



Restrictions Roadblock report

Four years after pledging a world-leading 'roadmap' of accelerated chemical controls, most remain frozen or going nowhere

Acknowledgements

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Executive summary

The rapid growth in production of synthetic chemicals in recent decades and the resulting tide of human and environmental contamination has begun breaching planetary boundaries, some scientists say. Recognising the threat, European Commission president Ursula von der Leyen set a “zero pollution” goal for Europe and, on 25 April 2022, [tabled](#) the most far-reaching programme of chemical controls the world had ever seen: the Restrictions Roadmap.

The roadmap is a prioritisation tool designed to accelerate the use of existing powers, specifically the Restriction procedure, part of the troubled REACH Regulation. The roadmap targets a rolling list of chemicals with severe hazards and promises to considerably expand restrictions to a wide range of products, from baby nappies and toys to furniture and textiles. In 2022, the roadmap listed 22 chemicals or groups of chemicals, including notorious substances fought for decades by consumer, health, environmental and labour groups. Among others, it promised to ban flame retardants, which are frequently linked to cancer; bisphenols, widely used in plastics but which disrupt human hormones; PVC, the least recyclable plastic that contains large amounts of toxic additives; PFAS, the toxic ‘forever chemicals’ building up in the blood of almost all humans. It was an inspiring step-change in the way Europe treated the threat from chemicals and was approved unanimously by member states. It included a sufficiently clear deadline for nearly all the 22: regulators were to begin their work within two years. All would be restricted and largely off the European market by 2030, the EEB [estimated](#) at the time. This report assesses how much progress has been made four years on. The current regulatory status of all 22 files were checked and summarised in [Table 1, \(page 13\)](#). This allows a clear benchmarking of progress against a. the deadlines detailed in the roadmap and b. a three month obligation on the Commission to act “without

delay” on the advice of the EU chemicals agency, enshrined in REACH. The former are politically embarrassing, while the latter breach EU law.

The findings are dismal and clearly identify the European Commission as the chief roadblock to its own roadmap. After making rapid early progress, the Commission has today effectively frozen 14 of the 22 files, nearly two thirds of its 2022 agenda. Of these 14, it has yet to begin regulating 7 and is largely responsible for holding up the finalisation of 7 others. Just 6 restrictions have been adopted into law. The 3 month ‘legal deadline’ described above is a myth, we show, never having been met. Delays range from 13 to 47 months, with two years the average.



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In addition to the core analysis, authors show examples of how the Commission is also watering down the scope or implementation of Roadmap restrictions. Why the Commission has diverted its Roadmap into the slow lane is hard to decipher because it rarely justifies its actions, even when required to by law. Von der Leyen’s second term zeal for deregulation in favour of industry and the economy is a likely factor. Authors claim the industry’s tactic to hide information from authorities preparing restriction proposals and afterwards lobby the Commission claiming unbearable burden on their sectors has successfully stalled the roadmap. This would breach EU obligations, as we point out below.



This report highlights an abuse of power by the institution that is supposed to uphold the law.”

This report charts a betrayal of the roadmap and its mission. It highlights an abuse of power by the institution that is supposed to uphold the law. It is notable that the European Ombudsman last summer concluded that the Commission’s handling of chemical controls amounts to maladministration, relating to a sister process in REACH.

Maladministration has consequences. Annex 1 of this report tabulates the industrial uses, volumes and hazards of all 22 files, as defined by officials. For six of these files, annual chemical pollution in tonnes has been quantified by officials, allowing us in **Table 2, (page 14)** to quantify the chemical pollution directly attributable to the unlawful delays measured in this report.



100,000

tonnes of chemical pollution with severe hazards caused by 167 months of cumulative roadmap delays

It amounts nearly 100,000 tonnes of chemicals with severe hazards spreading in the environment, food systems, drinking water etc that would have been curbed or avoided altogether if the Commission had done its job and prevented 167 months of cumulative time it took them to advance these files. It is not possible to reliably extrapolate from this the consequences of this pollution in new allergies, cancer cases, infertility, disease and deaths in humans or animals, but they are surely considerable.

This report closes with policy recommendations that amount to a basic demand: get on with it!

1. Introduction

What is the EU's legal obligation regarding protection of health and the environment from chemical risks?

As a general principle, the European Union (EU) bears a legal obligation – established in the EU Treaties¹ – to ensure a high level of protection of both the environment and human health.

This obligation gets specifically translated into the management of chemicals with Article 1(1) of the EU's chemical regulation REACH² explicitly stating that one of its primary objectives is “to ensure a high level of protection of human health and the environment”³ and the functioning of the internal market follows as a secondary objective. Concretely, upon evidence of them posing an unacceptable risk to health or the environment, chemicals must be restricted.⁴

In such contexts, the Court of Justice of the EU has consistently confirmed that public health and environmental protection take precedence over economic interests, even when harm has not fully materialised.⁵ Prevention of chemical risks is therefore practically embedded into the REACH framework.



The process of restricting chemicals is not a general term, but relates to one of the key tools under the REACH regulation to address the risk posed by chemicals in the EU.”

What is the Restrictions Roadmap and why do we need it?

Despite a strong EU legal framework requiring early action and precaution against chemical risks, the production and release of chemicals during the last decades has accelerated, thereby further pushing humanity beyond safe planetary boundaries.⁶ Chemical pollution is now occurring at a scale that outpaces regulatory capacity and environmental resilience – it is considered a systemic planetary threat that chemical regulation has repeatedly failed to prevent.⁷

In the few years preceding the adoption of the 2020 Chemicals Strategy for Sustainability, progress in eliminating the most hazardous chemicals had become extremely slow - on average, it took authorities 5 years and seven months to adopt a restriction.⁸ The process of restricting chemicals is not a general term, but relates to one of the key tools under the REACH regulation to address the risk posed by chemicals in the EU. It was burdensome for authorities and fragmented, despite the tools available under REACH to adopt restrictions. Priorities were unclear, and procedures opaque. The predominantly substance-by-substance approach proved resource and time-consuming while allowing companies to engage in regrettable substitution (i.e. the replacement of a restricted chemical by a closely related one exhibiting similar harmful properties).

1 Article 3(3) of the Treaty of the EU (TEU) commits the EU to Sustainable Development and a high level of environmental protection. Articles 35 and 37 of the Charter of Fundamental Rights of the EU require a high level of protection for human health and the environment. Article 191 of the Treaty of the Functioning of the EU (TFEU) directs environmental policy to protect the environment and human health on the basis of precaution, even in cases of scientific uncertainty.

2 Regulation (EC) No 1907/2006

3 REACH was initially adopted as a systemic reform of the pre-existing EU chemicals framework with the goal “to do more to protect public health and the environment in accordance with the precautionary principle”. See REACH, Recital 9.

4 REACH, Articles 68(1) and 68(2). “A restriction on the placing on the market – including, in accordance with the definition in Article 3(12) of Regulation No 1907/2006, import – of a substance is often the most effective measure for achieving the objective pursued by that that regulation, which is to ensure a high level of protection of human health and the environment”. General Court, Case T-226/18, Global Silicones Council v European Commission, para 170.

5 General Court, Case T-837/16 – Sweden v Commission, para 112.

6 Persson, L., Carney Almroth, B. M., Collins, C. D., Cornell, S., de Wit, C. A., Diamond, M. L., Fantke, P., Hassellöv, M., MacLeod, M., Ryberg, M. W., Søgaard Jørgensen, P., Villarrubia-Gómez, P., Wang, Z. and Hauschild, M. Z. (2022). Outside the Safe Operating Space of the Planetary Boundary for Novel Entities. *Environmental Science & Technology*, 56(3), 1510-1521. <http://doi.org/10.1021/acs.est.1c04158>

7 Martin Scheringer, Hans Peter H. Arp, and Ian T. Cousins, Boundaries, Limits, Global Threats – How Can the Impacts of Global Synthetic Pollutants Be Reduced?, *Environmental Science & Technology* 2026 60 (6), 4499-4505, DOI: 10.1021/acs.est.5c13807

8 EEB(2022) The Need for Speed. <https://eeb.org/wp-content/uploads/2022/07/Need-for-speed-final.pdf>

In this context, the 2020 Chemicals Strategy for Sustainability signified a shift by setting the European Commission's ambition towards a "toxic-free" environment.⁹ It promised better protection for citizens and the environment from chemical contamination, stronger and more coherent rules on production and use of chemicals, and the substitution of the most harmful substances as far as possible.

Adopted in April 2022, the Commission published the **Restrictions Roadmap**¹⁰ ('the Roadmap') to concretely implement this ambition and identified groups of priority substances deemed particularly harmful for the environment and human health that require urgent action.

The substance groups have at least one of the following hazards:

- cancerogenic, mutagenic or reprotoxic (CMR),
- persistent, bioaccumulating and toxic (PBT) or very persistent and very bioaccumulating (vPvB),
- endocrine disruptors (ED) i.e. they interfere with the hormonal system for human health or the environment,
- immunotoxicants,
- neurotoxicants,
- respiratory sensitisers,
- Toxic for specific organs (STOT).

The Restrictions Roadmap is only the EU Commission's plan to restrict chemicals. That means EU Member States who also have a right of initiative on this process may still submit restriction proposals in addition and independently of the roadmap. It also means it is not a legal instrument per se. But it effectively operationalises the obligation embedded in REACH to progressively reduce risks from the most harmful substances. By identifying a list of the most harmful chemicals to be prioritised and setting a concrete, strategic and time-bound plan for restrictions, it gives practical



The Roadmap guides and constrains the implementation of REACH in a way that can promptly and efficiently deliver on the elimination of the worst chemicals.”

effect to the Commission's legally anchored responsibility to step up risk reduction for the most harmful chemicals. While awaiting a broader revision of the REACH Regulation legal text, which can streamline and accelerate restriction procedures, the Roadmap guides and constrains the implementation of REACH in a way that can promptly and efficiently deliver on the elimination of the worst chemicals; it creates a structured pathway against which regulatory action can be assessed.

The Roadmap is a rolling list and subject to regular updates by the Commission. The latest update was published in 2025,¹¹ but the analysis of this report refers to the original Roadmap from 2022.

First signs of disappointment

One year later, ClientEarth and EEB published an assessment¹² of the progress on fulfilling the Restrictions Roadmap's promise but unfortunately, found among the restrictions proposed, too little ambition across the board to address the risk identified.

EU institutions are bound by the principle of good administration¹³ which imposes obligations of transparency, impartiality, and procedural efficiency upon all EU bodies acting in the exercise of public authority. This translates into an obligation upon institutions such as ECHA and the Commission to conduct restriction and authorisation procedures under REACH within the legal timeframes. EU authorities also have a legal duty to explain any delays that cause them to miss legal deadlines.¹⁴

9 <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0667>

10 EC (2022) COMMISSION STAFF WORKING DOCUMENT Restrictions Roadmap under the Chemicals Strategy for Sustainability, 25.04.2022 <https://ec.europa.eu/docsroom/documents/49734>

11 EC 2025, *Restrictions Roadmap amendment 2025*, CARACAL-55, 30/06/2025

12 <https://eeb.org/wp-content/uploads/2023/04/roadmaptonowhere.pdf>

13 Art. 298(1) TFEU and Art. 41 of the Charter of Fundamental Rights of the EU.

14 This is rooted in the fundamental duty to state reasons of Art. 296 TFEU; see Case C-370/07 Commission of the European Communities v Council of the European Union, para. 42.

The implementation of the Roadmap demonstrated insufficient regulatory ambition, resulting in largely ineffective risk management of hazardous substances due to a narrow scope, excessive exemptions, long transitional periods, and continuous and unjustified delays in restriction procedures. Overall, we concluded that the framework was already falling short of achieving its primary objective of taking the most harmful groups of chemicals from the market, as much as possible.

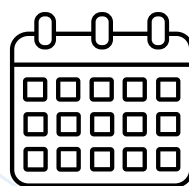


What these diverse restrictions have in common is the science based process they are following, which is clearly defined by the law.”

What does a standard restriction process look like?

To understand the analysis of the Roadmap, having a clear picture of the restriction process referred to is essential. Restrictions can be designed in multiple diverse ways, e.g. they can be a targeted limitation to specific processes by setting emission limits or broadly ban the manufacture, use, import and selling of a substance in the EU – by itself or in a product. What these diverse restrictions have in common is the science based process they are following, which is clearly defined by the law.

Under the main REACH restriction procedure (Article 68.1), ECHA – based on a request through a Commission mandate – or a Member State under its own initiative, may propose an EU-wide restriction of chemicals. Once this intention is announced in ECHA's publicly accessible Registry of Intention or 'RoI' (what this report labels **stage 1**), the restriction proposal (jargon "Annex XV dossier") must be submitted to ECHA



30 months

Maximum time it should take for a normal restriction process

within one year.¹⁵ Following the submission of the restriction proposal (which we label **stage 2**) and passing of the completeness check, two ECHA expert committees, namely the Risk Assessment Committee (RAC) and the Socio-Economic Assessment Committee (SEAC), should formulate an opinion within 12 months.¹⁶ Their work is to carefully assess the information on dangers and balance these against socio-economic and other considerations, allowing the next stage to proceed quickly on a robust scientific basis. After the publication of the ECHA committees' combined ECHA opinion (**stage 3**), the Commission has three months to make "without delay"¹⁷ a proposal for a legal text¹⁸ (**stage 4**), what should be largely based on the Committees' opinion. This Commission proposal must be approved by the committee of Member State experts (REACH Committee) in a qualified majority vote.¹⁹ Some back and forth redrafting by the Commission and voting by the committee can occur on a given file, but despite this, we argue the Commission is responsible for shepherding stage 4 through to completion. After a positive vote, the restriction is adopted, unless the World Trade Organisation, the European Parliament or the Council formally oppose it within a period of three months. With that the process ends and the restriction enters into force (**stage 5**). All in all, a 'normal' restriction process should not take longer than 30 months, or two years and a half years.

¹⁵ Articles 69(3) and 69(4) REACH.

¹⁶ Articles 70 and 71 REACH: RAC should formulate an opinion within 9 months after the publication of the restriction proposal, while the SEAC has 12 months.

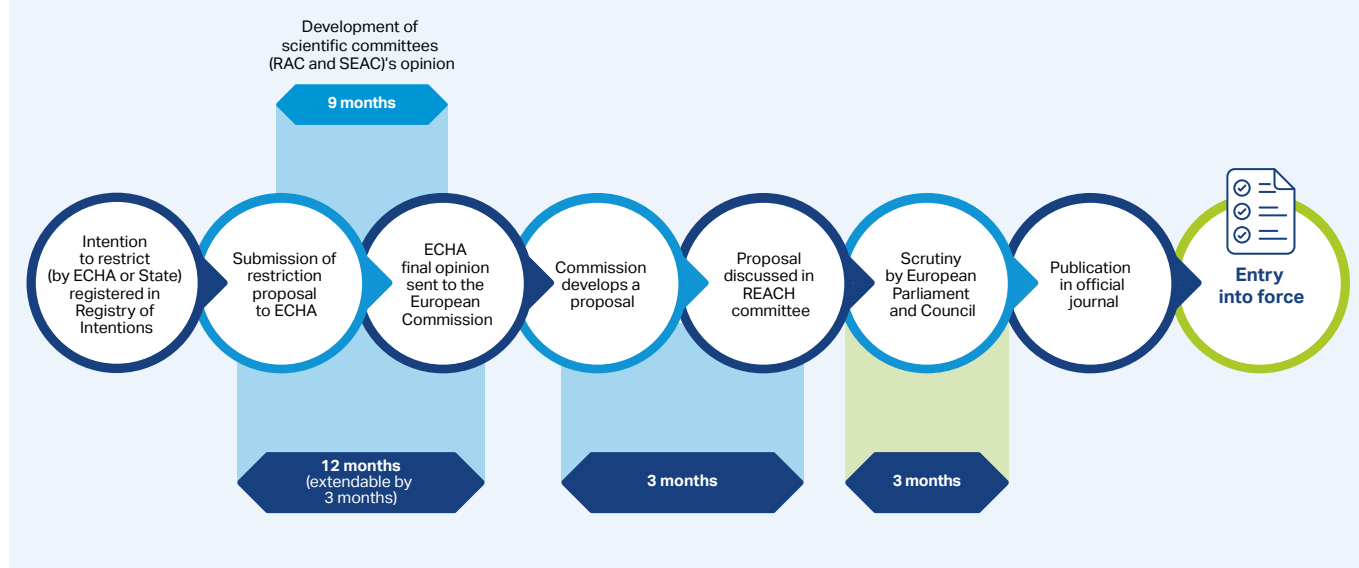
¹⁷ Article 72(2) REACH

¹⁸ Article 73 REACH

¹⁹ Article 133(4) REACH

Figure 1

Overview of the restriction process from the Registry of Intention to the Entry into force



What does this report cover?

To mark the Restrictions Roadmap's fourth anniversary, on 25 April 2026, this report brings the hopes and expectations linked to this document back on the table and takes another close look at how the EU's plans to phase-out the most hazardous chemicals have advanced. With this new analysis, the authoring NGOs aim to hold the European Commission accountable on its obligations to protect humans and the environment through restricting the most harmful chemicals in Europe.

In scope of the analysis are the substances that were planned by the Commission to be restricted within the next few years. This certainty is represented by two groups (called '**pools**') in the Roadmap. Those substances included in what the Commission called '**Pool 0**' are the ones most certainly to be restricted soon, as the restriction process had just been initiated for them when the Restrictions Roadmap was published in 2022. What is framed in the Roadmap as '**Pool 1**' are restriction files that should enter the restriction process from 2022 onwards, and were seen as pretty certain to be regulated soon. For the substances in '**Pool 2**' it was quite uncertain, whether they would be restricted or not, and were thus not included in this analysis.

To give a more complete picture, seven restrictions that were already advanced in the restriction process in April 2022 are assessed in our report, despite not being mentioned in the Roadmap due to being advanced. In order to distinguish progress on these files from that of those mentioned in the roadmap, we list them separately in this report. They are not part of the statistics summarised in the executive summary or analysis sections.

In more detail, the analysis below is based on the information in the extensive table in the Annex of this report which includes basic information on all substances [column 'substance or group name'] covered in this report. The uses of each substance/group that the restriction addresses are listed [column 'Uses/Function'], as well as the substances' intrinsic problematic properties and where the pollution occurs [column 'Concerns'].

The column labelled 'Impact' gives further information on the health and /or environmental damage caused by the use of these chemicals – the information coming from the official documents (dossier, ECHA opinion) for each restriction. It includes the official approximation of the real, not fully known impact, through the annual releases of the substances into the environment or the amount of them still placed on the EU market. In some cases impacts are quantified in terms of health impacts (cancer, children IQ loss, sensitisation, etc) or environmental impacts (e.g. bird loss).

The column 'Status' records for each entry in which stage of the restriction process outlined above it is today based on the information included at ECHA's Registry of Restriction Intentions until Outcome.²⁰ The given dates for when each stage of the process was reached, allow also to compare the dates in the Roadmap with the reality for each file and whether the Commission met its own deadline. These dates are marked in green or red, depending on whether the roadmap deadlines were met or not. The last



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column on the 'delay' of the files refers to how much time has passed beyond the legal deadline of three months that is set for the Commission to present a draft restriction after ECHA's opinion is finalised. This information has been extracted from the Comitology Register of the Commission, which records the dates the Commission received ECHA's opinion. These dates are the start point for the Commission's three month deadline.²¹

For the 29 chemicals or groups of chemicals in scope of this report, based on the criteria explained, the authoring NGOs scrutinize whether the Commission is on track to meet the ambition it had set out 4 years ago and if it sticks to the timelines set by the law. The assessment in the overview table is followed by main take-aways that the authors identified. The report concludes with recommendations on what the Commission needs to improve to meet the expectations of those it is responsible for and, even more, its legal obligation.

²⁰ <https://echa.europa.eu/registry-of-restriction-intentions>

²¹ <https://ec.europa.eu/transparency/comitology-register/screen/documents>

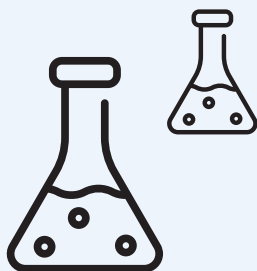
2. Analysis – outcomes/state of play of the restriction roadmap

2.1 Restrictions Roadmap state of play

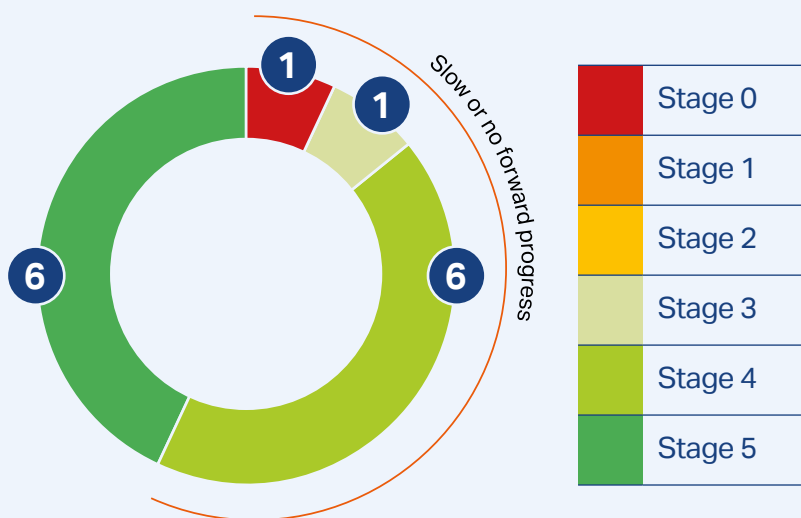
Analysis per pool

Pool 0

14



Substances or groups of chemicals in Pool 0



The restrictions in Pool 0 all included dates and these proved largely accurate to within a margin of +/- 3 months.

The dates indicated the submission of the files to ECHA for a scientific assessment (stage 3) and are easy to estimate for files already underway or already submitted. Most (12 of 14) substance(s) progressed through to completion of the assessment by ECHA and were transferred to the European Commission. Of those 12 substances, **6 are stalled**, one (Dechlorane Plus) for **44 months**, so with 41 months of delay.

Of all 14 files in Pool 0, **only 5 restrictions have entered into force**. The time it took the Commission to come up with a proposal for them was between 13 months (DMAC, NEP) and 47 months (Lead in PVC) beyond the legal timeline, with the average delay being 25.3 months.

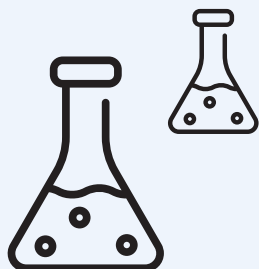
It never once met its legal deadline and instead went between five and 16 times over the limit.

Two of the 14 restrictions, the universal PFAS restriction and a group restriction of bisphenols harmful to the environment, have not yet reached the stage of finalised ECHA opinions, so delays cannot be calculated in the same way as for the others. The restriction of substances in baby-diapers was regrettably terminated.

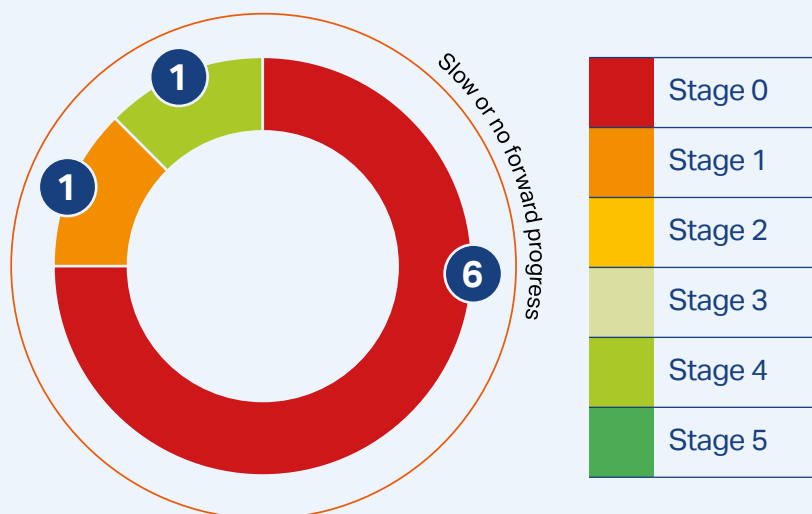
Analysis per pool

Pool 1

8



Substances or groups
of chemicals in Pool 1



Pool 1 has eight entries. For 6 of them the Roadmap pledged to begin regulating in 2022 or 2023. **Almost all** (6 of 8) groups of chemicals in this pool are still waiting for this. For one of them, a subgroup of flame retardants, the Commission began regulating in 2026, exceeding by years the Roadmap timeline. The eighth file, covering cancerogenic, mutagenic and reprotoxic substances (CMR) in childcare articles, is the only one in this pool where the Commission met the timeline. That restriction is now at stage 4, potentially also due to the fast track process the file is subject to, because the substances are particularly high risk. To date, the Commission has blocked finalisation for 29 months.

This shows that the restrictions which were expected still with a relatively high certainty to come in 2022 or 2023, as the Restrictions Roadmap indicates, are far from where they should be today.

The seven restrictions that were **already in the restriction process** had already passed the ECHA opinion making by the time the Roadmap was published and were not part of the Roadmap.

One might wonder why these substances were not included in the Roadmap and could think that this was because they were so certain to be adopted soon, that no "Roadmap" outlook was needed.

This assumption was however not fully met by reality. When taking a look at the time it took the Commission to come up with a proposal, although these chemicals have been proposed for restriction already many years ago, two files are still awaiting decisions by the EC, the restriction of skin sensitising, irritative and/or corrosive substances in textile, leather, hide and fur articles has been stuck for **more than 5 years** inside the Commission. Also the restriction of calcium cyanamide has been waiting for over 4.5 years in the Commission. Since the Commission published its first proposed restriction for calcium cyanamide, another year has passed without further updates. Of the five remaining files that were issued, only three became restrictions, while the remaining two (the PFHxS and the cobalt & salts file) entered another regulatory route, and, thus, the restriction process was terminated.

Analysis per stage

No progress at all has been achieved for nearly a third (7 files, or 32%) of the chemicals in the 2022 Restrictions Roadmap. Blame for inaction here clearly lies with the Commission. Another 32% (7 files) are either awaiting a Commission proposal of a draft legal restriction text or approval of its proposal by the REACH committee of member state representatives. Arguably, the responsibility for delays at this stage are shared. But this report holds that the Commission is ultimately to blame, being the Roadmap author, the shepherd of all restrictions, leading the REACH committee discussions and the overall authority in European law. The regulatory process has been completed only for six files (27%) announced in the Roadmap. Even files that were already in the process for many years are still awaiting a decision by the Commission, such as the restriction of skin sensitisers mentioned above.

Whether an EU Member State or the European Commission through ECHA proposed a restriction does not make a real difference regarding Commission delays. Files developed by EU Member States clearly experience more frequent delays during preparation, withdrawals or prolonged phases in the completeness check before entering the opinion-making. The three withdrawn restrictions were all proposed by a Member State. By contrast, restrictions initiated by the European Commission typically reach the opinion and decision-making phases more smoothly.

Based on this overview, summarised in **Table 1** below of the pools and the progress of the restrictions they include, one can clearly see that this is not only a failure on many individual files, but also the Roadmap fails to fulfil its core function i.e. to accelerate the regulation of many of the most hazardous chemicals still on the European market.

Despite the additional certainty that the Restrictions Roadmap was supposed to give, multiple cases have made no progress (BPA, phthalates, PVC) or only a limited part of what was targeted was addressed (flame retardants).

A huge pile of cases that went through the opinion making at ECHA are now stuck in the decision making phase at the Commission's desk. This signals a lack of political will in particular from the European Commission, but also from Member States whose representatives approve or reject all Commission restriction proposals in the REACH committee (stage 4). Those national decision makers who are blocking regulation clearly failed to prioritise the protection of people and nature over national interests.

The expected additional certainty from the Roadmap that didn't materialise applies to both subgroups defined in the Roadmap that this report covers, despite one group being way more certain (Pool 0), as the substances in it had already entered the restriction process. But even for those that were still awaiting a clear mandate, also there the European Commission was pretty certain about these restrictions coming soon (pool 1). Some single restrictions did stick relatively close to the foreseen timeline at the opinion making stage, such as 'terphenyl hydrogenated'. At the decision making stage, after the ECHA opinion was formed, none of the restrictions moved forward within the legal 3 month timeline, the fastest one resulting in a Commission proposal after 17 months, so a 14 months delay.

Delays have tangible impacts on people's health and the environment in terms of new cancer cases, child IQ loss, allergies, reproductive health problems, toxification of soils, water, etc.

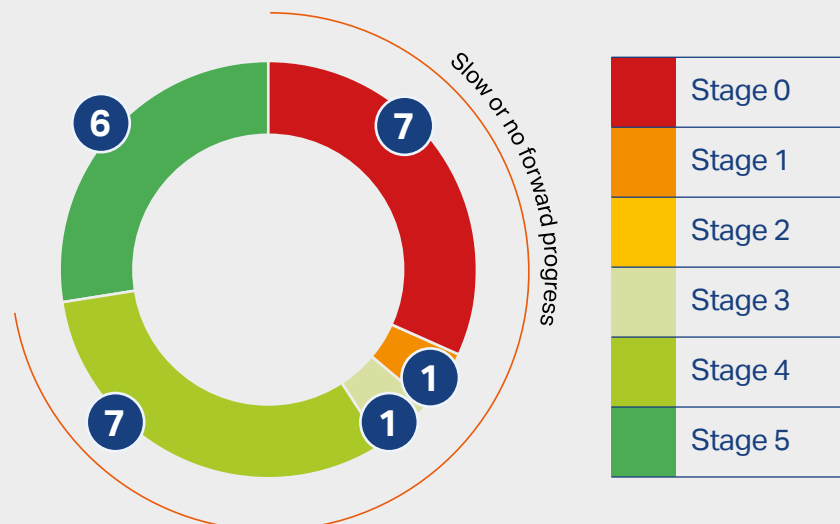
For example, one stalled restriction is that of calcium cyanamide, a fertiliser that officials estimate is spreading the carcinogen cyanamide across 230,000 hectares of agricultural land as well as waterways adjacent to fields, seemingly every year, but has been waiting at the Commission's desk for over 4 years.



Table 1
Stage in regulatory process of chemicals included in the Restrictions Roadmap of 2022

Stage in regulatory process	Statistics – Restrictions Roadmap of 2022				Active restrictions in 2022 beyond the Roadmap
	Total 22	%	Pool 0 chemicals	Pool 1 chemicals	
Stage 0 No intention yet	7	32%	– Bisphenols (EDC Env)	– PVC – OPFR – OrthoPhthalates – Lead chromate – Substances in thermal paper – Bisphenols (EDC Human Health)	
Stage 1 Intention to develop a restriction announced in Registry of Intention	1	5%		– Aromatic Brominated Flame retardants (ABFR)	
Stage 2 Proposal submitted	0	0%			
Stage 3 Proposal submitted	1	5%	– Universal PFAS		
Stage 4 Awaiting EC draft decision or REACH committee vote	7	32%	– MCCP – Lead in ammunition and fish. – Dinitrotoluene – Dechlorane plus – Terphenyl – Creosote	– CMR in childcare	– Skin sensitising, irritative and/or corrosive substances in textile, leather, hide and fur articles – Calcium cyanamide
Stage 5 Final decision taken - Entered into force	6	27%	– PFAS in FFF – PAH in clay – Lead in PVC – DMAC – Dioxins et al. in baby diapers – PFHxA		– Formaldehyde and formaldehyde releasers – PFHxS (no REST) – Microplastics – D4, D5, D6 – Cobalt & salts (no REST)

All substances





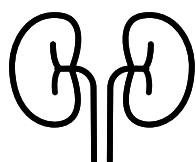
66,000

children per year suffering IQ loss via consumption of game meat



135m

Birds at risk of lead poisoning



100-1,000

cases of chronic kidney disease among EU hunters



98,355

tonnes of chemical pollution caused by the cumulative roadmap delays

The delay to restrict lead in ammunition is causing IQ loss in 66,000 children per year via consumption of game meat, officials estimate, as well as 100 to 1,000 cases of chronic kidney disease among EU hunters, not to mention putting at least 135 million birds at risk of lead poisoning.

For some of the 22 files it is possible to calculate the pollution directly attributable to the delays measured in this report.

We present these in the **Table 2** below, selecting six of the most appropriate Roadmap substance files where officials have provided an annual estimate of tonnes released into the environment. The total amounts to 98,355 tonnes of chemical pollution caused by the cumulative delays that run to 167 months for these six substance groups.

Table 2
Environmental pollution attributable to unlawful European Commission delays

Substance	Official annual pollution estimate in tonnes (t)	Unlawful Commission delay in months (m)	Tonnes (t) of pollution attributable to delays
PFAS FFF	470 (t)	14 (m)	548.3 (t)
MCCP	5,750 (t)	27 (m)	12,937.5 (t)
PAH clay targets	270 (t)	15 (m)	337.5 (t)
Lead in shooting & fishing	44,000 (t)	23 (m)	84,333.3 (t)
Lead in PVC	34 (t)	47 (m)	133.2 (t)
Dechlorane Plus	19 (t)	41 (m)	64.9 (t)
	50,543 (t)	167 (m)	98,355 (t)

2.2 Main take aways

The authors identified and discuss below the following three key takeaways of where this issue of falling behind the expectations are coming from:



1. Lack of action and delays in the processing and adoption of restrictions once in the pipeline, and/or



2. a significant lack of ambition in the restrictions proposed, and/or



3. a significant lack of ambition in the restrictions proposed, and/or

1. Lack of action and delays by the Commission are undermining health and environmental protection

The Commission's failure to start the regulatory process for some substances or to finalise it even remotely within its legal deadline for others mean that the regulation of **14 out of the 22** substances and groups of highly hazardous substances in the Restrictions Roadmap are in effect stalled today.



14 of the **22 substances and groups of highly hazardous substances in the Restrictions Roadmap are in effect currently stalled**

That means the widespread human health and environmental impacts continue without proper controls, often despite Member State and EU chemical expert recommendations that they be restricted.

The Commission's failure in 100% of cases to stick to a three month legal deadline is stark, as is the degree of exceedance: it has taken between 13 to 47 months to finalise dossiers, with an average delay of 25,3 months.



The EEB's comprehensive 2022 analysis of delays in EU chemical regulations, the 'Need for Speed' report, helped pinpoint and explain regulatory hurdles."

Restriction initiatives experience substantial delays once they enter the regulatory pipeline. As explained in the introduction, **all in all, a 'normal' restriction process should not take longer than 30 months, or two years and a half.**

The EEB's comprehensive 2022 analysis of delays in EU chemical regulations, the Need for Speed report,²² helped pinpoint and explain regulatory hurdles. The Commission's lengthy processing of ECHA opinions into a proposal was found to be one of the main bottlenecks. NGOs voiced hopes in the 'Need for Speed' report that grouping would be an effective tool for accelerating control. The Restrictions Roadmap which explicitly favoured grouping could therefore be considered a step in the right direction yet as this report shows, the restriction process is still incredibly slow and the amount of files that are stuck on the Commission's desk are unlawful and unacceptable. Among the reasons for these delays, the Commission argues that industry stakeholders provide them at the decision stage with new information that they have to analyse. This is a well known tactic of industry, which keeps information from authorities when preparing and assessing restriction proposals and afterwards delays and influences the outcome by sending the information, for example on costs for industry or alleged poor performance of alternatives to the Commission when it is preparing its draft decisions. Although the Commission should already rely mainly on the independent opinions of ECHA experts and of authorities at Member States, this tactic should be curtailed through a reform of the REACH legal text.



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Lengthy discussions by Member States on “high political” files, such as the restriction of lead in ammunition, showcase the need for authorities to keep their legal obligation to protect people and the environment from the risks posed by hazardous chemicals.

Rather than expediting the regulatory control of chemical risks, the apparent certainty of upcoming regulation outlined in the Roadmap backfired in some cases and produced the opposite outcome: it blocked de-facto other regulatory paths for these chemicals while waiting to be restricted. As the case of flame retardant tetrabromophthalate²³ shows, in effect, the Roadmap has not only failed to establish a clear and accountable timeline for restrictions on certain chemical groups and simultaneously impedes for members of these groups the alternative regulatory pathways. The Roadmap is, in several cases, a regulatory dead end.

The Ombudsman of the European Union recently found both of these developments concerning and considers that the systemic failure by the Commission to comply with the statutory three-month time limit to present draft decisions to the REACH Committee constitutes maladministration.^{24, 25}

2. The lack of ambition across the board

In various cases, the scope and ambition of the restrictions proposed appears significantly reduced compared to the level of protection initially anticipated by the Roadmap and, underlying it, the Chemicals Strategy, raising questions about whether the measures will be effective in concretely addressing risks to human health and the environment. For some restrictions, only a very limited number of substances belonging to a wide group have been targeted, as is the case of bisphenols and the minimalistic grouping proposed for the ABRF restriction. For others, the restriction includes exemptions or transitional periods until a ban takes effect that significantly weaken the intended effect as is the case of the PFHxA restriction that should have covered all uses and was reduced only to consumer uses. Some restrictions have simply not been proposed at all (e.g. PVC) or removed from the RoI (e.g. Bisphenols), with little or no justification.

These cases are a clear notice that the Commission has entered a phase of normalizing low ambition for protection. These developments are aligned with the tone of the Commission’s stated simplification agenda to improve industry competitiveness that now crystallizes as deregulation.²⁶

The universal PFAS restriction can be seen as a test case on how far the Commission will go in pulling back on its chemical ambitions. The Commission faces strong public pressure in favor of regulation, but massive lobbying of industry and pressure regarding competitiveness and simplification at an almost unprecedented scale. The corporate influence on the commissioners involved in the decision is well documented through the massive share of meetings held with industry representatives versus with civil society.²⁷

23 The EU’s expert agency on chemical regulation ECHA no longer considers substances assigned to Pool 1 for the inclusion in recommendations of Substances of Very High Concern (SVHCs). This identification as SVHC is the first step for entering another possible risk management process under REACH called Authorisation.

24 Decision on the risk management of dangerous chemical substances by the European Commission ([case OI/2/2023/MIK](https://case.OI/2/2023/MIK)).

25 <https://www.ombudsman.europa.eu/en/opening-summary/en/170893>

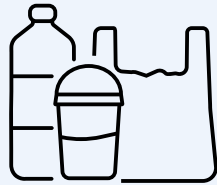
26 01/10/2025. Speech by President von der Leyen at the Copenhagen Competitiveness Summit https://luxembourg.representation.ec.europa.eu/actualites-et-evenements/actualites/speech-president-von-der-leyen-copenhagen-competitiveness-summit-2025-10-01_en?prefl_lang=de

27 Corporate Europe Observatory, CEO, 2026. Report: This is what Corporate Capture looks like! https://corporateeurope.org/sites/default/files/2026-03/REPORT_CORPORATE%20CAPTURE.pdf

3. Repeated issues of lacking transparency

A further concern relates to transparency. In several cases, key decisions have been taken without clear public explanation.

For example, the planned restriction of bisphenols (as endocrine disruptors for the environment) was withdrawn in 2023 to rewrite it and has seen no clear follow-up since



In a similar vein the future regulatory approach for PVC remains uncertain following the publication of the ECHA investigative report.

A worrying example of lack of transparency concerns the planned regulation of bisphenols that pose a risk to human health.

While a restriction is already envisaged for bisphenols that pose endocrine-disrupting risks to the environment, the Commission has considered complementing it with an additional restriction addressing endocrine-disrupting effects relevant to human health and extending the scope to cover further bisphenols. But work on the initial restriction (prepared by German authorities) is currently stalled. As a result, the timeline for issuing any complementary mandate remains open. This leaves significant uncertainty about how and when the well documented human health risks associated with these substances will be addressed.



A worrying example of lack of transparency concerns the planned regulation of bisphenols that pose a risk to human health.”

A similar line of argument has been used repeatedly to postpone the restriction of ortho-phthalates. This restriction was expected to be launched in 2023, yet it has still not entered the restriction process. France had announced that it had started work to confirm certain hazards through classification (in regulatory jargon, “CLH”) for substances that the restriction could also partially cover. A classification of the substances is however no prerequisite for a restriction, it merely provides an additional level of certainty regarding a substance’s hazardous property. The Restrictions Roadmap itself referred to the foreseen work on classification also as complementary - not as a precondition. Three years have now passed and no mandate has been issued. This delay cannot reasonably be justified by the ongoing classification work. Instead, other explanations have been put forward, notably that grouping the substances around the two shared hazards, endocrine disruption and reproductive toxicity, is too complex. But such challenges were entirely foreseeable and could have been anticipated when the Roadmap was first developed.

In the case of the PFHxA restriction, although RAC and SEAC provided an opinion supporting a broad restriction with derogations, the Commission shifted the initial approach to a targeted restriction, notably by removing the proposed restriction²⁸ on manufacture and deviating from the RAC and SEAC opinion without offering an explanation, as legally required.²⁹

The cases of bisphenols, ortho-phthalates and PFHxA are just three of several examples of unconvincing argumentation for delaying action. In the NGO’s view, these are half-baked excuses for not delivering to their mandate.

²⁸ Recital 5 of Regulation (EU) 2024/2462, see the respective entry in the table.

²⁹ Art. 73(1) REACH, second subparagraph: “Where the draft amendment diverges from the original proposal or if it does not take the opinions from the Agency into account, the Commission shall annex a detailed explanation of the reasons for the differences”.

3. Recommendations

We demand that the Commission complies with its legally binding obligations to ensure a high level of protection of both the environment and human health through the regulation of chemical substances and accelerate the implementation of the Restrictions Roadmap.

This will be done by:

- Presenting swiftly restriction proposals for all chemicals included in the Roadmap.
- Respecting the obligation to mitigate an identified unacceptable risk by introducing a new or amending an existing restriction (REACH Article 68(1)).
- Ensuring ECHA and Member States have sufficient resources and support to implement the Roadmap.
- Ensuring compliance with legal timelines set by the REACH regulation for the different stages of the restriction process. The EEB's 2022 [The Need for Speed Report](#) underpins this conclusion with concrete examples.
- Increasing transparency on implementation of the Roadmap, with justifications for any delays/changes in framing the restrictions. Insufficient explanations, as in the PFHxA case showed clearly, where the Commission deviated a lot from ECHA opinions ([see EEB 2023](#)) but didn't make the justification as needed per law (REACH Art. 73(1)) publicly available. If a delay is absolutely necessary for example due to an unusually large amount of comments or a particularly big dossier (like for microplastics and the PFAS restriction), justifying the delay is absolutely necessary.
 - Also the EU Ombudsman [expressed concerns](#) about "lack of transparency of the 'comitology procedures'", which includes restrictions under REACH.
- Improving the restriction process to reduce uncertainties and speed up decision making process, e.g.
 - Clarify how uncertainties should be assessed to reduce the burden of proof on the authorities having to demonstrate the risk.
 - Clarify conditions and information that should be available to authorities for granting derogations.
 - Increase the level of scrutiny and standard of assessment for derogations so that they remain the exception.
 - Enforce a strict understanding of the alternatives' assessment, ensuring that derogations are granted only where there is compelling evidence of no technical feasibility.³⁰
- Take enforcement seriously but do not allow enforceability concerns to lower the level of ambition. Compliance with chemicals legislation remains low, which makes it essential to strengthen enforcement by allocating adequate resources and capacities and by effectively sanctioning non-compliance.³¹ At the same time, enforceability concerns cannot justify inaction where unacceptable risks to human health or the environment have been identified. On the contrary, adopting a restriction would itself stimulate the development of testing capacity by creating clear regulatory demand. This would incentivise laboratories and the testing industry to invest in the necessary methods and infrastructure.

30 The 2020 Chemicals Strategy for Sustainability committed to prioritise "all" target substances for restrictions for "all" uses, unless proven essential for society#. In principle, derogations should remain exceptional, strictly justified, and limited to critical applications for which no suitable alternatives are proven to be readily available.# Jurisprudence has already clarified that, under REACH, suitable alternatives do not need to provide equivalent technical performance.# Interpreting this principle otherwise would make substitution virtually impossible, as it would require waiting until an alternative matches the exact performance of the hazardous substance before regulatory action could be taken. Such an approach would effectively prevent the restriction of hazardous substances. A certain reduction in performance should therefore be considered acceptable when assessing the availability of alternatives. Moreover, in line with the European Commission's guidance, technical functions of most harmful substances that only impart properties relating to convenience, leisure, decoration or luxury to the user of the final product should normally not be deemed necessary for health or safety or critical for the functioning of society, and therefore should never be candidates for derogations. European Commission, Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals, C/2024/2894, 26.04.2024, p. 13.

31 <https://www.clientearth.org/latest/documents/catch-them-cause-you-can/>.

- Ensuring that adequate information on hazards and uses is available for regulatory processes by ensuring compliance with registration obligations to generate the information on hazards and uses needed to prepare restriction proposals; reforming REACH to extend registration obligations to low tonnages and information requirements to all most harmful chemicals; ensuring information on alternatives are available early in the process; and ensuring industry provides information to authorities and experts preparing and analysing restriction proposals early in the process.


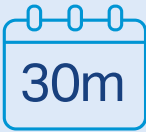

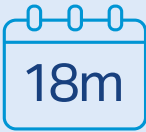


Annex – Full table






The table below gives a concise overview of the substances included in the 2022 Restrictions Roadmap (pool 0 – initiated restrictions and pool 1 – expected restrictions) and, at the bottom of the table, the restrictions that were already in the restriction process back then.


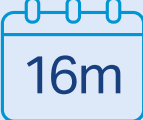

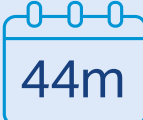

Key

- **Column 1:** The substance or group included
- **Column 2:** The concern related to the substance and why it should be regulated, as defined by officials
- **Column 3:** The function of the substance(s) and the areas of use which the restriction addresses, as defined by officials or scientists
- **Column 4:** The impact of non-regulation, reflected in annual emissions or use volumes, as defined by officials
- **Column 5:** In which stage of the restriction process the case is currently in ([see: What does a standard restriction process look like, above](#)), verified on 1 April 2026 at [<https://ec.europa.eu/transparency/comitology-register/screen/documents>]
- **Column 6:** Delay by the European Commission in months. Figures give its permitted 3 month legal limit and any further delay and the resulting total. This report uses 1 April 2026 as the end point for measuring delay, where appropriate.

Substances and group	Concern	Uses	Impact	Status in the regulatory process	Delay
Pool 0: Restrictions (2022) already on the Registry of Intention (RoI), mandate provided to ECHA or restriction dossier recently submitted [For non-experts: Restriction files that just entered the restriction process]					
<p>PFAS in Firefighting Foams Commission Regulation (EU) 2025/1988 of 2 October 2025</p> <p>Proposed by ECHA on behalf of the European Commission</p>	<p>PFAS are a large group of >10,000 substances that are persistent in the environment. PFAS show additional problematic properties that differ across substances. Substances that are mobile pollute water bodies, while other substances have serious human health impacts. Some PFAS are suspected carcinogens, cause harm to the developing child, trigger effects at low concentrations in organs such as on the liver, on fertility and the hormonal system. (continued)...</p>	<p>PFAS-containing firefighting foams are used for fires in many different applications involving flammable liquids and are used in equipment in a variety of sectors, (e.g., oil/chemicals, municipal, maritime, aviation, defence and hand-held fire extinguishers). They can be applied with both mobile and stationary equipment and are also used in training and testing of equipment.</p>	<p>Around 18,000 tonnes per year of PFAS based firefighting foams are manufactured in the EU. This amounts to a total annual emission of around 470 tonnes of PFAS from this use.</p>	<p>1 – 01/10/2020 2 – 23/03/2022 3 – 07/06/2023 4 – 29/04/2025 5 – 03/10/2025</p> <p>Stage 5 – entered into force</p>	<p>07/06/2023 – 28/11/2024</p> <p>17m</p> <p>[3m+14m delay]</p>

Substances and group	Concern	Uses	Impact	Status in the regulatory process	Delay
<p>PFAS in Firefighting Foams Commission Regulation (EU) 2025/1988 of 2 October 2025</p> <p>Proposed by ECHA on behalf of the European Commission</p>	<p>PFAS widespread use across the value chain globally leads to inevitable, cumulative, and effectively irreversible exposure of humans and the environment through contaminated water, food, air, and long-range environmental transport.</p>				
<p>Medium-chain chlorinated paraffins (MCCP) and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17</p> <p>Proposed by ECHA on behalf of the European Commission</p>	<p>MCCP are persistent, bioaccumulative and/or toxic chemicals (PBT and/or vPvB) that pollute water, air, soils and sludge in the EU and also in remote locations such as the Arctic, the Antarctic and the Tibetan Plateau at high altitude.</p>	<p>Mainly used as plasticisers, flame-retardants or lubricants in mixtures and articles that are used by industry, consumers and professionals, such as in PVC, adhesives and sealants, rubber, metalworking fluids, paints and coatings and leather fatliquor.</p>	<p>The current releases of MCCP to the environment are estimated to be between 5,200 and 6,300 tonnes per year in the EU.</p>	<p></p> <p>1 – 26/07/2021 2 – 21/09/2022 [RR: 15/7/2022] 3 – 08/09/2023 Stage 4 – under decision making at EC</p>	<p>08/09/2023 – now</p> <p></p> <p>[3m+27m delay]</p>
<p>Polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting Commission Regulation (EU) 2025/660 of 1 April 2025</p> <p>Proposed by ECHA on behalf of the European Commission</p>	<p>PAHs are a group of chemical substances, represented by 18 substances in this restriction. PAHs are carcinogenic and/or persistent, bioaccumulating and toxic (PBT) and/or very persistent and very Bioaccumulating (vPvB). For such substances no safe level of emissions, leading to human and environmental exposure, can be defined, thus regulators find a minimisation of their emissions is required.</p>	<p>PAH substances occur in some materials used as binders for the production of clay targets. Binders make up about 30% of the weight of a clay target. The targets, also called pigeons, are used for clay target shooting.</p>	<p>At least 270 tonnes of PAHs per year are released from clay targets. The restriction proposed could achieve a reduction of 99% of the PAH releases.</p>	<p></p> <p>1 – 06/07/2021 2 – 01/12/2021 [RR: 13/10/2021] 3 – 02/12/2022 4 – 22/10/2024 5 – 01/04/2025 Stage 5 – entered into force</p>	<p>02/12/2022 – 06/06/2024</p> <p></p> <p>[3m+15m delay]</p>
<p>Lead in outdoor shooting & fishing</p> <p>Proposed by ECHA on behalf of the European Commission</p>	<p>Lead is toxic for reproduction and the nervous system and may also be an endocrine disrupter. Critical effects in humans include developmental neurotoxicity such as children's IQ reduction, effects on blood pressure and chronic kidney disease.</p> <p>(continued)...</p>	<p>Lead is a heavy metal that is used in ammunition such as shot and bullets and also fishing tackle.</p>	<p>Approximately 44,000 tonnes of lead are dispersed in the environment every year.</p> <ul style="list-style-type: none"> – 57% from sports shooting, – 32% from hunting and the rest from fishing activities. <p>This is related to the loss of >1 IQ point of 66,000 children and 100 – 1,000 cases of chronic kidney disease among EU hunters.</p>	<p></p> <p>1 – 03/10/2019 2 – 24/03/2021 [RR: 15/01/2021] 3 – 02/12/2022 Stage 4 – under decision making at EC</p>	<p>02/12/2022 – 21/02/2025</p> <p></p> <p>[3m+23m delay]</p>

Substances and group	Concern	Uses	Impact	Status in the regulatory process	Delay
Lead in outdoor shooting & fishing Proposed by ECHA on behalf of the European Commission	It poses a significant danger to birds that eat it, either directly (e.g. accidental ingestion when lead pellets are mistaken for food) or indirectly (e.g. by eating game that was shot with lead bullet).		At least 135 million birds , including at least 92 species , are at risk of primary poisoning from lead gunshot, 14 million are at risk of secondary poisoning and 7 million birds are at risk because of the ingestion of fishing sinkers and lures.		
Lead and its compounds in PVC Proposed by ECHA on behalf of the European Commission Commission Regulation (EU) 2023/923 of 3 May 2023	Lead is toxic for reproduction and the nervous system and may also be an endocrine disrupter. Critical effects in humans include developmental neurotoxicity such as children's IQ reduction and effects on blood pressure and chronic kidney disease.	Lead is used as a stabiliser in hard PVC plastics, such as home (e.g. windows, venetian blinds) and construction articles.	It is estimated that 34 tonnes per year of lead are released to the environment from PVC.	 <ol style="list-style-type: none"> 1 – 15/12/2015 2 – 16/12/2016 [RR: 16/12/2016] 3 – 15/03/2018 4 – 07/12/2022 5 – 03/05/2025 Stage 5 – entered into force	15/03/2018 – 08/06/2022  [3m+47m delay]
2,4-dinitrotoluene Proposed by ECHA on behalf of the European Commission	The substance 2,4-dinitrotoluene may cause cancer. The restriction targets risks to human health for consumers and professional workers. For this substance no safe level can be defined.	Uses which can expose consumers to the substance include civilian small arms ammunition and safety systems in vehicles such as air bags and seat belt pretensioners. Professionals are more likely exposed through sampling bottles used in industrial settings. The exposure is however unknown.	No quantitative assessment was made of the emissions avoided as a result of the restriction.	 <ol style="list-style-type: none"> 1 – 27/01/2021 2 – 24/06/2021 [RR: 16/07/2021] 3 – 09/09/2022 4 – 01/12/2025 Stage 4 – under decision making at EC	09/09/2022 – 03/06/2025  [3m+30m delay]
Universal PFAS Proposed by Germany, Denmark, the Netherlands, Norway and Sweden	PFAS are a large group of >10,000 substances that are persistent in the environment. PFAS show additional problematic properties that differ across substances. PFAS that are mobile pollute water bodies, while other substances have serious human health impacts. Some PFAS are suspected carcinogens, cause harm to the developing child, trigger effects at low concentrations in organs such as on the liver, on fertility and the hormonal system. (continued)...	PFAS are used across more than 20 sectors across the entire value chain from production of other materials, industrial processes, professional applications such as pesticides, wide dispersive uses as medicinal products and consumer products. One of the main uses by volume are fluorinated gases in air-conditioning and refrigeration. Consumer uses include e.g. rain jackets and frying pans.	70,000 tonnes per year of PFAS are released to the environment in the EEA. The restriction as proposed by the authors, would lead to a 76% emission reduction .	 <ol style="list-style-type: none"> 1 – 15/07/2021 2 – 22/03/2023 [RR: 13/01/2023] Stage 3 – under ECHA opinion making	n/a





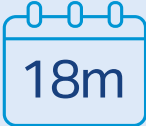
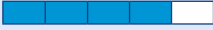

Substances and group	Concern	Uses	Impact	Status in the regulatory process	Delay
Universal PFAS Proposed by Germany, Denmark, the Netherlands, Norway and Sweden	PFAS widespread use across the value chain globally leads to inevitable, cumulative, and effectively irreversible exposure of humans and the environment through contaminated water, food, air, and long-range environmental transport.				
DMAC, NEP Proposed by the Netherlands Commission Regulation (EU) 2025/1090 of 2 June 2025 ³²	These chemicals are classified as toxic to reproduction, meaning they can harm the unborn child and pose significant risks to workers through inhalation and exposure via the skin. Exposure to DMAC has been linked to liver and developmental toxicity, including reduced fetal body weight and incidences of birth defects in animal studies. NEP is expected to cause systemic effects such as weight loss and reduced general well-being. Inhalation may also lead to irritation.	Both substances are widely used in industrial and professional settings e.g., in the production of coatings, pharmaceuticals, pesticides, road and construction applications, and polymers.	DMAC production in the EU has been estimated in the range of 15,000 – 20,000 tonnes per year and NEP is registered in a volume band of 1,000 – 10,000 tonnes per year across the EU. No quantitative assessment of the impacts was available, however the restriction was expected to yield health benefits, also by ensuring that the risk levels would not increase in the future as a result of increased DMAC and NEP use.	 1 – 09/12/2019 2 – 22/04/2022 [RR: 08/04/2022] 3 – 09/06/2023 4 – 22/10/2024 5 – 02/06/2025 Stage 5 – entered into force	09/06/2023 – 02/10/2024  [3m+13m delay]
Dechlorane Plus Proposed by Norway	The substance with the nickname Dechlorane Plus is a Substance of Very High Concern (SVHC) due to being very persistent and very bioaccumulating. It is widespread in the environment and found also in human blood, placenta and breast milk.	Dechlorane Plus is imported to the EU, where it is mainly used in the automotive industry as a flame retardant. A minor use is as an additive to greases.	The proposed restriction would lead to an emission reduction of 89% , while inaction would lead to annual emissions of 19 tonnes/year .	 1 – 26/08/2020 2 – 04/06/2021 [RR: 09/04/2021] 3 – 08/06/2022 Stage 4 – under decision making at EC	08/06/2022 – now  [3m+41m delay]
Bisphenols as endocrine disruptors for the environment Proposed by Germany	Bisphenols are known to be endocrine-disrupting, i.e. they interfere with the hormonal system of both humans and wildlife. Amphibians and fish are known to be sensitive to bisphenol-induced endocrine disruption through exposure in water bodies. ³³ (continued)...	BPA is manufactured and/or imported in the European Economic Area in a tonnage range of >1,000,000 tonnes per year . ³⁴ BPA can be easily replaced by similarly problematic bisphenols, e.g. BPS, BPF, BPB.	BPA is assumed to be constantly and ubiquitously emitted to the environment. The restriction proposal estimated overall bisphenol emissions amount to 568 tonnes per year (with variations from 251 – 1,773).	 1 – 27/08/2021 2 – 07/10/2022 [RR: 07/10/2022] Withdrawal 21/08/2023 Stage 0 – intention pending [after withdrawal of initial proposal] ³⁵	n/a





32 According to this Regulation, DMAC and NEP cannot be marketed or used above 0.3 % concentration unless safety reports include specified DNELs for long-term inhalation and dermal exposure. Companies must implement risk management measures and operational conditions that ensure workers' exposure stays below those DNELs.

33 <https://echa.europa.eu/de/-/group-assessment-of-bisphenols-identifies-need-for-restriction#:~:text=ECHA%20and%20the%20Member%20States,health%20and%20the%20environment>

34 <https://echa.europa.eu/de/substance-information/-/substanceinfo/100.001.133>.

35 Germany led the initiative to regulate bisphenols which EDs for the environment, submitting a group-based Annex XV restriction to ECHA in 2022. The proposal was however withdrawn soon after consultation feedback, with intent to resubmit an updated dossier. The timeline for resubmission has not been clarified.

Substances and group	Concern	Uses	Impact	Status in the regulatory process	Delay
Bisphenols as endocrine disruptors for the environment Proposed by Germany	Bisphenols is a family of approx. 148 substances , of which at least 30 have been identified as requiring regulatory action.	Large amounts of products containing bisphenols are furthermore imported into the EU. Bisphenols are widely used in plastics, epoxy resins, thermal paper, adhesives, and industrial coatings.			
Terphenyl, hydrogenated Proposed by Italy	Terphenyl, hydrogenated, is a Substance of Very High Concern (SVHC) due to being very persistent and very bioaccumulating.	The restriction addresses the main use as a heat transfer fluid in industrial installations, as well as minor uses including being a plasticiser for polymer applications.	There is a lack of robust data to estimate the exact emission levels of the substance. Emissions to the environment are expected to occur from all uses covered by the proposed restriction.	 1 – 21/04/2021 2 – 05/04/2022 [RR: 08/04/2022] 3 – 09/06/2023 Stage 4 – under decision making at EC	09/06/2023 – now  [3m+30m delay]
PAH, PCB, Dioxins, Furans and Formaldehyde Substances in single-use baby diapers Proposed by France	PAH, PCB, Dioxins, Furans and Formaldehyde are highly toxic chemicals, related with a wide range of health impacts, including cancer, damage to reproductive, endocrine, immune and nervous system, among others.	These toxic chemicals are manufacturing process residues. They are not intentional ingredients of diapers. RAC was unable to conclude on the risks posed by these chemicals due to various uncertainties of the risk assessment. However it did not discard that they could pose a risk to babies.	14.5 million babies and infants in Europe are exposed to the chemicals targeted in this restriction proposal via single-use diapers.	 1 – 09/10/2019 2 – 15/12/2020 [RR: 09/10/2020] 3 – 08/12/2021 ECHA formed a negative opinion. Status – EC decided not to propose the restriction.	n/a
Undecafluoro-hexanoic acid (PFHxA), its salts and related substances Proposed by Germany Regulation (EU) 2024/2462	PFHxA is extremely persistent and mobile in the environment and difficult, if not impossible to remove from drinking water and contaminated sites. It has been linked to reproductive toxicity, and exposure to it is multi-generational.	About 80% of the releases of PFHxA are estimated to occur from products and articles from the textiles, paper, cardboard (food contact materials) and firefighting foams sectors.	RAC was unable to reach a quantitative conclusion on the magnitude and likely range of PFHxA emissions, except for certain sectors. Nevertheless, it concluded that releases to the environment from wide-dispersive uses are inevitable.	 1 – 21/12/2018 2 – 20/12/2019 [RR: 20/12/2019] 3 – 08/12/2021 4 – 29/02/2024 5 – 19/09/2024 Stage 5 – entered into force	08/12/2021- 14/06/2023  [3m+15m delay]
Creosote and Creosote related substances Proposed by France	Creosote and related substances are Persistent, Bioaccumulating & Toxic (PBT) which leads to food chain accumulation and they show carcinogenic effects. For such substances no safe level of emissions, leading to human and environmental exposure, can be defined, thus regulators find a minimisation of their emissions is required.	Creosote substances are used to treat wood for protection in uses such as railway sleepers and utility poles for electricity. The restriction addresses the wood's reuse for the same or different purpose.	No quantitative assessment was made of the emissions avoided as a result of the restriction.	 1a – 14/10/2021 2a – 14/01/2022 [RR: 01/02/2022] Withdrawal 18/07/2022 1b – 06/09/2022 2b – xx/12/2022 3 – 01/12/2023 Stage 4 – under decision making at EC	01/12/2023- 12/02/2026  [3m+23m delay]

Substances and group	Concern	Uses	Impact	Status in the regulatory process	Delay
Pool 1: Planned restrictions not yet on the RoI for restriction [For non-experts: Restriction files that should enter the restriction process in the near future]					
<p>PVC and its additives</p> <p>Proposed by ECHA on behalf of the European Commission</p>	<p>PVC poses a risk to human health and the environment throughout its entire lifecycle. The starting material for PVC, the vinyl chloride monomer, is flammable and may cause cancer.</p> <p>Throughout its lifecycle, PVC articles can further release additives which are not bound to the material, as well as microparticles that end up in the environment where they hardly degrade.</p>	<p>PVC is a widely used plastic which occurs in a soft and a rigid form.</p> <p>Soft PVC, which contains more additives and leads to higher emissions, is used for example in cables, flooring, toys and medical applications.</p> <p>Hard PVC is used in applications like pipes and window frames.</p>	<p>No long-term emission estimate is available. The volumes of PVC in the EU's economy are however expected to increase.</p> <p>About 18,000 – 26,000 tonnes per year of heat stabilisers, plasticisers and flame retardants are released into the environment from PVC articles.</p>	<p></p> <p>1 – n.a.</p> <p>[RR: 2022]</p> <p>Stage 0 – intention without a date</p>	n/a
<p>CMRs in child care articles</p> <p>Proposed by ECHA on behalf of the European Commission</p>	<p>Substances causing cancer, genetic mutations or harming reproduction.</p> <p>Children are particularly vulnerable to chemical exposure. A safe level can not be established for such substances, therefore demanding a ban in order to protect children.</p>	<p>Childcare products such as car seats, diapers, nappies, mattresses and many more.</p>	<p>CMR substances from 35 different chemical groups were either measured (n=65) or suspected to be present (n=116) in childcare articles.</p> <p>A quantitative estimate for the likelihood of exposure is not available.</p>	<p></p> <p>1 – 29/11/2022</p> <p>[RR: 2022]</p> <p>2 – 31/10/2023</p> <p>3 – n.a.</p> <p>Stage 4 – under decision making at EC</p>	<p>31/10/2023 – now</p> <p></p> <p>[3m+26m delay]</p>
<p>Organophosphate flame retardants (OPFRs) (tris(2-chloroethyl) phosphate (TCEP), tris(2-chloro-1-methylethyl) phosphate (TCPP), tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP))</p> <p>Proposed by Denmark</p>	<p>Risk for children (carcinogenicity) in flexible polyurethane foams.</p> <p>TCEP is also toxic for reproduction.</p>	<p>Flame retardants in articles such as baby mattresses, car safety seats, baby slings, and residential upholstered furniture.</p>	<p>No recent data – 2016 data from the Danish EPA suggests that TCPP consumption was ~40,000 t/y in 2000 (11,000 – 110,000 t/y under REACH), and <10,000 t/y for TDCP. TCEP is no longer used but may persist at low levels in certain articles.</p>	<p></p> <p>1a – 06/06/2018</p> <p>2a – Withdrawn 19/07/2019</p> <p>1b – n.a.</p> <p>[RR: "TBD"]</p> <p>Stage 0 – intention pending</p>	n/a

Substances and group	Concern	Uses	Impact	Status in the regulatory process	Delay						
Ortho-phthalates (C4-C6)	Ortho-phthalates have been linked to reprotoxic and endocrine-disrupting effects in humans and the environment.	Ortho-phthalates are widely used plasticisers that add flexibility and resilience to plastics, while also serving multiple functions (solvents, binders, etc.), and are utilised across a broad range of products, including polymers, coatings, adhesives, cosmetics, and food contact materials.	These chemicals are released to the environment throughout their lifecycle because they are not chemically bound into plastics and thus can leach or volatilise into air, water and dust. Biomonitoring from the HBM4EU (2014–2021) shows that C4–C6 phthalates are widely detected in European children and adolescents, with some levels exceeding health-based guidance values. ³⁶	<table border="1"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td> </tr> </table> <p>1 – n.a. [RR: 2023] Stage 0 – intention pending³⁷</p>							n/a
Lead chromate ; Lead sulfochromate yellow (C.I. Pigment Yellow 34) ; Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	They are classified as 'substances of very high concern' due to a combination of harmful properties, including inter alia carcinogenicity, reproductive and developmental toxicity. ³⁸ The substance may be toxic in the aquatic environment and cause damage to human organs in case of multiple exposures.	These substances are inorganic pigments historically used to produce bright yellow, orange and red colours, mainly in industrial applications. They belong to the broader group of lead chromate pigments, which combine lead and hexavalent chromium compounds.	In the EU, lead chromate pigments were historically used in the thousands-of-tonnes range, but REACH authorisation ³⁹ has drastically reduced their use. Imported paints and articles may still contain these chemicals. ⁴⁰	<table border="1"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td> </tr> </table> <p>1 – n.a. [RR: "TBD"] Stage 0 – intention pending / on hold</p>							n/a
Substances in thermal paper ⁴¹	Several problematic substances can be found in thermal paper. A prominent example is Bisphenol S (BPS), a substitute for the restricted Bisphenol A (BPA) in thermal paper, has been linked to reproductive toxicity and endocrine-disrupting effects. Also further bisphenols and other substances might become part of the restriction.	Thermal paper (a base paper with at least one coating which changes colour when exposed to heat, allowing the printed characters to appear) is used in payment receipts. Workers (primarily cashiers) and consumers regularly handle thermal paper.	No quantitative assessment of emissions of substances in thermal paper across the EU is known. Thermal paper is, however, placed on the market all across the EU.	<table border="1"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td> </tr> </table> <p>1 – n.a. [RR: "2022 /TBD"] Stage 0 – intention pending⁴²</p>							n/a

36 Vogel N, Schmidt P, Lange R, Gerofke A, Sakhi AK, Haug LS, Jensen TK, Frederiksen H, Szigeti T, Csáákó Z, Murinova LP, Sidlovska M, Janasik B, Wasowicz W, Tratnik JS, Mazej D, Gabriel C, Karakitsios S, Barbone F, Rosolen V, Rambaud L, Riou M, Murawski A, Leseman D, Koppen G, Covaci A, Lignell S, Lindroos AK, Zvonar M, Andryskova L, Fabelova L, Richterova D, Horvat M, Kosjek T, Sarigiannis D, Maroulis M, Pedraza-Díaz S, Cañas A, Verheyen VJ, Bastiaensen M, Gilles L, Schoeters G, Esteban-López M, Castaño A, Govarts E, Koch HM, Kolossa-Gehring M. Current exposure to phthalates and DINCH in European children and adolescents – Results from the HBM4EU Aligned Studies 2014 to 2021. *Int J Hyg Environ Health*. 2023 Apr;249:114101. doi: 10.1016/j.ijheh.2022.114101. Epub 2023 Feb 16. PMID: 36805185.

37 A [report](#) published in 2022 assessed whether the use of 10 phthalates should be restricted articles.

38 ECHA (2009) SVHC supporting document – Lead Chromate. https://chem.echa.europa.eu/api-obligation-list/v1/candidateList/documents?name=72e48ec734d226b7a9551bd302ff2ea3_svhc_supdoc_lead_chromate_publication_en.pdf

39 Currently, their use in the EU has been subject to REACH authorisation. Their continued use in the EU therefore requires companies to demonstrate that risks are controlled and that suitable alternatives are not yet available.

40 "Art 69(2) proposal on hold until discussions/restriction proposal on lead in PVC is completed" (see entry 5 of pool 0) which was adopted in May 2025.

41 This restriction is meant to be a follow-up to restriction of bisphenol A in thermal paper (2016).

42 No follow-up to ECHA's opinion and [Commission Regulation \(EU\) 2016/2235](#), which asked to monitor the use of BPS as a potential substitute in thermal paper (a "regrettable substitution" case, as BPS has been linked to similar toxic effects as BPA)




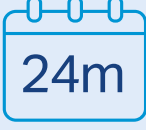




Substances and group	Concern	Uses	Impact	Status in the regulatory process	Delay
Bisphenols (4,4'-isopropylidenediphenol (bisphenol A) and structurally related bisphenols (including derivatives))	Bisphenols that pose a specific concern for human health (HH) are generally those for which human exposure is frequent or direct, and where evidence shows endocrine-disrupting effects relevant to human biological systems. 2023 biomonitoring data showed that 92% of Europeans have BPA in their urine. ⁴³	Bisphenols relevant to human-health are usually present in applications that lead to direct or repeated human exposure, such as food and beverage cans, reusable plastic containers, kitchenware, toys, or electronics casings.	More than 1 million tonnes of BPA alone are manufactured or imported in the EU each year. Exposure occurs primarily through dietary intake due to migration from food contact materials, with canned foods identified as a major source. Earlier exposure assessments estimated dietary intakes of up to 0.875 µg/kg body weight/day in children. ⁴⁴	 1 – n.a. [RR: "2022 /TBD"] Stage 0 – mandate pending "Timing not decided"	n/a
Flame retardants Partially addressed Aromatic brominated flame retardants ABFR Proposed by ECHA on behalf of the European Commission	<p>The group of flame retardants includes a lot of different chemistries which also differ in the risk they pose.</p> <p>The risks to human health and the environment are diverse.</p> <p>The five non-polymeric aromatic brominated flame retardants proposed for a restriction are confirmed to be persistent, bioaccumulating and toxic (PBT) or very persistent and very bioaccumulating (vPvB). For such substances no safe level of emission can be defined and EU regulators require a minimisation of their emissions. The emissions are mainly found in air and soil with the majority of emissions coming from shredding at the waste stage.</p>	<p>Flame retardants have the general function to prevent or delay the ignition of flammable materials. Sometimes the substances can have multiple functions. Flame retardants are mainly used in sectors such as electric and electronic devices, textiles, building and construction materials and transport vehicles.</p> <p>Substances identified as ABFR that are addressed through the restriction proposal are used in products such as electric and electronic equipment, construction products and textiles.</p>	<p>Europe consumes about 25% of the global flame retardant market, which has the size of ~2.39 Million tons per year.⁴⁵</p> <p>Among the five flame retardants in scope, the one with the highest demand has an annual volume of ~26.700 tonnes/year. Around 4,870 tonnes per year of a subgroup of ABFR are estimated to be released into the environment.⁴⁶</p>	 1 – 12/12/2025 [RR: "2023"] Stage 1 – Dossier submission pending	n/a

43 <https://www.eea.europa.eu/en/analysis/publications/human-exposure-to-bisphenol-a>.

44 <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.3978>.


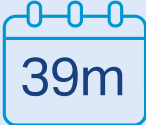
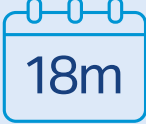
45 ECHA (2023) Regulatory strategy for flame retardants https://echa.europa.eu/documents/10162/2082415/flame_retardants_strategy_en.pdf/9dd56b7e-4b62-e31b-712f-16cc51d0e724?t=1678871526283

46 ECHA, 2024, ABFR [investigation report](#) and [annex](#)

Substances and group	Concern	Uses	Impact	Status in the regulatory process	Delay
Substances not listed due to already ongoing restriction process / opinions done before Restrictions Roadmap published					
Skin sensitising, irritative and/or corrosive substances in textile, leather, hide and fur articles Proposed by France and Sweden	Once a person is sensitised to an allergen, they must avoid exposure to the allergen for the rest of their life in order to prevent allergic reactions.	Skin sensitising substances are present in textiles, leather hide and fur articles as residues of manufacturing processes, but also used as dyes.	4 to 5 million persons (0.8% – 1 % of the EEA population), are estimated to be sensitised due to chemical substances present in textile and leather. New cases are estimated to rise to 45,000 – 180,000 per year . The restriction is expected to protect 70% – 90% of the already sensitised population from developing allergic contact dermatitis.	 <ol style="list-style-type: none"> 1 – 11/01/2018 2 – 14/06/2019 3 – 17/09/2020 Stage 4 – under decision making at EC	17/09/2020 – now  [3m+63m delay]
Formaldehyde and formaldehyde releasers Proposed by ECHA on behalf of the European Commission	Formaldehyde has acutely toxic properties which can irritate skin and the respiratory tract. It is further genotoxic and carcinogenic. The risk from formaldehyde through inhalation is considered the most relevant.	Formaldehyde and its releasers are mainly used in the production of wood products and furniture, wallcoverings and production of chemicals. The restriction targets formaldehyde releases occurring indoors.	690,000 or more individuals are estimated to profit from reduced exposure to formaldehyde if emission limits as proposed by the restriction are adopted (reference year 2016).	 <ol style="list-style-type: none"> 1 – 11/01/2018 2 – 20/03/2019 3 – 17/09/2020 4 – 10/02/2023 5 – 14/07/2023 Stage 5 – entered into force	17/09/2020 – 06/10/2022  [3m+21m delay]
Calcium cyanamide Proposed by ECHA on behalf of the European Commission	Cyanamide is a carcinogen, a reprotoxicant and endocrine disruptor for human health and non-target organisms. It also has chronic effects on aquatic organisms.	Calcium cyanamide is a nitrogen fertiliser, that is transformed into cyanamide, urea and cyanoguanidine when applied to fields, polluting soils and water.	The restriction would avoid the pollution of 230,000 hectares of agricultural land as well as waterways adjacent to fields.	 <ol style="list-style-type: none"> 1 – 11/01/2018 2 – 19/07/2019 3 – 17/09/2020 Stage 4 – under decision making at EC	17/09/2020 – 03/04/2025  [3m+52m delay]
Perfluorohexane sulfonic acid (PFHxS), its salts and related compounds Proposed by Norway	PFHxS has severe liver, neurotoxic, neurodevelopmental, reprotoxic and endocrine-disrupting effects. It has been detected in water, snow, air, animals (even polar bears) and humans.	PFHxS belongs to the PFAS group and has been used as a surfactant, water- and stain protective coating for carpets, paper, leather and textiles and in fire-fighting foams, among others, often as a replacement for PFOS.	Information about the current global manufacture of PFHxS is limited. However, PFHxS is found to be widely distributed globally, even in remote regions, and is one of the most frequently detected PFAS in human blood in the general population. ⁴⁷ Annual releases to the environment of 0.44 tonnes of PFHxA are expected from 2020 onwards.	 <ol style="list-style-type: none"> 1 – 12/04/2018 2 – 19/06/2019 3 – 11/06/2020 4 – 09/02/2023 Stage 5 – Restriction process terminated by EC decision to follow another regulatory measure instead (POPs regulation). Publication 30/05/2023 (entered into force 28/08/2023)	11/06/2020 – 30/05/2023  [3m+33m delay] ⁴⁸

47 <https://docs.unep.org/en/UNEP/POPS/POPRC.14/6/ADD.1>

48 Decision: Not a REACH restriction process - covered by Regulation (EU) 2019/1021, which implements the Stockholm Convention on Persistent Organic Pollutants (POPs). Commission Delegated Regulation (EU) 2023/1608 of 30 May 2023 -

Substances and group	Concern	Uses	Impact	Status in the regulatory process	Delay
<p>Intentionally- added Microplastics</p> <p>Proposed by ECHA by the European Commission Commission Regulation (EU) 2023/2055 of 25 September 2023⁴⁹</p>	<p>Microplastics are ecotoxic, causing a wide range of adverse effects on a wide range of species. In addition, microplastics can be transferred to humans through the food chain. Microplastics are highly persistent and any releases will contribute to the environmental stock over time. They are ubiquitous in the environment, including fresh and marine water and sediment, the terrestrial environment and the air.</p>	<p>Microplastics are solid particles of polymer-based materials. Their main use is as infill material in sport pitches, but have many other uses including in cosmetics, detergents, agriculture, paints and coatings, construction, oil and gas and medical devices.</p>	<p>Releases to the environment from intentional added microplastics are estimated to be 42,400 (13,200 – 95,000) tonnes per year.</p> <p>The restriction would reduce 70% of these emissions over the 20 year period considered.</p> <p>The annual emission reduction after all transitional periods have expired is estimated to be >90%.</p>	<p></p> <p>1 – 17/01/2018 2 – 22/08/2019 3 – 10/10/2020 4 – 27/04/2023 5 – 25/09/2023</p> <p>Stage 5 – entered into force</p>	<p>10/12/2020 – 30/08/2022</p> <p></p> <p>[3m+17m delay]</p>
<p>Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5); dodecamethylcyclohexasiloxane (D6) in substances and mixtures.</p> <p>Proposed by ECHA on behalf of the European Commission Commission Regulation (EU) 2024/1328 of 16 May 2024</p>	<p>D4,D5 and D6 are persistent, bioaccumulative and toxic chemicals (PBT and vPvB) that pollute water and air and accumulate in soil and aquatic sediments.</p>	<p>D4, D5 and D6 are silicon monomers used in the production of silicone polymers and also in consumer products, mostly cosmetics.</p>	<p>The restriction would reduce total releases to the environment by 90% from 18,000 to 1,200 tonnes per year.</p>	<p></p> <p>1 – 13/04/2017 2 – 11/01/2019 3 – 12/03/2020 4 – 11/12/2023 5 – 16/05/2024</p> <p>Stage 5 – entered into force</p>	<p>12/03/2020 – 20/06/2023</p> <p></p> <p>[3m+36m delay]</p>
<p>Cobalt carbonate; cobalt diacetate; cobalt dichloride; cobalt dinitrate; cobalt sulphate</p> <p>Proposed by ECHA on behalf of the European Commission</p>	<p>The five substances may cause cancer and are suspected of causing genetic defects. Further properties are their respiratory and skin sensitization.</p>	<p>The 5 cobalt salts within the scope of this restriction are used in professional and industrial uses. The substances function e.g. as intermediate in the manufacture of other products such as Chemicals, batteries, and dies. They further function among others as catalysts and are used in surface treatment and biotechnology.</p>	<p>The exposure to this chemical affects about 35,000 workers at ~20,000 industrial sites and result in approximately 40 cancer cases after lifetime exposure, this is, one statistical cancer case per year.</p>	<p></p> <p>1 – 20/07/2017 2 – 19/12/2018 3 – 17/09/2020 4 – n.a.</p> <p>Stage 5 – Restriction process terminated by EC decision to follow another regulatory measure instead (occupational exposure limits).</p>	<p>17/09/2020 – 08/04/2022</p> <p></p> <p>[3m+15m delay]</p>

49 An amendment to this entry was recently approved by the REACH Committee [on 16 December 2025](#), currently pending entry into force. In short, the amendment: a) clarifies that the derogation in Annex para. 4(b) includes all medicinal products, including those used in clinical trials and pre-clinical safety testing; b) introduces a derogation for product and process-oriented research and development (PPORD), including outside industrial sites; c) limits the para. 5(c) solid matrix derogation to intended end uses of at least one year; d) defers the application of that limitation by two years to allow stakeholders sufficient time to take appropriate measures; and e) exceptionally, it provides that the amendments concerning medicinal products and PPORD apply retroactively from 17 October 2023.



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