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REACH Substances Restrictions in Articles: 2023 Roundup

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17 October, 2023

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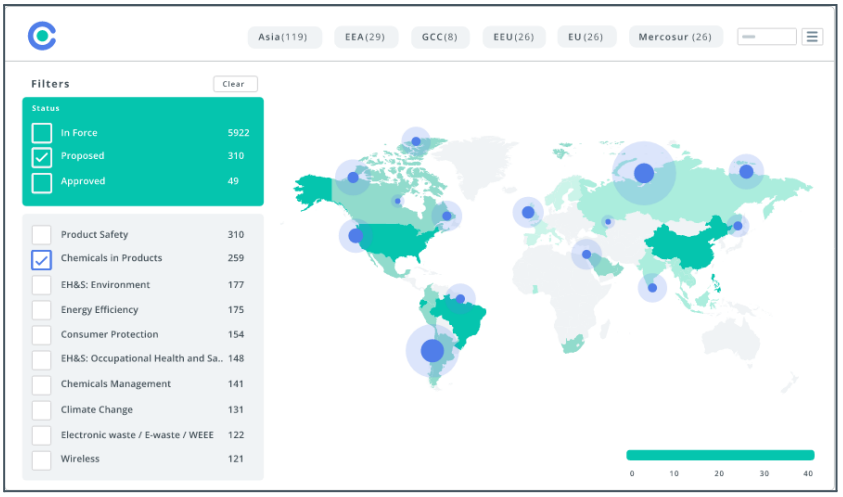

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1. Introduction

The European Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is the European Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals in force since June 2007.

Its overarching goal is to support the development of safe and sustainable chemicals, protect the environment and to reduce human exposure to the most harmful substances. This is achieved each year through the update of two major REACH lists, these being:

- The Candidate List of Substances of Very High Concern (SVHC) for Authorisation[1]; and
- The list in Annex XVII of hazardous substances, mixtures, or articles that are restricted or prohibited to be used in consumer products placed in the EU market.

Over the past decade, these REACH critical lists have grown exponentially in scope and impacts on producers of articles imported or placed into the EU market. This paper aims to provide an overview of the changes and additions made to these lists since the start of 2023 as well as the regulatory proposals introduced for their expansion.

2. New Additions to the Candidate List

SVHC are substances that have been determined through a rigorous evaluation process to have serious effects on human health and the environment. They are identified and placed on the Candidate List if they meet the criteria for carcinogenic, mutagenic or toxic to reproduction (CMR) substances; persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) to the environment

[1] *Candidate List Table*

substances, or they are substances for which there is scientific evidence that they give rise to an equivalent level of concern to CMRs, PBTs or vPvB substances, for example, endocrine disruptors. The inclusion of a SVHC to the Candidate List triggers a number of immediate legal obligations on suppliers of articles containing such substances in a concentration above 0,1% w/w of the article. They are required to:

- Inform recipients of the articles about the presence of the SVHC and on how to use it safely;
- Inform consumers requesting this information within 45 days of receipt of the request;
- Submit a notification to 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.

The Candidate List is dynamic, with new substances normally added twice per year in June and December. However, for this year, the first update to the List occurred on **21 January** with the addition of **nine** new substances widely used for example in flame retardants, paints and coatings, inks and toners, coating products, plasticisers and in the manufacture of pulp and paper. These substances are:

- 1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene] (EC no. 253-692-3, CAS no. 37853-59-1);
- 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (TBBP-A) (EC no. 201-236-9, CAS no. 79-94-7);
- 4,4'-sulphonyldiphenol (bisphenol S) (EC no. 201-250-5, CAS no. 80-09-1);
- Barium diboron tetraoxide (EC no. 237-222-4, CAS no. 13701-59-2);
- Bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof;
- Isobutyl 4-hydroxybenzoate (EC no. 224-208-8, CAS no. 4247-02-3);
- Melamine (EC no. 203-615-4, CAS no. 108-78-1);
- Perfluoroheptanoic acid and its salts;

- Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine (EC no. 473-390-7, no CAS).

The second inclusion followed on **14 June 2023**, to increase the total number of SVHC on the Candidate List from **233 to 235** substances or groups of substances. The two newly added SVHC are:

- Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (TPO) (CAS 75980-60-8, EC number 278-355-8) used in inks, toners, coating products, polymers, adhesives, sealants and putties; and
- Bis(4-chlorophenyl) sulphone (BCPS) (CAS 80-07-9, EC number 201-247-9) used in the manufacture of chemicals, as well as in plastic and rubber articles.

ECHA Recommendation for SVHC Listing to Annex XIV

The REACH Regulation requires ECHA to recommend to the EU Commission SVHC for inclusion in Annex XIV - also known as the REACH Authorisation List. As a general rule, where a substance is included in the Authorisation List it cannot be supplied for use or used after the sunset date[2] unless that use is exempted or an authorization has been granted.

Following a consultation held between 02 February and 02 May 2022, ECHA published on **12 April 2023**, its eleventh recommendation[3] to the European Commission requesting the addition of **eight** SVHC to the REACH Authorisation list.

The substances and groups concerned are the following:

[2] *For each substance included on the Authorisation List two dates are specified: - a* sunset date*, or the date after which the placing on the market and/or use of the substance is prohibited unless an authorization is granted to the user; and a* latest application date *or the date by which the authorization application must be received by ECHA if the applicant wishes to continue to use the substance after the sunset date.*

[3] *https://echa.europa.eu/documents/10162/07521ad6-5563-e5ab-b989-1b1ea49eab4e*

- Ethylenediamine, CAS 107-15-3, EC 203-468-6;
- Diisohexyl phthalate, CAS 71850-09-4, EC 276-090-2;
- Lead, CAS 7439-92-1, EC 231-100-4;
- Glutural, CAS 111-30-8, EC 203-856-5;
- 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one, CAS 71868-10-5, EC 400-600-6;
- 2-benzyl-2- dimethylamino-4'-morpholinobutyrophenone, CAS 119313-12-1, EC 404-360-3;
- 2-(4-tertbutylbenzyl) propionaldehyde CAS 80-54-6, EC 201-289- and its individual stereoisomers;
- Orthoboric acid, sodium salt, CAS 13840-56-7, EC 237-560-2 and its derivatives.

The European Commission will have the final say on which substances from the recommendation list will be included in the Authorisation List and what conditions may apply to each substance.

3. Annex XVII Restrictions Update

The substances' restrictions procedure provides a safety net to manage chemical risks that have not been adequately addressed by another part of the REACH processes, in particular by the registration obligation. Restrictions are designed to control unacceptable risks from the manufacture, use, or placing of a substance on the market. Described in REACH Annex XVII, the restrictions may apply to a substance (or group of substances) on its own or in a mixture, or to an article containing the substance. They can take many forms including general prohibitions on all uses; bans on specific uses (e.g., as a flame retardant); a ban for articles available to the general public; or limits on the concentration of the substance in consumer products such as EEE, textiles, etc.

The List of restricted substances is updated through regular amendments to REACH Annex XVII, resulting in the introduction of a new restriction entry, modifications or deletion of an existing entry of the Annex.

There are currently 78 entries under REACH Annex XVII, each with its own specific restrictions. Producers, importers, suppliers, distributors of consumer articles placed on the EU market, shall ensure that their products are compliant with any restrictions laid down in these entries. 2023 has so far brought three critical changes to Annex XVII with the revision of one existing entry and the addition of two new ones.

3.1. Restrictions for Lead and its Compounds in PVC Articles in Entry 63

On 03 May 2023, Entry 63 of Annex VII that already contains restrictions on the placing on the market and use of lead and lead compounds in certain jewelry articles, articles that may be placed in the mouth by children, as well as use in gunshot used in or near wetlands, was amended by Commission Regulation (EU) 2023/923[4]. The revision introduces a new restriction for lead and its compounds in articles produced from polymers or copolymers of vinyl chloride in concentrations ≥ 0.1% by weight of the PVC material.

This restriction does not apply to articles within the scope of EU Regulations 1935/2004/EC, 2011/65/EU, 94/62/EC, and 2009/48/EC. Also, PVC articles already on the market are not subject to this restriction until **28 November 2024**. Additional derogations and transitory periods cover the placing on the market of:

- PVC articles containing recovered flexible PVC until **28 May 2025**;
- PVC-silica separators in lead acid batteries and PVC articles containing recovered rigid PVC until **28 May 2033**, provided the recovered rigid PVC contains less than 1.5% lead. Of additional note, during the exemption period, suppliers of PVC articles containing recovered rigid PVC with 0.1% or more of lead by weight of the PVC material, shall label such articles or their packaging

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R0923

with the statement: ***"Contains ≥ 0,1 % lead"***). They shall also submit upon request documentary evidence (such as proof of traceability and recycled content accepted per EN 15343:2007 or equivalent standards for PVC articles produced in EU) to substantiate claims on origin of recovered PVC in those articles.

3.2. New Restriction for Formaldehyde and Formaldehyde Releasers

On 14 July 2023, a new **Entry 77** was incorporated to REACH Annex XVII, with the aim to prohibit the placing on the market of articles containing formaldehyde (CAS: 50-00-0) and substances that release formaldehyde.

Classified as a carcinogen (category 1B) and a skin sensitizer (category 1), according to CLP Regulation (Regulation (EC) No. 1272/2008), formaldehyde is widely used in various industries, such as the production of adhesives, resins, wood-based materials, furniture, floor coverings, foams, textile and leather products.

In order to protect consumers health with the potential risks associated with formaldehyde emissions, the new Entry 77 sets specific limits for formaldehyde in indoor air for a number of consumer products if, under the test conditions specified in Appendix 14, the concentration of formaldehyde released from them exceeds the following values:

- ≤ 0.062 mg/m3 for indoor use furniture and wood-based articles (applicable after 06 August 2026);
- ≤ 0.080 mg/m3 for articles other than furniture and non-wood-based articles (applicable after 06 August 2026);
- ≤ 0.062 mg/m3 for interior of vehicles (applicable after 06 August 2027).

Second hand articles, products that naturally release formaldehyde as well as articles that are exclusively intended for outdoor use, such as articles in structures that are used exclusively outside the building shell and the vapor barrier, are excluded from the

scope of the ban. Further exemptions include articles falling under the scope of entry 72 to REACH Annex XVII; the Biocidal Products Regulation (EU) 528/2012; Medical Devices (Regulation (EU) 2017/745); Personal Protective Equipment (Regulation (EU) 2016/425 and FCM Regulation (EU) 1935/2004).

3.3. Restrictions on Intentionally Added Microplastics

Following a lengthy legislative process and arduous discussions between member states and consultations with various stakeholders, the EU Commission finally published on 27 September 2023, its long-awaited regulation[5] aiming to reduce emissions of intentional microplastics from as many products as possible.

The new regulation introduces a new **Entry 78** in Annex XVII in order to prohibit the sale of microplastics and products intentionally containing microplastics that are released when used.

A broad definition of microplastics is provided to cover all synthetic polymer particles below 5mm that are organic, insoluble and resist degradation. Common products in the scope of the restriction include artificial sport surface infill materials, cosmetics, detergents, glitter, plant protection products, toys, medicines and medical devices, and many more.

In addition to the ban on placing on the market, Regulation 2023/2055 also introduces information requirements for certain suppliers of microplastics and products containing microplastics. These apply for instance to suppliers of lip products, nail products and make-up, who are required to include on the label, the packaging, the safety data sheet or the package leaflet the following statement: *"This product contains microplastics".*

For certain products such as veterinary and medicinal products, food additives, in vitro medical devices containing microplastics, suppliers must each year report specific

[5] https://eur-lex.europa.eu/eli/reg/2023/2055/oj

information to the ECHA. Likewise, for articles that do not release microplastics during use, manufacturers are obliged to provide instructions for proper use and disposal to prevent microplastics releases.

The new measures will enter into force on 17 October 2023, with an immediate impact on loose glitter and microbeads. To enable businesses to take appropriate measures to comply with the restriction measures, several transitional periods are established. These deadlines range from **four years** for rinse-off cosmetic products; **five years** for detergents, products for agricultural and horticultural uses and some pesticides; **six years** for medical devices within the scope of Regulation (EU) 2017/745 and encapsulated fragrances; **eight years** for biocidal products and granular infill for use on synthetic sports surfaces and **twelve years** for some leave-on makeup products, such as lipsticks and nail polish.

4. Current Key Restrictions Proposals

4.1. Broad PFAS Restriction Proposal Under REACH

PFAS, often called *"forever chemicals"*, are a large group of persistent and mobile chemicals, which are found everywhere. Specific sub-groups of PFAS are already subject to the POPs Convention, EU POPs Regulation (PFOS, PFOA, PFHxS). Other groups such as long-chain PFCAs and TDFA are restricted in Annex XVII or included in the Candidate List (HFPO-DA, its salts, and its acyl halides, also known as GenX chemicals); perfluorobutane sulfonic acid (PFBS) and its salts; and perfluoroheptanoic acid (PFHpA) and its salts. Finally, certain PFAS categories are controlled by sector-specific regulations such as the EU F-gas, Biocidal Products or Drinking Water Regulations.

In order to end this piecemeal approach of regulating PFAS and to avoid regrettable substitution of one PFAS by another one which may not even be engineered or exist yet, a proposal aiming for a universal restriction of PFAS emissions into the environment and to make products and processes safer for people was prepared and

submitted to ECHA on 13 January 2023, by authorities in Denmark, Germany, the Netherlands, Norway and Sweden.

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[6], approximately 10,000 substances would be covered and almost all industries including electronics, textiles, cosmetics, food contact materials, consumer cookware, packaging, semiconductors or medical devices would be impacted.

According to the proposal, the manufacture, placing on the market, and all uses of PFASs on their own, as constituents in other substances, in mixtures and in products would be banned, unless the following specific concentration limits are complied with:

I. 25 ppb for any PFAS (polymeric PFAS excluded from quantification);
II. 250 ppb for sum of PFAS (polymeric PFASs excluded from quantification);
III. 50 ppm for PFASs (polymeric PFAS included).

The proposal specifies a number of time limited derogations, ranging between the general transition period of 18 months, to 12 years after the entry into force for specific uses where sufficiently strong evidence is available that technically and economically feasible alternatives are not available on the market or possible alternatives are still in development.

Few more general derogations without a time limit are also included. This is the case for PFAS used as active substances in plant protection products, biocidal products, and human and veterinary medicinal products.

Finally, the proposal prescribes reporting obligations for manufacturers, formulators and importers of PFAS, mixtures and articles containing PFAS, and making use of any of the derogations.

[6] *Page 23*
https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/terminology-per-and-polyfluoroalkyl-substances.pdf

Process Status and Next Steps

A six-month consultation on the proposal started on 22 March 2023 and concluded on 25 September 2023. Upon this process, ECHA announced[7] to have received more than 5,600 comments from more than 4,400 organizations, companies and individuals. The comments will now be scrutinized by its scientific committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC).

Normally, RAC/SEAC opinions are ready within a year of the start of scientific evaluation. However, due to the complexity of the proposal and the extent of the information which have been received from the consultation, their final opinions may take more time.

As with previous Annex XVII proposals, ECHA will then deliver RAC/SEAC final opinions to the EU Commission who, together with Member States, will then decide on the potential restriction, concluded by a draft amendment to the list of restrictions in REACH Annex XVII. In line with the initial timeline set by ECHA, the adoption process is likely to be finalized in 2025, with the restrictions expected to apply in 2026 or 2027[8].

To avoid supply chain disruption and ensure timely and effective compliance, it is advisable that businesses begin now, to identify and or confirm the uses of PFAS in their products portfolios, and to put in place strategies for the development of suitable replacements to PFAS.

7 *https://echa.europa.eu/-/echa-receives-5-600-comments-on-pfas-restriction-proposal#:~:text=More%20than%204%20400%20organisations,in%20the%20European%20Economic%20Area*.

8 *https://echa.europa.eu/-/echa-receives-pfass-restriction-proposal-from-five-national-authorities#:~:text=A%20six%2Dmonth%20consultation%20is,in%20participating%20in%20the%20consultation*.

4.2. Proposal to Extend the Uses of Bis(2-ethylhexyl) phthalate (DEHP) in Medical Devices

This EU Commission draft regulation put to the WTO attention on 04 May 2023, aims to align with the new deadlines introduced by Regulation (EU) 2023/607[9] as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

To this effect, the draft regulation only proposes to postpone the approaching latest application date of 27 November 2023 and sunset date of 27 May 2025, for uses of bis(2-ethylhexyl) phthalate (DEHP) in medical devices within the scope of Directives 90/385/EEC, 93/42/EEC and 98/79/EC as set out in Regulation (EU) 2021/2045 to **11 January 2029** and **01 July 2030** respectively.[10]

4.3. Proposed Restriction of the Use of Undecafluorohexanoic Acid (PFHxA), its Salts and PFHxA-Related Substances

Proposed on 19 June 2023, this draft amendment to REACH Annex XVII aims to limit the release of PFHxA, its salts and related substances (i.e. substances which, based upon their structural formulae, have the potential to degrade or be transformed to PFHxA) and to prevent its accumulation in the environment.

The draft proposes to ban the use and placing on the market of PFHxA, its salts and PFHxA-related substances in certain mixtures and in a wide range of consumer goods including textiles and leather in consumer products, paper and cardboard used as food contact materials, mixtures for consumer use, cosmetic products, etc.

The proposal is expected to be adopted by the end of 2023. Numerous phase out timelines from 18 months to 5 years from the date of entry into force of the regulation, are set for different product categories.

[9] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R0607
[10] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R2045&qid=1637745288796&from=EN

4.4. Proposal for Additional Restrictions of D4, D5, D6

On 22 June 2023, the EU notified the World Trade Organization with its proposal to expand the scope of existing **Entry 70** of REACH Annex XII restricting the use of Octamethylcyclotetrasiloxane (D4) and Decamethylcyclopentasiloxane (D5) in wash-off cosmetic products with the addition of Dodecamethylcyclohexasiloxane (D6).

The proposal prohibits the placing on the market of D4, D5 and D6 as a substance on their own, as a constituent of other substances, or in mixtures. The draft further provides for the restrictions 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 consumer/professional products such as solvent for the dry cleaning of textiles, leather and fur.

The draft also specifies derogations for certain industrial and 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.

The adoption of the proposal is expected for the end of the year. As regards the timeline for implementation, the draft 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 proposed for restrictions on:

- D4 and D5 in rinsed cosmetic products in force since 31 January 2020 remain unchanged;
- D6 in rinse-off products - 2 years after the entry of the enacted regulation;
- D4, D5 and D6 in non-rinse-off cosmetics, the restriction - 3 years after the entry into force.

It is also noteworthy that at the same period, ECHA launched a public consultation to gather comments on characteristics (persistence, bioaccumulation, long-range

environmental transport, and adverse effects) of D4, D5, and D6 for their proposed listing in Annex B to the Stockholm Convention on Persistent Organic Pollutants. Upon the conclusion of this consultation, a formal proposal to list these substances in Annex B will be forwarded to the Persistent Organic Pollutants Review Committee (POPRC) by the EU Commission. POPRC will conduct a risk profile assessment of these substances and make a recommendation to the Conference of the Parties to the Stockholm Convention (COP) on whether or not they should be listed in Annex B.

4.5. SVHC Identification Proposals

On 01 September 2023, ECHA released proposals from Austria, Belgium, Denmark, Germany and the Netherlands to identify 6 chemical substances as SVHC under REACH[11].

The substances object of the proposals are reportedly used in air care products (fragrances and air fresheners), coating products, paints, adhesives and sealants, laboratory chemicals and polymers, washing and cleaning products.

Three of the substances are proposed because they are suspected of having very persistent and very bioaccumulative (vPvB) properties in accordance with REACH (Article 57e). The substances are:

- 2-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol (UV-329)[CAS 3147-75-9, EC 221-573-5]
- Bumetrizole (UV-326), [CAS 3896- 11-5, EC 223-445-4]
- Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol [CAS - , EC 700- 960-7]

2,4,6-tri-tert-butylphenol (2,4,6-TTBP) [CAS 732-26-3, EC 211-989-5] proposal by Belgium is based on its potential toxic for reproduction (Article 57c); PBT (Article 57d) and vPvB (Article 57e).

[11] https://echa.europa.eu/substances-of-very-high-concern-identification

2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one [CAS 119344-86-4, EC 438-340-0] is proposed for assessment as it is suspected of having toxic for reproduction properties (Article 57c).

Finally Dibutyl phthalate (DBP) [CAS 84-74-2, EC 201-557-4] already included in the Candidate List since 2008 due to its CMR properties, is part of the proposals on the basis of its potential endocrine disrupting properties in accordance with REACH (Article 57(f).

Comments related to uses, exposure of risk, and alternatives for the substance are mostly expected by ECHA until **16 October 2023**.

Upon the consultation process, if the six proposed substances are definitely identified as SVHC, the total number of SVHC will increase from 235 to 241. This would occur in either December of this year or January 2024.

4.6. Additional Proposed Restrictions Regulatory Actions

During the course of this year, ECHA also launched several calls for evidence to gather information and opinions from interested parties to support the development of restrictions on the use of PVC and its additives. This process is an opportunity for stakeholders to express their views and concerns in the preparatory phase of a restriction proposal.

Besides, as required by REACH Article 69(2), ECHA also initiated 3 calls of evidence to gather relevant information and comments on its draft screening reports to decide whether the use of the following substances in articles is adequately controlled, and if a restriction is needed:

- sixteen 1,3-dioxanes (also known as 'Karanal');
- UV-328, UV-327, UV-350 and UV-320; and
- trixylyl phosphate (EC 246-677-8).

As part of the EU Restrictions Roadmap under the Chemicals Strategy for Sustainability, ECHA also published on 15 of March 2023, its regulatory strategy for flame retardants (FRs).[12] The document aims to avoid regrettable substitution through a broad and generic grouping approach to FRs restriction. It identifies aromatic brominated FRs as candidates for an EU-wide restriction due to their known or potential PTB/vPvB properties under REACH.

For some organophosphorus-based FRs, the report indicated that more data is needed to determine if a restriction is necessary. ECHA suggests reassessing the situation for those groups in 2025 on the basis of information gathered between now and 2024.

The work to finalize all these restrictions initiatives is ongoing and will probably continue through 2024 and beyond.

5. Conclusion

This paper has reviewed the most recent new and pending regulatory measures on substances' restrictions in articles introduced this year under EU REACH. In order to have access to the EU market, manufacturers of articles containing the restricted substances in scope must comply with the range of requirements set in these rules.

Through these developments, the EU regulator is continuously leading the way on global stricter regulations aiming to reduce the impacts on human health and the environment caused by exposure to hazardous substances.

All these regulatory changes will dramatically shape the future of the uses of these regulated substances in our society and also have drastic impacts on businesses' supply chains. This will be particularly the case for the ongoing PFAS universal restrictions proposal, if it is finally adopted by the EU Commission as it currently stands, with no further exemptions for certain classes of PFAS such as fluoropolymers

[12] https://echa.europa.eu/documents/10162/2082415/flame_retardants_strategy_en.pdf/9dd56b7e-4b62-e31b-712f-16cc51d0e724?t=1678871526283

which are crucial for medical devices, semiconductors, electronics and renewable energies industries.

Compliance & Risks will be following developments on all these regulatory initiatives with great care and attention, and posting them in C2P as they unfold.