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2024 Regulatory Developments on Hazardous Substances in Products in the EU, Switzerland and the UK

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01. About The Author

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Dieudonné Ymedji is a Senior Regulatory Compliance Specialist with the Global Regulatory Compliance team since 2007.

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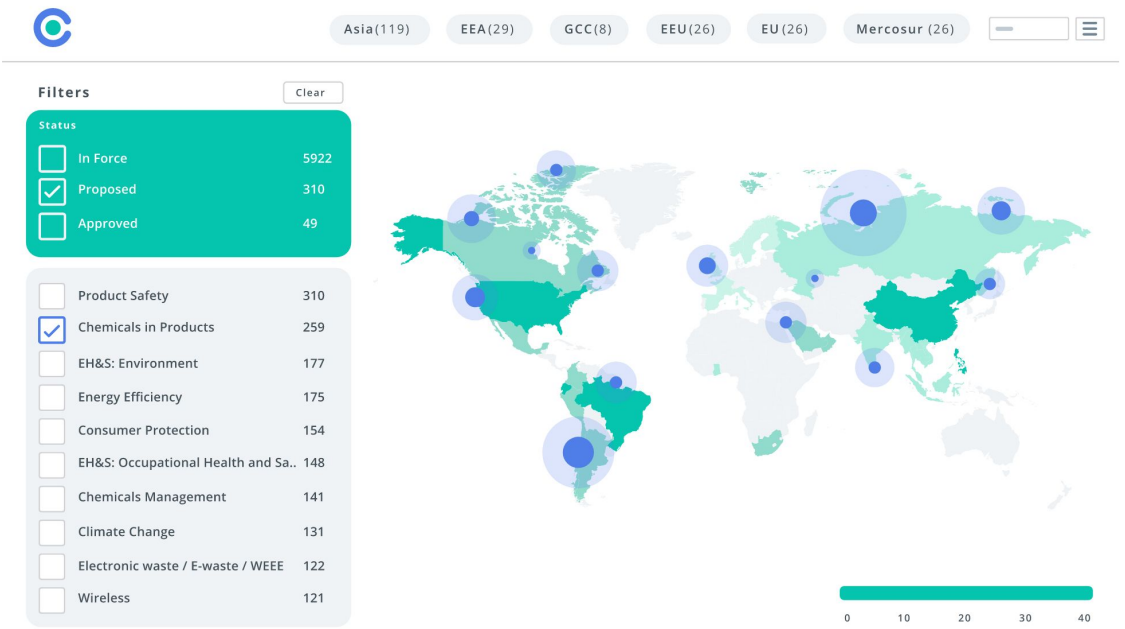

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03. Introduction

In 2024, as in the preceding years, regulations regarding the production and use of hazardous substances have continued to evolve with the introduction of new and proposed restrictions in the EU, Switzerland, and the UK.

These developments intend to bring consumers closer to a toxic-free environment and ensure the removal of harmful substances from products, such as electrical and electronic equipment, textiles, or food packaging they use every day.

This paper highlights the changes and additions made throughout this year to the EU REACH Candidate List and Annex XVII, and the recent revisions to the POPs regulation 2019/1021. It also provides an overview of the recent revisions to two major Swiss chemicals ordinances and discusses the current state of UK REACH and POPs regulations.

04. REACH SVHC Updates

Two updates of the candidate list of substances of very high concern for authorization were carried out by the European Chemicals Agency (ECHA) on 23 January and 27 June 2024 to add 6 new substances to the 235 already listed.

The new chemicals, mainly found in products such as printer inks and toners, adhesives, sealants, polymers, or cleaning products, are:

- 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol; (UV-329) CAS number 3147-75-9
- 2-(2'-hydroxy -3' -tert-butyl-5'-methylphenyl)-5-chloro benzotriazole; Bumetrizole (UV-326) CAS number 3896-11-5
- 2,4,6-tri-tert-butylphenol; phenol, 2,4,6-tris(1,1-dimethylethyl); (2,4,6-TTBP) CAS number 732-26-3
- 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one; (Irgacure 379) CAS number 119344-86-4
- Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol (OAPP)
- Bis(α,α-dimethylbenzyl) peroxide (dicumyl peroxide, CAS number 80-43-3)

Following unanimous agreement of ECHA's Member State Committee at its last October meeting, **Triphenyl phosphate** *(TPhP; EC no. 204-112-2)*, widely used as a plasticizer and flame retardant, will be included in the Candidate List due to its endocrine disrupting properties in the environment. ECHA indicated that this addition will be formalized in early November to bring the Candidate List to **242** substances and groups of substances.

As a result of all these inclusions to the Candidate List, suppliers of articles that contain > 0.1% w/w of any of these substances must **inform recipients of the articles about the presence of the SVHC and on how to use it safely or update the safety data sheet they provide to their customers.**

They shall also notify ECHA within six months from the date the substance has been included in the list and, since **05 January 2021**, submit to ECHA via the Substances of Concern in articles as such or in complex objects or products (SCIP database), information on articles containing any SVHC.

Besides the recent additions, ECHA initiated on 30 August 2024, a public consultation for a further update of the Candidate List with six potential SVHC. These substances, commonly used as flame retardant and stabilizer for plastics and rubber or additive for high-performance coatings and lubricants, are:

- 6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (CAS: 2156592-54-8)
- O,O,O-triphenyl phosphorothioate (CAS: 597-82-0)
- Octamethyltrisiloxane (CAS: 107-51-7)
- Perfluamine (CAS: 338-83-0)
- Reaction mass of triphenylthiophosphate and tertiary butylated phenyl derivatives (CAS: 192268-65-8)
- Tris(4-nonylphenyl, branched) phosphite

Stakeholders had until 14 October 2024 to provide input on the proposal.

Based on the comments received, ECHA's Member State Committee may need to decide by the end of December 2024 or in January 2025 whether to include these substances in the Candidate List. A unanimous decision will result in an increase of SVHC for eventual inclusion in the authorization list from **241** to **247**.

05. REACH Annex XVII Updates

The list of restricted substances is updated regularly through amendments to REACH Annex XVII. This process can involve the introduction of a new restriction, the revision, or the deletion of an existing entry. Currently, there are 79 entries in REACH Annex XVII, each containing specific restrictions. Producers, importers, suppliers, and distributors of consumer articles in the EU market must ensure their products comply with the restrictions outlined in these entries. As of 2024, there have been two significant changes to Annex XVII, including a revision of one existing entry and the addition of a new one.

5.1. Revision of D4, D5, and D6 Restrictions Scope

On 16 May 2024, the EU Commission issued Regulation (EU) 2024/1328 to revise existing entry 70 of REACH Annex XII regarding the restriction of Octamethylcyclotetrasiloxane (D4) and Decamethylcyclopentasiloxane (D5) in wash-off cosmetic products.

The amendment expands the substances in scope to include Dodecamethlcyclohexasiloxane (D6) and broadens the products covered beyond rinse-off cosmetics. This includes solvent for the dry cleaning of textiles, leather and fur, and medical devices within the meaning of Regulations (EU) 2017/745 and 2017/746.

The amendment prohibits the placing on the market of D4, D5, and D6 as substances on their own, as constituents of other substances, or in mixtures. It further provides for restriction of the use of D4, D5, and D6 in a concentration equal to or greater than 0.1% by weight of the respective substance in all types of cosmetics products and various consumer and professional products, including dry cleaning, waxes, washing, and cleaning products.

Derogations are specified for certain industrial, consumer, and professional use applications of D4, D5, and D6, including sealants, protective coatings, dental impression materials, and medical devices for scar and wound management and stoma care.

As regards the timeline for implementation, the amendment provides manufacturers and industries concerned with some time to enable them to adapt to the new requirements and develop more eco-friendly alternatives. To this effect, the following transitory periods are set for the restriction of:

- D4 and D6 as a solvent for the dry cleaning of textiles, leather and fur, **6 June 2026;**
- D4, D5 and D6 in all cosmetic products other than non-rinse-off cosmetics, **6 June 2027;**
- D4, D5 and D6 in medical devices as defined in Article 1(4) of Regulation (EU) 2017/745 and in Article 1(2) of Regulation (EU) 2017/746, medicinal products, as defined in Article 1, point 2, of Directive 2001/83/EC, and for veterinary medicinal products, as defined in Article 4(1) of Regulation (EU) 2019/6, **6 June 2031;**
- D5 as a solvent in the dry cleaning of textiles, leather and fur, **6 June 2034.**

5.2. Restrictions of Undecafluorohexanoic acid (PFHxA), its salts and PFHxA-related Substances

On 19 September 2024, the European Commission made a significant decision regarding chemical management by adopting Regulation (EU) 2024/2462. This regulation introduces new restrictions on a subgroup of PFAS, known for their persistence in the environment. Specifically, it creates a new **entry 79** to REACH Annex XVII to address the restriction of undecafluorohexanoic acid (PFHxA), its salts and PFHxA-related substances.

Under this new entry, the placing on the market of consumer textiles, food packaging, consumer mixtures, cosmetics, and some firefighting foam applications is prohibited if they contain PFHxA, its salts, and related substances in excess of ≥25 ppb or ≥1000 ppb. The restriction measures are effective in all EU member states since **10 October 2024**, with the following phase-out transitory periods:

- **10 April 2026** for firefighting foams and firefighting foam concentrates for training, for testing and for public fire services;
- **10 October 2026** for textiles, leather, fur and hides in consumer products, footwear, paper and cardboard used as food contact materials, mixtures for consumer use, cosmetic products;
- **10 October 2027** for textiles, leather, furs and hides, other than in clothing and related accessories for the general public; and
- **10 April 2029** for firefighting foams and firefighting foam concentrates for civil aviation.

The regulation also provides exemptions for certain products and applications for which no alternatives are currently available. This includes personal protective equipment intended to protect users against risks within the scope of risk category III as described in Regulation (EU) 2016/425; medical devices within the scope of Regulation (EU) 2017/745 and 2017/746; construction textiles, and applications of PFHxA in semiconductors, batteries, or fuel cells for green hydrogen.

Companies that use PFHxA or related substances should not lose sight of the upcoming blanket PFAS ban envisaged by the EU legislator. By anticipation, they should start putting in place a broad phase-out program covering all substances likely to be classified as PFAS.

5.3. Update on PFAS Restrictions Proposal

In February 2023, an EU universal PFAS ban proposal from Denmark, Germany, the Netherlands, Norway and Sweden was submitted to ECHA. The scope of the proposal is unprecedented and very broad in its potential application. Based on the widely adopted OECD definition of PFAS published in 2021, approximately 10,000 substances would be covered and almost all industries including electronics, textiles, cosmetics, food contact materials, consumer cookware, packaging, semiconductors and medical devices would be impacted.

With regard to the process status and next steps, ECHA's RAC and SEAC scientific committees started in March of this year to evaluate the proposal based on the sectors of use described in the proposal dossier and new sectors identified in the record number of more than 5,600 comments received during the public consultation. To date, they have provisionally concluded on the proposal's scope, the hazards associated with PFAS, and its potential impacts on the following key sectors:

- Consumer mixtures, cosmetics, and ski wax
- Metal plating and the manufacture of metal products
- Petroleum and mining

Textiles, upholstery, leather, clothing, carpets; food contact materials and packaging; applications of fluorinated gases; transport; and energy are the next sectors to be discussed at the RAC/SEAC upcoming meetings of November.

Upon completion of this scrutiny process, RAC and SEAC will then each deliver a final opinion on the restriction dossier. As with previous Annex XVII proposals, ECHA will then deliver these final opinions to the EU Commission who, together with Member States, will then decide on the potential restriction and conclude with a draft amendment to the list of restrictions in REACH Annex XVII.

In light of the initial timeline set by ECHA, the adoption process is likely to be finalized and take effect by 2027 at the earliest.

5.4. Proposal to Include DMAC and NEP to Annex XVII

On 30 July 2024, the European Commission notified the World Trade Organization (WTO) about a new regulatory proposal for Annex XVII of REACH. The proposal aims to add two new restriction entries for **N,N-dimethylacetamide (DMAC)** and **1-ethylpyrrolidin-2-one (NEP)** respectively.

DMAC is used as a solvent or processing agent across many sectors, such as the production of textile fibers, medical membranes, agrichemicals, electrical wire insulation, pharmaceuticals, while NEP is used as a solvent in specialized coatings and as a cleaning agent in the manufacture of optical lenses.

Prepared by ECHA and supported by its RAC and SEAC scientific committees in their March and June 2023 opinions, the restriction proposal aims to protect workers from exposure to harmful chemicals. It prohibits the manufacture and placing on the EU market of DMAC and NEP in concentrations equal to or greater than 0.3 %, unless manufacturers update safety reports and ensure compliance with Derived No-Effect Levels (DNELs). DNELs proposal for DMAC is set at 13 mg/m³ for long-term inhalation exposure and 1.8 mg/kg body weight per day for long-term dermal exposure, while NEP DENEL long-term inhalation and dermal exposure are established to 4.0 mg/m³ and 2.4 mg/kg body weight per day respectively.

The proposed changes are set to take effect 20 days following publication in the EU Official Journal and its application for most sectors in the following 18 to 48 months.

06. Changes to POPs Regulation

The recast EU POPs regulation 2019/1021 aims to protect human health and the environment by eliminating or restricting the production and use of POPs, as defined in the Stockholm Convention. Substances listed in Annex I are prohibited from production, manufacturing, placing on the market, and use in articles.

On 27 September 2024, the EU Commission published two regulations to amend and expand the scope of POP substances in Annex I.

6.1. Revision of HBCDD unintentional trace contaminant (UTC) limit

Regulation (EU) 2024/2555, which entered into force on 17 October 2024, amends Annex I to lower the existing unintentional trace contaminant (UTC) limit for **HBCDD** and its main diastereoisomers from 100 mg/kg (0.01% by weight) to 75 mg/kg in substances, mixtures, or articles.

HBCDD, known for its persistent, bioaccumulative, and toxic properties, is widely used as a flame retardant in various materials including textiles, packaging material, and high-impact polystyrene (HIPS) for electrical and electronic uses. It is also on the REACH candidate list and is subject to authorization.

Taking into account Regulation (EU) 2022/2400, which amends Annex IV to Regulation (EU) 2019/1021 to reduce the permissible limit for a number of substances (*including HBCDD*) in waste, the amendment maintains the existing 100 mg/kg limit for HBCDD used in recycled polystyrene in the production of expanded and extruded polystyrene insulation materials for buildings or civil engineering works. Additionally, to adapt to scientific and technical progress, particularly analytical methods and recycling technologies, this exemption shall be reviewed and assessed by the Commission by **1 January 2026**.

6.2. Addition of methoxychlor to Annex I

To align the Union's legislation with its international commitments under the Stockholm Convention, the second amendment (Regulation (EU) 2024/2570) includes **methoxychlor**, a pesticide previously used as a replacement for dichlorodiphenyltrichloroethane (DDT), in Annex I of the list of restricted substances.

Contrary to Decision SC/11-9, 2023, adding methoxychlor without any specific exemptions in Annex A to the Stockholm Convention, the new regulation sets at 0.01 mg/kg a limit value for methoxychlor occurring as an UTC in substances, mixtures, and articles.

Since 17 October 2024, manufacturers, importers, and distributors handling methoxychlor or products containing methoxychlor must comply with the new restrictions, which do not provide for a transitory period.

In addition to the aforementioned regulations, two proposals to include **Dechlorane Plus** and UV-328 in Annex I are currently under review and are likely to be finalized by the end of the year.

6.3. Proposed listing of Dechlorane plus to Annex I

This proposal, presented to stakeholders on 26 June 2024, aims to achieve an EU toxic-free environment by setting out measures to restrict the manufacture, use and placing on the market of Dechlorane Plus™ along with its syn-isomer and anti-isomer.

Dechlorane Plus is a synthetic substance mainly used as a flame retardant in adhesives/sealants and polymers. Due to its very persistent and very bioaccumulative (vPvB) properties, it was identified by ECHA as SVHC in 2018 and as a persistent organic pollutant by Decision SC-11/10, 2023 of the Conference of the Parties to the Stockholm Convention. The proposal allows concentrations of dechlorane plus occurring as an unintentional trace contaminant (UTC) equal to or below 1 mg/kg in substances, mixtures, or articles.

To facilitate the various compliance efforts that industry will undertake, the proposal also provides specific exemptions for certain essential applications such as aerospace, space and defense applications, medical imaging and radiotherapy devices, until 26 February 2030.

In light of Decision SC-11/10, the proposal also foresees derogations for replacement parts. It allows their continued use, where dechlorane plus was initially used in production, until the end of their service life or 31 December 2043, whichever comes first.

Lastly, to avoid recalling articles that contain Dechlorane Plus and were already in use by their final users in the Union before the expiry date of the relevant exemptions, the proposal permits their continued use.

6.4. Proposed listing of UV-328 to POPs Regulation Annex I

The draft delegated regulation on the listing of UV-328 (CAS RN 25973-55-1) to Annex I, open to a public consultation between 30 July and 27 August 2024, imposes stringent controls on its manufacture, marketing, and use in the EU/EEA territories.

Substance member of the phenolic benzotriazoles (BZTs) group, UV-328 is frequently used in consumers products, including food contact materials and children's products as a UV absorber and stabilizer. It is already regulated as SVHC subject to authorization under REACH Annex XIV and as a persistent organic pollutant on the basis of Decision, SC-11/11, 2023.

Under the proposal, the ban of the production of UV-328 in substances on their own; in mixtures, or in articles, shall apply from 26 February 2025. However, by way of derogation, the placing on the market and use of UV-328 present in land-based motor vehicles; mechanical separators in blood collection tubes; and triacetyl cellulose (TAC) film in polarizers and photographic paper may continue until 26 February 2030. For their spare parts, the proposal allows continued use until the end of their service life or until 2044, whichever comes first.

Companies importing products that contain dechlorane plus or UV-328 into the EU should now start to prepare for the rollout of requirements surrounding the proposals by transitioning to safer alternatives and reassessing their supply chains.

07. Updates to Swiss Chemicals Ordinances

To improve environmental protection and human health, as well as facilitate trade and reduce trade barriers, the Swiss legislation on restrictions of hazardous substances in products is closely aligned with EU regulations on chemicals.

To this effect, a significant change was made to the Ordinance on Chemical Risk Reduction (ORRChem) and the Protection Against Dangerous Substances and Preparations Ordinance (ChemO).

On 31 May 2024, an amendment to Annex 2.10 of the ORRChem was made with the objective of adapting to the recast EU Fluorinated Gases Regulation 2024/573 and to reduce emissions of ozone-depleting and potent climate-warming refrigerants. The amendment provides for the ban on the placing on the market of new systems and devices containing refrigerants that are particularly harmful to the ozone layer. This includes cooling and heating technologies such as:

- Appliances for the refrigeration and freezing of food and perishable goods;
- Appliances for cooling or heating rooms;
- Appliances for cooling or heating processes;
- Mobile air conditioning installations used in motor vehicles, rail vehicles or ships;
- Mobile refrigeration installations for the transport of food or perishable goods;
- Mono-split installation (air conditioning and heat pump) with a refrigerant charge of less than 3 kg per circuit, if the refrigerant used has a GWP of 750 or more;
- Self-contained installation for the refrigeration and freezing of food and perishable goods, if the refrigerant used has a GWP of 150 or more;
- Heat pumps used for local or remote heat distribution
    - with a cooling capacity greater than 600 kW;
    - if the air-stable refrigerant used has a GWP greater than 2100; or
    - equipped with an indoor element and an outdoor element (split heat pumps) and with a capacity of less

than 3 kg per refrigeration circuit, if the air-stable refrigerant used has a GWP equal to or greater than 750.

Changes to Point 2.2 of Annex 2.10 specify exemptions from the prohibition under certain conditions, such as when no substitutes are available according to current technology or when norms prohibit the use of non-stable refrigerants. A further derogation is provided for installations and applications with an evaporation temperature below -90 °C.

The other key change introduced to Annex 2.15 centers around the takeback and EPR scheme for waste batteries. It strengthens the takeback of the increasing number of batteries intended for the propulsion of electric cars. As part of their takeback obligations, stakeholders in scope are allowed to charge for additional costs incurred for the disposal of significantly damaged batteries. In addition, a new provision allows for the reimbursement of the anticipated disposal tax when exporting batteries.

Finally, in light of the update to the EU candidate list operated by ECHA on 24 January 2024, the Swiss list of candidate substances was updated last July with the inclusion of seven new entries into Annex 3 of the ChemO. As a result, the Swiss candidate list now consists of **240** substances and groups of substances, one less than the corresponding EU list. This listing, similar to the EU, triggers obligations along the supply chain (i.e., notifying the Swiss Common Notification Authority of Chemicals and communicating on safe use). To minimize the risks of penalties for non-compliance and damage to their reputation or brand, product manufacturers and importers should promptly determine if their products contain any new substances above 0.1% w/w and substitute them with safer alternatives when feasible.

08. UK REACH and POPs Regulations Updates

Since 1 January 2021, following Brexit, the UK has been implementing its own regulation on chemicals, separate from the EU REACH and POPs regulations. UK manufacturers are no longer subject to these regulations, except for products marketed in Northern Ireland, where EU rules continue to apply.

8.1. Current State of Substances Restrictions under UK REACH

UK REACH, similar to EU REACH, aims to protect human health and the environment in Great Britain (GB), including England, Scotland, and Wales. It requires companies that manufacture or import chemicals into the UK to register them, provide safety data, and comply with specific restrictions and authorization requirements for certain harmful substances.

It's important to note that since the UK left the EU, no new substances have been identified or added to the UK SVHC list. This list remains unchanged from the EU REACH list from December 2020, which included **209** SVHC. The UK Health and Safety Executive (HSE) does not expect any updates to this list before 2025. In contrast, the EU REACH Candidate List has expanded to include 241 substances, with the addition of 32 new SVHCs.

In its UK REACH work programme 2023-2024, published last February, it transpires that some deviation may occur in the future between the UK and EU SVHC lists. The HSE specifies in this report that it will select candidate substances for SVHC identification from a wider range of sources, reflecting the identified issues in GB. These may or may not include substances that have been submitted for SVHC identification in EU REACH to date.

Regarding the restriction or ban on the manufacture, use, or sale of certain harmful substances, the UK is not remaining closely aligned with EU REACH. More than three years after leaving the EU, no new bans or restrictions on harmful substances have been implemented under UK REACH Annex XVII.

So far, only two restrictions on harmful substances in tattoo ink and lead in ammunition have been initiated.

To improve the regulatory process for restrictions and close the gap with the EU, the 2023-24 Work Programme places emphasis on developing regulatory options rather than implementing immediate restrictions. This entails gathering evidence, conducting regulatory management options analyses (RMOAs), enhancing stakeholder engagement and undertaking preparation work for Annex 15 dossiers. Alongside the Work Programme, a rationale document identifies the following five regulatory priorities:

1. Development of a restriction dossier on PFAS in fire-fighting foams and an assessment of potential additional restrictions on further wide dispersive uses of PFAS and PFAS likely to be released from consumer articles;
2. Continue the review and update ongoing work to address risks assessment on the use of hazardous flame retardants;
3. Continue the evaluation of options to expand the existing UK REACH restriction on the use of Bisphenol-A (BPA) in thermal paper to include other bisphenols;
4. Review the evidence base and evaluate options for a potential restriction of formaldehyde emissions from consumer articles, particularly from manufactured wood, such as medium density fibreboard; and
5. Monitor the progress of the call of evidence initiated to investigate the risks of intentionally added microplastics.

8.2. Draft Persistent Organic Pollutants (Amendment) Regulations 2024

To remain aligned with international standards and commitments under the Stockholm Convention, the UK government laid before the Parliament on 8 October 2024, a draft statutory instrument aiming to implement the latest changes to Annex A of the Stockholm Convention by Decisions SC-11/9, SC-11/10 and SC-11/11.

The proposal prohibits the manufacturing, placing on the market, and use of UV-328, dechlorane plus, and methoxychlor in the UK while allowing for specific UTC limits and exemptions as outlined in the Stockholm Convention.

In parallel to the proposed restrictions of the newly listed substances, the draft also makes a series of technical amendments to Annexes 4 and 5 of the UK POPs Regulation. To this effect, it:

- Sets waste concentration limits for each of them;
- Introduces additional waste controls for pentachlorophenol (PCP), perfluorooctanoic acid (PFOA), dicofol and perfluorohexanesulfonic acid (PFHxS));
- Reduces the existing waste concentration limit for polybrominated diphenyl ethers;
- Adds a new UTC limit for hexachlorobenzene and PCP;
- Revises the existing UTC limit for PFOA relating to the production of polytetrafluoroethylene micropowders; and
- Sets out a new expiry date of 31 December 2026 for an existing exemption that allows the use of PFOA in perfluorooctyl bromide containing perfluorooctyl iodide to produce pharmaceutical products.

The proposal is set to come into force 21 days after the day on which it was made. However, for replacement parts for medical purposes where UV-328 was originally used in their manufacture, the proposal, contrary to the POPs Convention, provides for their continued use until the end of their service life or until 2044, whichever comes first.

A similar derogatory timeframe is also proposed for the use of legacy spare parts for motor vehicles, where dechlorane plus was initially used in production.

09. Conclusion

This paper provided an overview of the most recent regulatory updates on chemical restrictions across the EU, Switzerland, and the UK in 2024.

To access these markets, manufacturers of articles containing the restricted substances in scope must comply with the range of requirements set out in the new enacted rules.

Unlike previous years, the EU regulators have not made significant new proposals for chemical restrictions or authorization requirements this year. However, 2025 is expected to be different with the resumption of work on the long-awaited REACH revision, the progress towards a complete ban on PFAS and the introduction of essential-use criteria to allow specific industrial applications for PFAS where no viable substitutes are available and the chemicals are deemed critical for health or technology.

In contrast to Switzerland, which closely aligns its hazardous chemical regulations to the EU ones, the UK is still striving to implement an effective regulatory regime to keep pace and close the growing gap with the EU on harmful substances restrictions.

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