https://example.com/here-en-alpha

#### New Distributor Responsibilities and UFI Compliance in Poison Centre Notifications

The recent amendments to the Classification, Labelling, and Packaging (CLP) Regulation introduce significant responsibilities for distributors. Distributors are now required to ensure that hazardous mixtures are correctly classified, labelled, and packaged before they are placed on the market. They must also verify that suppliers have fulfilled their Poison Centre Notification (PCN) obligations, including the assignment and proper labeling of Unique Formula Identifiers (UFIs). To help companies manage UFIs effectively, the European Chemicals Agency (ECHA) published an infographic on January 21, 2025, emphasizing the 'one UFI – one composition' principle. Adherence to this principle is critical for compliance and to facilitate accurate emergency response by poison centres. Read more <a href="here">here</a> and here.

#### Progress on the EU PFAS Restriction Proposal in 2024

The European Chemicals Agency (ECHA) has made significant progress on the restriction proposal for per- and polyfluoroalkyl substances (PFAS) in 2024. In March, ECHA's Scientific Committees began evaluating the proposal, focusing on the potential health and environmental impacts of PFAS. In June, ECHA provided updates showing significant progress in assessing the risks associated with these substances. In July, the EU introduced restrictions on a specific PFAS sub-group, perfluorohexanoic acid (PFHxA), to reduce associated health and environmental risks. These developments underscore the EU's commitment to regulating PFAS and protecting public health and the environment. Read more here, here and here.

# **Key Dates for 2025**

From **January 1, 2025**, all hazardous mixtures must be notified to poison centers using the harmonized format under Annex VIII of the CLP Regulation. From **May 1, 2025**, new hazard classifications under the CLP Regulation, including endocrine disruptors and persistent, bioaccumulative, and toxic substances, will apply for substances placed on the market.



### Ukraine

On July 23, 2024, Ukraine officially adopted the Technical Regulation on the Safety of Chemical Products, known as UA-REACH, aligning its chemical safety legislation with the European Union's REACH framework. The regulation mandates the registration, classification, and risk management of all chemical substances manufactured, imported, or sold in Ukraine in quantities exceeding one tonne per year. Its primary objective is to protect human health and the environment by ensuring that companies properly assess and manage risks throughout the life cycle of chemicals. The Ministry of Environmental Protection and Natural Resources of Ukraine oversees the enforcement of UA-REACH, managing the registration process, compliance evaluations, and enforcement actions against non-compliant entities.

Under UA-REACH, companies are required to register chemicals, submit technical dossiers, and, for quantities above 10 tonnes per year, provide Chemical Safety Reports detailing hazard assessments and risk management measures. Hazardous chemicals, especially those that are carcinogenic, mutagenic, and reprotoxic (CMRs) or those harmful to aquatic life, face more stringent assessment requirements, with staggered registration deadlines ranging from October 2026 to March 2030. The pre-registration period runs from January 26, 2025, to January 26, 2026, after which a public list of pre-registered substances will be published. Compliance includes structured procedures, classification by IUPAC and CAS numbers, and adherence to Group Standard approvals. UA-REACH applies to manufacturers, importers, authorized representatives, and industrial end-users, with penalties ranging from administrative fines to market restrictions and criminal sanctions for non-compliance.

# Key News from 2024

#### Ukraine Implements CLP Regulation to Align with EU Standards

On May 10, 2024, Ukraine adopted the Technical Regulation for the Classification of Hazards, Labelling, and Packaging of Chemical Products to align with the EU's Classification, Labelling and Packaging (CLP) Regulation. Effective November 15, 2024, this regulation standardizes the hazard classification, labelling, and packaging requirements for chemical products in Ukraine. Market participants will need to ensure compliance with these new standards in order to continue operating in the Ukrainian market. Read more <a href="here">here</a> and <a href="here">

### Ukraine Implements UA-REACH Regulation

On July 23, 2024, the Ukrainian Cabinet of Ministers adopted Resolution No. 847, introducing the new Technical Regulations on the Safety of Chemical Products, known as UA-REACH. Effective January 26, 2025, this regulation mandates the registration of all chemicals produced, imported, or sold in Ukraine in quantities exceeding one tonne per year. The aim is to improve safety and compliance standards for chemical products in the Ukrainian market. Read more here and here.



# Key News from 2024

#### Ukraine Aligns with EU on Ozone-Depleting Substances

Ukraine has adopted new labelling requirements for ozone-depleting substances and fluorinated greenhouse gases. On September 9, 2024, Ukraine notified the WTO of the adoption of Order No. 661, entitled "On Approval of the Procedure for Labeling of Controlled Substances, Goods, and Equipment". The Order was issued by the Ministry of Environmental Protection and Natural Resources on June 10, 2024, and will enter into force on March 1, 2025. Read more <a href="here">here</a>.

### Ukraine Adopts Restrictions on Hazardous Substances in Electronics

Ukraine has adopted new restrictions on the use of hazardous substances in electrical and electronic equipment, in line with global standards to reduce environmental and health risks. The move aims to control the presence of harmful chemicals in electronics and promote safer manufacturing and disposal practices. Read more <u>here</u>.

#### Ukrainian Ministry of Environmental Protection Launches EPR Pilot Project

The Ministry of Environmental Protection and Natural Resources of Ukraine has launched a pilot project on Extended Producer Responsibility (EPR). The project aims to increase environmental accountability by requiring manufacturers, brand owners, and importers to manage the life cycle of their products, including waste collection and recycling. The initiative focuses on different waste streams to promote sustainable practices. Read more <a href="here">here</a>.

### **Key Dates for 2025**

Ukraine-REACH was implemented on **January 26, 2025,** marking a key milestone in the country's chemical regulation framework. On the same day, pre-registration for existing substances begins, allowing companies to prepare for compliance.

By **November 15, 2025,** companies must meet the CLP notification deadline for substances placed on the market before November 15, 2024, while substances introduced after this date must be notified within 30 days of their first placement. Additionally, by this date, all chemical products available on the Ukrainian market before November 26, 2024, must comply with classification, labeling, and packaging (CLP) requirements, ensuring accurate hazard communication.

The pre-registration deadline is set for **January 26, 2026**, with late pre-registration permitted within six months of the first manufacture or import after this date but before applicable registration deadline.



### **United Kingdom**

The UK Registration, Evaluation, Authorisation, and Restriction of Chemicals (UK-REACH) serves as the legal framework for regulating chemicals in Great Britain (England, Scotland, and Wales) following the UK's withdrawal from the European Union. UK-REACH was established on January 1, 2021, under the European Union (Withdrawal) Act 2018, UK-REACH and retains the core principles of EU-REACH while making changes to make it workable in the UK. The Regulation applies to chemical substances manufactured or imported in quantities of one tonne per year or more, whether as individual substances, mixtures (e.g. paints, inks) or components of articles (e.g. furniture, clothing, vehicles). To legally place chemicals on the UK market, manufacturers, importers, and distributors must register their substances under UK-REACH, with transitional arrangements in place to support businesses affected by the repeal of EU-REACH in the UK. Northern Ireland continues to follow EU-REACH under the Northern Ireland Protocol.

Certain substances are exempt from UK-REACH, including radioactive substances, waste, non-isolated intermediates, and substances under customs supervision. Additionally, some substances are regulated under more specific legislation, such as human and veterinary medicines, food additives, plant protection products, and biocides. In addition to UK-REACH, the Great Britain Classification, Labelling, and Packaging (GB CLP) Regulation came into force on January 1, 2021, requiring manufacturers, importers, and downstream users to properly classify, label, and package hazardous substances before placing them on the market. Unlike the EU CLP Regulation, the GB CLP allows the UK to make independent decisions on mandatory hazard classifications and labelling, deciding whether to align with EU decisions or introduce its own classification system.

# Key News from 2024

### DEFRA Proposes Alternative Transitional Registration Model for UK REACH

On May 6, 2024, the UK Department for Environment, Food and Rural Affairs (DEFRA) launched a consultation on an Alternative Transitional Registration Model (ATRm) for UK REACH. The ATRm aims to reduce costs for companies transitioning from EU REACH to UK REACH, while maintaining the protection of for human health and the environment. Key proposals include reducing hazard information requirements for transitional substances, enhancing use and exposure data, and formalizing data sharing arrangements between registrants. The outcome of the consultation is expected in 2025. Read more here.

#### **UK Extends Restrictions on Chemicals in Cosmetics**

The United Kingdom has expanded its list of prohibited substances in cosmetic products, to include 13 new chemicals identified as carcinogenic, mutagenic, or toxic for reproduction (CMR). This action is in line with the latest scientific assessments and aims to enhance consumer safety by preventing the use of these hazardous substances in cosmetics. Companies are advised to review the updated regulations to ensure compliance and avoid potential market withdrawals. Read more <u>here</u>.



# Key News from 2024

### UK Updates to the Mandatory Classification and Labelling (GB MCL) List

The United Kingdom has recently updated its Mandatory Classification and Labelling (GB MCL) list to reflect the latest scientific assessments and enhance consumer safety. On January 11, 2024, the Health and Safety Executive (HSE) proposed to update the status of 90 substances on the GB MCL list from the 14th and 15th Adaptations to Technical Progress (ATPs) to the CLP Regulation. Subsequently, on March 12, 2024, the HSE announced the addition of 25 chemical substances to the GB MCL list with an effective date of March 2, 2024, and a compliance date of September 2, 2025. In addition, on June 26, 2024, the GB MCL list was updated to give legal effect to the GB MCLs for 88 substances, while removing entries for titanium dioxide (in powder form) and granulated copper. These updates are intended to ensure accurate hazard communication and regulatory compliance. Companies are advised to review the updated list to ensure compliance and avoid potential market withdrawals. Read more here, here and here.

