A ROADMAP TO NOWHERE?



THE EU'S BOLD PLAN TO QUIT THE MOST HARMFUL CHEMICALS IS A YEAR OLD.

WE ASSESS ITS EFFECTIVENESS.

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A roadmap to nowhere?

The EU's bold plan to quit the most harmful chemicals is a year old.

We assess its effectiveness.

There is evidence that the planetary boundary for chemicals has been exceeded.¹ Around 200 000 chemicals are used in Europe, with approximately 70% of them being harmful to health or the environment.² While chemical production continues to grow in volumes and diversity, EU authorities face many difficulties in effectively managing the risks of these chemicals.³

The recent European Environment Agency zero pollution monitoring assessment⁴ shows the significant long term impacts chemicals have on the environment and health. In Europe, the scale of the pollution is widely documented, with direct impact on communities.⁵ Similarly, hazardous chemicals continue to flow into consumer products and little is done to avoid exposure or possible health consequences.⁶ The risks posed by chemicals are a high concern among Europeans⁷, and one that needs to be urgently tackled.

With the publication of its Chemicals Strategy for Sustainability⁸ in 2020, the European Commission pledged to move Europe towards a "non-toxic environment". Its first step towards this was to launch a Restrictions Roadmap, using existing legal powers to restrict thousands of the most notorious chemicals that are known to be dangerous but still widely used, including in consumer products. The roadmap proposes stronger grouping of chemicals of similar properties of concern, sometimes covering thousands of related chemicals. This is a substantial improvement over the painstakingly slow and ineffective one-substance by one-substance approach, which has been the norm until the roadmap.⁹

8 EUR-Lex - 52020DC0667 - EN - EUR-Lex (europa.eu)

¹ "Outside the Safe Operating Space of the Planetary Boundary for Novel Entities". Linn Persson, Bethanie M. Carney Almroth, Christopher D. Collins, Sarah Cornell, Cynthia A. de Wit, Miriam L. Diamond, Peter Fantke, Martin Hassellöv, Matthew MacLeod, Morten W. Ryberg, Peter Søgaard Jørgensen, Patricia Villarrubia-Gómez, Zhanyun Wang, and Michael Zwicky Hauschild Environmental Science & Technology 2022 56 (3), 1510-1521. DOI: 10.1021/acs.est.1c04158

² Chemicals production and consumption statistics - Statistics Explained (europa.eu)

³ EEB, The Need For Speed – Why it takes the EU a decade to control harmful chemicals and how to secure more rapid protections, July 2022.

⁴ EEA, 2022a.

⁵ Le Monde "<u>PFAS Pollution mapping project</u>" shows the many hot spots of PFAS continuation across Europe. Some communities in <u>Belgium</u>, <u>France</u> or <u>Sweden</u>, to name a few, have measured extremely high levels of PFAS in their blood and have asked for remedies.

⁶ BEUC, <u>Worrying number of dangerous products reaching consumers highlights need for greater action by authorities</u>, March 2023.

⁷ See Eurobarometer, 2020.

⁹ See pp. 9 and 10 of Chemicals Strategy for Sustainability.

Launched on 25 April 2022, the Restrictions Roadmap provides a clear plan of the bans that will be initiated and eventually adopted over the coming years under the REACH Regulation (Articles 68.1, 68.2 or 69.2).¹⁰ It is a flexible tool, subject to periodical review and annual update of a "rolling list" of substances earmarked for restriction.¹¹

The roadmap states in its preamble that it will support "maximis[ing] the reduction of unacceptable chemical risks with all available resources, by means of broader restrictions, through both grouping of substances, and addressing a wider range of uses (industrial, professional, consumer uses and service life of articles¹²)".¹³ From the roadmap described, widely used chemicals, such as 2 000 harmful chemicals used in childcare products or bisphenols, many of which are proven endocrine disruptors, should be banned by 2030. While providing predictability to authorities and industry, the Restrictions Roadmap is without doubt a true promise of detox and the largest ever planned removal of hazardous chemicals anywhere in the world.¹⁴

Yet, so far, the Restrictions Roadmap has failed to live up to its promise, both in terms of speed and approach. Exactly one year after its launch, some new restrictions have been initiated in line with the proposed schedule, but it is clear that many are severely limited in their scope and therefore do not meet the level of ambition set by the roadmap - "...broader restrictions, through both grouping of substances, and addressing a wider range of uses...".¹⁵ The main reason being the mismatch between what the REACH text commands and the interpretation that has been made of it over the years.

The roadmap can still prove its worth. But if not rectified, the current approach is bound to deflect the roadmap of its original purpose and undermine any policy efforts towards a non toxic environment. It's like committing to go on a diet, which involves avoiding particular kinds of food known to be unhealthy, while ending up eating that exact junk food you know is not good for you. If not applied more consistently and ambitiously, the Restrictions Roadmap will turn into a fake detox.

Our report evaluates specific restriction initiatives against the roadmap's initial objectives with a view to identify the main bottlenecks and make recommendations to turn the tide. The three objectives of the roadmap are¹⁶:

"Ensure that the commitments under the strategy can be fulfilled in a transparent and timely manner".

The roadmap aims to support the promise under the chemicals strategy to ban all uses, unless essential, of the most harmful substances, in a faster and simpler way, so that consumers, vulnerable groups and workers are protected from the worst

¹⁰ <u>https://ec.europa.eu/docsroom/documents/49734</u>

¹¹ ECHA regularly assesses the need for regulatory action for groups of substances and in that context it has already identified around 200 substances needing restrictive measures (see Restrictions Roadmap, page 4).

 $^{^{12}\,}$ Service life is the period of time an article remains in service (or in use).

¹³ Restrictions Roadmap, page 2.

¹⁴ The great detox - largest ever ban of toxic chemicals announced by EU (eeb.org).

¹⁵ Restrictions roadmap, p.2.

¹⁶ Described in the roadmap, page 2.

chemicals.¹⁷ The "generic approach to risk management"¹⁸ should gradually become the default approach.

To make sure the process runs efficiently and is sufficiently transparent for the public, REACH frames its restriction process within firm deadlines. Under the main procedure (Article 68.1), a Member State or ECHA, based on a Commission request, may propose an EU-wide restriction but must do so within a year¹⁹ of notifying of their intention to restrict. Following the submission of the restriction proposal, two ECHA expert committees, namely the Risk Assessment Committee (RAC) and the Socio-Economic Assessment Committee (SEAC), should formulate an opinion within 12 months.²⁰ After the publication of the combined ECHA opinion "without delay"²¹, the Commission has three months to make a proposal for a legal text.²² This Commission proposal must be approved by the committee of Member States (REACH Committee) in a qualified majority vote.²³ After that process, the restriction enters into force, unless the European Parliament or the Council formally oppose it within a period of three months. All in all, a 'normal' restriction should not take longer than two years and a half.

There are two other restriction processes under REACH, however they have not been much used in the past. Article 68.2 REACH provides for a fast-track process for restrictions for carcinogenic, mutagenic and reprotoxic substances coming into contact with consumers. Through this process the Commission can propose a restriction directly, without needing an opinion by ECHA expert committees, therefore gaining in principle at least one year. Article 69.2 REACH allows ECHA to propose a ban for substances already subject to authorisation but that can still be found in articles.

"Provide an overview, through its Rolling List, of how we are using the available authority resources".

A sheer number of authorities and national and EU level are involved in drafting, assessing and deciding on restrictions in the EU, including national officials, dozens of RAC and SEAC members, ECHA staff, Commission officials from both the Directorate General responsible for the internal market and industry (GROW) and the Directorate General responsible for environmental policies (ENV), national representatives at the REACH Committee, European Parliament and Council. The implementation of the roadmap should aim to provide visibility on how resources are spent. But it should also, eventually, contribute to maximising the efficient use of taxpayer resources by shifting the burden of proof from authorities to companies willing to continue marketing and

¹⁷ Identified as "those that meet the criteria for CMRs, PBTs, vPvBs, endocrine disruptors (ED), immunotoxicants, neurotoxicants, respiratory sensitisers and STOT substances (Specific target organ toxicity)" (Roadmap, p. 2).

¹⁸ According to the Chemicals strategy (p.9): a 'generic approach to risk management' is an automatic trigger of predetermined risk management measures (e.g. packaging requirements, restrictions, bans, etc.) based on the hazardous properties of the chemical and generic considerations of their exposure (e.g. widespread uses, uses in products destined to children, difficult to control exposure). It is applied in a number of pieces of legislation on the basis of specific considerations (e.g. characteristics of the hazard, vulnerability of certain population groups, non-controllable or widespread exposure)."

¹⁹ Articles 69(3) and 69(4) REACH.

²⁰ See Articles 70 and 71 REACH: the Risk Assessment Committee should formulate an opinion within 9 months after the publication of the restriction proposal, while the Socio-Economic Assessment Committee has 12 months to give its opinion.

²¹ Article 72.2 REACH.

²² Article 73 REACH.

²³ Article 133(4) REACH, referring to the regulatory procedure with scrutiny under Decision 1999/468/EC, Article 5a.

using hazardous chemicals, by speeding up the process and avoiding repeated endless discussions over the years, by avoiding developing multiple overlapping restrictions or targeting irrelevant substances.

"Provide transparency to stakeholders on the restriction work by authorities and allow companies to anticipate (potential) upcoming restrictions, e.g. by already beginning substitution activities".

EU institutions must work in line with principles of good administration in order to promote transparent and efficient procedures.²⁴ In the context of the Restrictions Roadmap, transparency means making accessible key information needed for the public and main stakeholders to understand and anticipate policy changes. It implies sharing information on which chemicals and which uses are targeted, timelines for the different steps of the process, the delays and reasons for the delays, evidence used to support proposals, opinions by expert committees and decisions by the policy makers, in particular on derogations for the restrictions.

The first section of this report provides a rapid overview of all ongoing restriction processes (A) and analyses two specific restriction case studies (B). Bisphenols, known as hazardous for decades but still causing daily exposure for most Europeans, and PFAS, a group of persistent chemicals to which mass production started in the 1970s. Today, almost all Europeans are being exposed to PFAS, which is why they have been the target of several restrictive measures (e.g. PFHxA, PFAS in Fire fighting foams, 'universal' PFAS). The second section summarises the main findings from the evidence collected in the first section. We propose some considerations on why the restrictions fail to meet the original expectation from the roadmap.

1. Assessment: what has been done so far

A.) Overview of restrictions undergoing assessment since the adoption of the Restrictions Roadmap

For our assessment, we focus on what the roadmap calls "Pool 0" substances, that is those already undergoing assessment by ECHA, awaiting a decision by the Commission or that have been adopted in the past year. Other pools, restrictions that are only "planned" or "potential", are not considered because they have not begun yet. A majority of Pool 0 substances were already subject to restriction procedures before the roadmap was announced. Yet they should be judged against the roadmap's aims because officials, especially the European Commission, have the power to correct and accelerate those proposals, especially in light of the Chemicals Strategy for Sustainability and the Restriction Roadmap's new-found ambition.

The assessment will present:

The scope of the restriction, i.e. what it covers and does not cover, compared to the roadmap ambition to consider broader restrictions, through both grouping of substances, and addressing a wider range of uses (industrial, professional, consumer uses and uses in articles).

The overall efficiency and transparency of the process leading to the adoption of the restriction:

- Low: the process takes longer than a year after the legal deadlines stated above have expired and is not transparent.²⁵
- Medium: the process takes between 6 months to a year beyond the legal deadlines and provides little transparency.
- High: the restriction is processed within the legal timeline or three months after, and provides sufficient transparency to all stakeholders involved.

The overall expected effectiveness to tackle the risk

- Low: the restriction includes few chemicals from the group targeted and/or excludes too many important uses (e.g. high volumes, consumer uses).
- Medium: the restriction is overall fit for purpose but may have limited impact, for example due to problematic derogations or if the chemical use is marginal.
- High: the group of hazardous chemicals is banned for all uses and only a few well-justified derogations apply.

²⁵ The restriction process and its timeline are described in detail here: <u>Restriction process - ECHA (europa.eu)</u>

Subject of restriction	Chemical background information	Scope of the restriction	Overall efficiency and transparency of process	Overall expected effectiveness to tackle
PFAS in fire-fighting foams Submitted by ECHA	PFAS is a group of around 5,000 substanc- es also known as 'forev- er chemicals'. They are indeed highly persistent, which means they accu- mulate and remain in the environment and human body. These chemicals are being used across sectors in a wide range of products including consumer articles, such as water-repellent clothing, food contact materials, fire-fighting foams and cookware. For many years civilian and military airports and other govern- mental facilities have used PFAS-containing fire fighting foams to extinguish big fires quickly. This widespread use has contributed to drinking water con- tamination and is also linked to occupational cancer in firefighters. Fluorine-free foams are increasingly used.	The proposal is to ban the use of all PFAS from fire-fighting foams.	MEDIUM Process status: The ECHA opinion de- velopment is ongoing. The proposal was sub- mitted in March 2022. One year later, the process at ECHA is still ongoing, meaning that the agency breached its deadline to formulate an opinion within 12 months.	MEDIUM The ban solely focuses on the specific use of PFAS in fire-fighting foams. The PFAS chemi- cals are used in a greater variety of products. Other issues with the current proposal include lengthy transition peri- ods (e.g. five years for portable fire extinguish- ers), and excessively broad derogations (e.g. for fire fighting foams for use at high risk Seveso plants). There is finally an overlap with the PFHxA restriction, which also covers the use of some PFAS in fire fighting foams, and is currently awaiting a decision by the Com- mission. The PFHxA proposal provided for stronger provisions than the current proposal, e.g. by not considering a derogation for Seveso establishments. It is unclear how this overlap and the apparent lack of scientific consistency in the ECHA commit- tees' opinions will be addressed.
N,N-dimeth- ylacetamide (DMAC) and 1-ethylpyr- rolidin-2-one (NEP) Submitted by the Nether- lands	DMAC and NEP are used as solvents in the production of agrochem- icals, pharmaceuticals and other chemicals. They are classified as toxic to reproduction, with the risk of damag- ing the unborn child. The industrial and profes- sional use of DMAC and NEP is considered to pose a health concern in particular for workers.	The main restriction proposal is not a ban but the implementation of a derived no-effect level (DNEL), i.e. a level of exposure to a substance above which humans should not be exposed.	HIGH Process status: The proposal was submitted in April 2022 and is undergoing ECHA assessment. A slight delay at ECHA can be expected.	LOW The introduction of a DNEL means the prob- lematic chemicals are not banned. They will continue to be produced, with the risk of unjust worker exposure. It plac- es the responsibility on the manufacturers to im- plement additional risk management measures to make sure the DNEL is respected and the dermal exposure and associated risks reduced. This type of restriction flaws the system as highly hazardous chem- icals used in industrial sites should follow the authorisation route.

²⁶ For more information see the European Environment Agency briefing on Emerging chemical risks in Europe – PFAS.

²⁷ https://www.iaff.org/pfas/

²⁸ IPEN_F3_Position_Paper_POPRC-14_12September2018d.pdf.

 $^{29} \ \text{See for more information: } \underline{\text{https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas.}}$

Subject of restriction	Chemical background information	Scope of the restriction	Overall efficiency and transparency of process	Overall expected effectiveness to tackle the risk
Medium-chain chlorinated paraffins (MC- CPs) and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17 Submitted by ECHA	MCCPs are part of a group of chemicals known as chloroal- kanes which are widely produced globally. Around 55 000 tonnes of the medium-chain chloroalkanes are used annually in the EU, mostly as plasticisers and flame retardants in a variety of industrial and consumer products including PVC, paints, adhesives and sealants and rubber. ³⁰ They are Substances of Very High Concern under REACH for their persistent, bio- accumulative and toxic properties (PBT), and very persistent and very bioaccumulative (vPvB). Pollution is now so widespread that MCCPs are found in the most remote locations, such as Antarctica. In parallel, they are proposed for listing in the Annexes to the Stockholm Con- vention on Persistent Organic Pollutants (POPs). ³¹	69 substances as part of the MCCP group with PBT/vPvB properties are included in the restric- tion proposal. This list is not exhaustive.	Unclear Process status: The proposal was submitted in September 2022. ECHA opinion development is ongoing. There have been no delays so far.	HIGH Several restriction options are being proposed. Restriction Option 1 is a ban on the manufacture and placing of the market of the identified MCCPs without derogation, which could prove effective to manage the risk. However, other re- striction options include transitional or perma- nent derogations for the metalworking sector that may significantly reduce its effectiveness.
Polycyclic aromatic hydrocarbons (PAHs) in clay rifle shooting targets Submitted by ECHA	PAHs are a large group of organic compounds, found in nature or manmade. They are very toxic and very persistent. Many may also cause cancer. ³² They are nota- bly used to produce clay targets. Currently, some 400 million clay targets are sold in Europe annu- ally, where many end up scattered in the environ- ment. ECHA estimated that 270 tonnes per year of 18 indicator PAHs are emitted to the EU environment per year through this use.	The proposal is to ban 18 PAHs in clay targets.	MEDIUM Process status: ECHA published its opinion on 2 December 2022. The Commis- sion proposal should have been proposed early March, but is still awaited.	MEDIUM This restriction proposal follows the rejection of two authorisation ap- plications submitted by companies for using coal tar pitches containing PAHs to manufacture clay targets. Coal tar pitch is indeed banned in the EU due to its car- cinogenic and persistent properties. The current restriction aims to avoid regrettable substitutions as some alternatives may also contain PAHs and also avoid imports of targets containing these PAH. We consider the effectiveness limited due to its limited scope, as clay targets are not a major source of PAH emissions to the envi- ronment.

³⁰ See <u>Annex XV Dossier</u> proposing the restriction of MCCPs and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17. ³¹ See: <u>POPRC.17 Press Release (brsmeas.org)</u>

³² Human health effects of polycyclic aromatic hydrocarbons as ambient air pollutants - Report of the Working Group on Polycyclic Aromatic Hydrocarbons of the Joint Task Force on the Health Aspects of Air Pollution (who.int).

Subject of restriction	Chemical background information	Scope of the restriction	Overall efficiency and transparency of process	Overall expected effectiveness to tackle the risk
Lead in am- munition and fishing tackle Submitted by ECHA before the Restric- tions Road- map.	The hazardous proper- ties of lead, in particular its toxicity for reproduc- tion and neurotoxicity, are well documented. ³⁴ A substantial body of data also suggests that lead could be an endo- crine disruptor. ³⁵ In par- ticular, there is evidence that massive lead (as used in lead ammunition and fishing tackle) 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). ³⁶ Approximately 44 000 tonnes of lead are dis- persed in the environ- ment every year: 57 % from sports shooting, 32 % from hunting and the rest from fishing activi- ties. 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 fish- ing sinkers and lures.	The proposal is to ban all lead ammunition for firearms and airguns, as well as fishing sinkers and lures for outdoor activities.	LOW Process status: It took two years for ECHA Committees to formulate their opinion on this restriction, dou- ble the legal deadline. The Commission's draft decision was delayed so far of one month as the legal deadline was 2nd of March 2023.	MEDIUM Albeit limited in its scope - focused on a very specific use of lead in ammunition - the proposal covers the main emissions from hunting and fishing and, if adopted as such, the restriction is expected to meet its primary objective. The main concern lies on the derogation pro- posed for licenced sport shooters and for sport shooters and for sport shooters and for sport shooters difficult to enforce. Additionally it would allow significant emis- sions from ranges. The delays in the de- cision making process are also delaying the implementation of a ban that would stop further bird poisoning.
Lead compounds in PVC Submitted by ECHA before the Restriction Roadmap.	The hazardous proper- ties of lead, in particular its toxicity for reproduc- tion and neurotocity, are well documented. ³⁷ A large use of lead is as a heat stabiliser in polyvinyl chloride (PVC), a widely produced syn- thetic plastic.	Restriction of lead compounds used as sta- bilisers in PVC articles in concentrations equal to or greater than 0.1 % weight for weight (w/w) with a 15-year deroga- tion for certain building and construction articles made from recycled PVC (with a higher restriction limit of 1 % w/w)	LOW Process status: Restric- tion adopted. The proposal was submitted in December 2016 and the ECHA procedure ended by April 2018, over a year beyond the legal limit. The Commission decision of 2019 was finally objected to by the European Parliament in 2020. ³⁸ The Commission adopt- ed a revised decision in June 2022, more than 6 years after the process was initiated.	MEDIUM The intention was to limit the presence of lead in PVC, in particular in imported construction materials as the Europe- an industry does not use lead as stabiliser in PVC any more. However, the derogations that allow recycled PVC containing higher lead concentra- tions reduces the effec- tiveness of the proposal and allows this toxic chemical to be recircu- lated into households.

³³ Coal tar pitch, high temperature (CTPHT) was included in Annex XIV of REACH due to its carcinogenic, persistent, bioaccumulative and toxic (PBT), and very persistent and very bioaccumulative (vPvB) properties (Commission Regulation (EU) No 2017/999). These properties are due to the presence of polycyclic aromatic hydrocarbons (PAHs) in the substance.

³⁴ Substance Information - ECHA (europa.eu)

³⁵ Dyer. (2007.) "Heavy Metals as Endocrine-Disrupting Chemicals." In Endocrine-Disrupting Chemicals,111-33. Contemporary Endocrinology. Humana Press. doi:10.1007/1-59745-107-X_5.

³⁶ Effects of lead from ammunition on birds and other wildlife: A review and update - PMC (nih.gov).

37 Substance Information - ECHA (europa.eu)

³⁸ Parliament objects to lead in PVC to protect public health and the environment | News | European Parliament (europa.eu).

Subject of restriction	Chemical background information	Scope of the restriction	Overall efficiency and transparency of process	Overall expected effectiveness to tackle the risk
Dechlorane Plus Submitted by Norway.	Dechlorane Plus is a flame retardant that has been mostly used in motor vehicles since the 1960s. This chemical is suspected to provoke oxidative damage, neurodevelopmental toxicity and endocrine disruption, but it is also known to adversely impact biodiversity. The chemical is currently under assessment by the POPs Convention Committee.	Complete ban	MEDIUM Process status: The ECHA opinion on the proposal was made public in September 2022. A Commission proposal is still awaited, 4 months after the legal deadline.	MEDIUM The restriction has an all encompassing scope that would make it effective in dealing with the risk posed by De- chlorane Plus. However, it is not produced in the EEA therefore it will impact mainly imports. As it is a widely dis- persed global pollutant, it might be better left to the international POPs committee.
PFAS (universal) Submitted jointly by Germany, the Netherlands, Sweden, Norway and Denmark.	See row 2.	The proposal is to ban the manufacture, placing in the market and use of all PFAS under REACH. This excludes those used as active substanc- es in pesticides, biocides and pharma/veterinary products. Various restriction options are being proposed.	Unclear Process status: A restriction proposal was submitted to ECHA on 7 February 2023 19 months after its noti- fication to the registry of intention - i.e. with a delay of seven months. It is now undergoing evaluation by the RAC and SEAC. It is expected to be a very long and arduous process looking at the complexity of the file and the number of interested stakeholders.	 HIGH The proposal covers as principle most PFAS from the PFAS group with a few exemptions. It bans the manufacture, import and use, meaning that PFAS cannot be imported, exported, or hoarded. However, a flurry of 25 derogations for either 5 or 12 years after the end of the general transition period are proposed. There are no time-unlimited derogations, expressing hope that innovation will come up with alternatives when there is time pressure. In a novel way, the dossier submitters also mention 20 "square bracket" derogations, i.e. derogations that could be considered if evidence justifying their need is made available. Also, transparency is improved compared to other restrictions as users of derogations are asked to submit annually information on uses and quantities to ECHA. This way, progress in implementing alternatives can be monitored and emissions can be estimated.

Subject of restriction	Chemical background information	Scope of the restriction	Overall efficiency and transparency of process	Overall expected effectiveness to tackle the risk
Dinitrotoluene (2,4-DNT) Submitted by ECHA (Art. 69.2 proce- dure).	2,4-dinitrotoluene is a known human carcino- gen. Banned in the EU in 2015, it is still found in consumer products including vehicles, ceramics and plastic bottles used in industrial settings.	The restriction proposal targets the placing on the market or use of 2,4 dinitrotoluene in articles for the general public or to professional workers in concentrations greater than 0.1 % weight by weight.	MEDIUM Process status: The ECHA opinion was made available in Janu- ary 2023, however with a delay of four months following the finalisation of its opinion. According to the legal timeline, the Commission should present a proposal in April 2023.	MEDIUM The risk posed by dinitrotoluene is limited, notably because its overall use is in decline in the EU. Only three EU companies have been reported as importing 2,4-DNT, for two of them in quite low vol- umes. Moreover, several uses are exempted from the proposed restric- tion. ³⁹
BPA and relat- ed bisphenols of similar concern Submitted by Germany.	Bisphenols are a group of 200 substances, many of which have been extensively studied and are known to be endocrine disruptors to humans and wildlife. Bisphenols are widely used in the EU, notably to make plastics. More than one and a half mil- lion tonnes of Bisphenol A per year is imported or manufactured in the EU for diverse uses, ranging from the automotive and aviation industries to construction, textiles, paper and consumer goods.1,242,000 tonnes are used to produce polycarbonates and 275 000 tonnes are used to manufacture epoxy resins. Other uses add up to 25 000 tonnes.	The proposal is to ban the use of five bisphe- nols that are already classified as endocrine disrupting for the envi- ronment.	HIGH Process status: The restriction proposal was submitted to ECHA in November 2022. It is now undergoing ECHA assessment in line with the legal timeline.	LOW The scope is very nar- row: only five chemicals, compared to the number of bisphenols of concern on the EU market (148 substances). ECHA has identified that 34 bisphenols have individ- ually sufficient informa- tion to be restricted, but the proposal covers only five (BPA, BPB, BPS, BPF and BPAF). In addition, the propos- al exempts the main uses of BPA, this is the production of polymers and resins like polycar- bonate and epoxy resins. Therefore, the vast majority of bisphenols' volume would remain untouched, and people and the environment will remain exposed during production, use and waste management. The proposal focuses on evironmental con- cerns. If the impacts on human health were also considered, derogations for polymers and resins would be more difficult to justify.
Terphenyl Submitted by Italy	Terphenyl is persistent, bioaccumulative and toxic (PBT), <u>classified</u> as a Substance of Very High Concern in 2018. It is not manufactured in the EU but is imported. 90% by weight is used as a high-temperature heat transfer fluid.	The proposal is to restrict the use of terphenyl hydrogenated except when used as heat transfer fluid or as a plasticiser applications for the production of aircrafts and their spare parts.	HIGH Process status: The dossier was submit- ted in April 2022. It is now following the nor- mal ECHA procedure.	LOW The scope of the re- striction is very limited, excluding the main use as a heat transfer fluid, as well as for the use responsible for the most emissions (plasticiser). The choice of the restric- tion route is moreover questionable as ECHA already recommend- ed in 2021 to ban the substance in all uses by placing it on the Authorisation List. ⁴⁰

³⁹ See RAC and SEAC final opinion: 4447b8da-cdd7-098f-449a-9b81129412b5 (europa.eu)

⁴⁰ See ECHA 10th recommendation - <u>Recommendations for inclusion in the Authorisation List - ECHA (europa.eu)</u>...

Subject of restriction	Chemical background information	Scope of the restriction	Overall efficiency and transparency of process	Overall expected effectiveness to tackle the risk
Substances unintentionally present in sin- gle-use baby diapers Submitted by France	Extremely hazardous substances such PAHs, furans, dioxins, formal- dehyde and polychlori- nated biphenyls (PCBs) have been <u>found</u> by French officials in con- sumer products, includ- ing baby diapers made by large well-known brands across Europe. Some are classified as carcinogenic and/or genotoxic.	The proposal is a ban on the placing on the EU market of a list of sub- stances ⁴¹ in single-use diapers for children under 3 years old.	MEDIUM Process status: The re- striction was withdrawn. The restriction propos- al was submitted in December 2020. ECHA published an opinion in December 2021. The Commission eventually rejected the restriction in December 2022, after a delay spanning three times the legal limit.	LOW The Commission stated that it abandoned the restriction because con- sumer risk is uncertain. These hazardous sub- stances are still found at levels where health risks cannot be ruled out, according to ECHA's risk committee RAC. ⁴²
PFHxA Submitted by Germany.	PFHxA is part of the PFAS group. It has a very high persistence, its emissions lead to an in- creasing pollution stock in the environment. The substance is also mobile and has surface active properties that cause contamination of groundwater, surface waters and the marine environment on a wide geographical scale. Fur- thermore, its removal, e.g., from contaminated drinking water and soil is currently not feasible. Exposure of humans takes place mainly via drinking water and food, including infants via breast milk. Ani- mal studies show that PFHxA may impact the development, hormone system and reproduc- tion.	Manufacture, placing on the market and using PFHxA and related substances.	LOW Process status: The restriction propos- al was submitted in December 2019. ECHA breached its assessment deadline by a whole year. Since December 2021 the proposal has been sitting on the desk of the Commis- sion, breaching its legal deadline by 3 months. There is no transparency on when a proposal will be published.	MEDIUM The scope of the pro- posal covers the main uses of PFHxA. RAC and SEAC provided an opinion supporting the restriction. However long delays suggest the Commission might wait for the restriction of PFAS in FFF proposed by ECHA, which is less protective than PFHxA proposal, and wait for the universal PFAS restriction on other uses, so all derogations can be renegotiated.
Creosote and related sub- stances. Submitted by France	Creosote is a proven carcinogen and PBT reg- ulated used to preserve wood from insects and fungi. It is in particular used to treat railway sleepers, telephone and electricity posts, fences and enclosures.	The restriction propos- al targets the reuse and second-hand use of wood treated with creosote and related substances that are authorised under the Biocidal Products Reg- ulation.	HIGH Process status: The proposal was submitted in December 2022. The proposal is being assessed by ECHA.	MEDIUM This restriction is meant to complement existing bans on the use of creo- sote under the Biocidal Product Regulation ⁴³ and harmonise practices across Europe. Many countries indeed already have strict measures or bans in place for the reuse of creosote. The current restriction is therefore not expect- ed to tackle a major pollution issue as the exposure to creosote is very limited, but rather to fill in gaps.

⁴¹ The list includes polycyclic aromatic hydrocarbons (PAHs), polychlorodibenzo-p-dioxins (dioxins or PCDDs), polychlorodibenzofurans (furans or PCDFs), polychlorobiphenyls (PCBs) and formaldehyde. See <u>Annex XV report</u> for more details.

⁴² See <u>RAC Opinion</u>.

43 EUR-Lex - 32022R1950 - EN - EUR-Lex (europa.eu).

B.) Diving in in two restriction case studies

Bisphenols and PFAS are among the most widely studied chemicals worldwide and have long been targeted for regulation, even if only partially (bans of bisphenol A in till receipts and some PFAS not used any more in the EU such as PFOA or PFOS are in force). Their impacts on health and the environment are well studied and increasingly understood by the general public, but so far EU regulatory measures have failed to provide a coherent and effective policy response. The roadmap announcement of group restrictions for both chemical families constituted a long-awaited opportunity to deliver effective regulation.

The Bisphenols restriction

The Restrictions Roadmap announced a group restriction of "4'-isopropylidenediphenol (bisphenol A) and structurally related bisphenols (including derivatives) of similar concern for the environment" based on endocrine disruption⁴⁴ "for the environment".

Bisphenols are a big family of chemicals that are mainly used to produce polycarbonate plastics and resins. They can be found in

a wide range of products available to the consumer. Within the group, Bisphenol A has received particular regulatory attention as it is one of the most widely studied chemicals, produced over 1 million tonnes per year in the EU, and proven to severely interfere with the hormonal and reproductive systems of humans and wildlife.⁴⁵ Endocrine-disrupting properties throughout a broad range of bisphenols have long been described in the academic literature.⁴⁶ In the EU it is considered a Substance of Very High Concern and has been banned so far in only two products, thermal paper and baby bottles.⁴⁷ Although concern over the hazards of bisphenols goes beyond BPA, reports have long warned of the possibility of regrettable substitution within that chemical group, a risk increased by the piecemeal approach to chemical regulation that has applied up to now.48 While the regulatory measures in place target some of the risk posed by a few bisphenols, such as Bisphenol A and B, most of that risk remains unaddressed (see Figure 1). ECHA recently confirmed the need to restrict 34 of the 148 bisphenols already known to be hazardous⁴⁹ while EFSA has lowered the existing tolerable daily intake of BPA by four orders of magnitude.⁵⁰

⁴⁴ ED stands for "Endocrine disruption".

⁴⁵ Endocrine-disrupting chemicals can affect reproduction not only in humans but also in other species and organisms, see for example: Marlatt, V. L., Bayen, S., Castaneda-Cortès, D., Delbès, G., Grigorova, P., Langlois, V. S., Martyniuk, C. J., Metcalfe, C. D., Parent, L., Rwigemera, A., Thomson, P., & Van Der Kraak, G. (2022). Impacts of endocrine disrupting chemicals on reproduction in wildlife and humans. Environmental Research, 208, 112584.

⁴⁶ As an example, S. Kitamura et al. (2005), Toxicological Sciences, 84 (2), 249–259 is such a meta-study. Its publication date shows that endocrine effects were described and recognised long before Art. 57 of REACH became effective.

⁴⁷ Bisphenols - ECHA (europa.eu).

⁴⁸ Why a group restriction of the bisphenols is long overdue (chemtrust.org).

⁴⁹ <u>1bd5525c-432c-495d-9dab-d7806bf34312 (europa.eu).</u>

⁵⁰ <u>https://www.efsa.europa.eu/en/news/bisphenol-efsa-draft-opinion-proposes-lowering-tolerable-daily-intake#</u>

FIGURE 1

Regulatory overview for Bisphenols



Partially restricted

(in thermal paper, material in contact with food and baby bottles)

The proposal of a group restriction for all bisphenols brought by Germany⁵¹ on 7 October 2022 was therefore long overdue. But the current proposal pales in comparison to the problem it seeks to address (see Figure 1):

- The proposed restriction only covers bisphenols identified as endocrine disrupting to the environment, neglecting those known to impact human health.
- The proposal includes only the bisphenols officially considered as endocrine disruptors, dismissing the evidence that supports that all bisphenols may have similar impacts. The roadmap promised to restrict all bisphenols, while the proposal targets just 5 individual substances (BPA, BPB, BPS, BPAF, BPF). Given the length of the current regulatory processes, it might take decades before other bisphenols join the group restriction.
- The proposal focuses on the use of bisphenols, which means the problematic emissions of bisphenols to the environment, during the manufacture and waste stage are also ignored. For

many bisphenols, the restriction proposal emphasises that pollution during use cannot be estimated. What is clear is that the use of bisphenols of similar concern to BPA "is going to increase as substitution of BPA is increasing" and thus "their concentration in environmental compartments and biota is almost certainly going to increase as well".⁵²

- Uses of bisphenols will not be banned if it can be proved that releases of BPA from materials and articles containing it (migration) is under a certain level. It is assumed that the manufacture and use of bisphenols is not per se a problem but that emissions can be controlled. This is at odds with the scientific assumption that bisphenols are non-threshold chemicals⁵³ and therefore, no level of exposure can be considered to be safe.
- To an already extremely narrow scope in terms of chemicals included, the proposal as it stands may have the effect of derogating 98% of their uses, namely polycarbonates and resins.

⁵¹ Annex XV proposal: <u>450ca46b-493f-fd0c-afec-c3aea39de487 (europa.eu)</u>

⁵² ED stands for "Endocrine disruption".

⁵³ Endocrine-disrupting chemicals can affect reproduction not only in humans but also in other species and organisms, see for example: Marlatt, V. L., Bayen, S., Castaneda-Cortès, D., Delbès, G., Grigorova, P., Langlois, V. S., Martyniuk, C. J., Metcalfe, C. D., Parent, L., Rwigemera, A., Thomson, P., & Van Der Kraak, G. (2022). Impacts of endocrine disrupting chemicals on reproduction in wildlife and humans. Environmental Research, 208, 112584.

FIGURE 2

Scope of the restriction proposal



Leather products

- Ca. 10% of bisphenols with ED
- Part of volumes consumed in EU
 - BPA > 1 million t/a
 - BPB < 10 t/a
 - BPS > 10 000 t/a

The restriction in its current state is likely to have little effect on bisphenol pollution.⁵⁴ The cost effectiveness of this process in a context of limited public resources is also doubtful the Commission having already established that it might propose another restriction for bisphenols covering the human health concern angle.⁵⁵

The PFAS restrictions

PFAS are currently gaining visibility thanks to media attention on many unfortunate pollution cases affecting humans and the environment.⁵⁶

PFAS are a special class of chemicals because of the chemical bond between a carbon atom and a fluorine atom, which is both extremely stable and unknown to the natural world. For these reasons, PFAS tend not to be degraded at any time scale relevant to humans - hence their nickname forever chemicals. Thousands of PFAS have been identified and listed; however, "only" several hundreds of them are of major industrial importance.

PFAS were first developed eighty years ago, and the nefarious effects of some of them have been recognised for half a century now. Producers of PFOS and PFOA, the two oldest, most emblematic and problematic PFAS, gradually replaced them with other PFAS over the last two decades. Ironically, regulation of PFOS and PFOA mostly followed a voluntary phase-out, rather than law triggering it: the Stockholm Convention added PFOS (and its manifold derivatives) to annex B "restriction" in 2009. REACH restricted PFOA (and derivatives) in 2017, to become effective in 2020 - this ban was quickly replaced by an international ban under the Stockholm convention for a full ban as of February 2023, at last. More recently, the Stockholm Convention has also put a ban on PFHxS and its derivatives, the industrially less relevant "little brothers" of PFOS - i.e. a PFAS with six instead of eight fully fluorinated carbon atoms in the chain. REACH, finally, restricted the use of a few niche PFAS in spray applications and banned the (largely defunct) C9-C14 carboxylic PFAS, i.e. the even longer versions of PFOA, whereas the market had moved towards the shorter PFAS such as PFHxA also called "C6".

In other words, until the present date, REACH has not acted effectively on any major current use of PFAS yet. It was preferred to keep authorities and stakeholders busy banning mostly phased out chemicals - like outlawing steam engines and typewriters.

More recently, three restrictions on PFAS in current use have been proposed:

- On PFHxA and related substances, "the C6 restriction"
- On PFAS in fire-fighting foam, "the foams restriction"
- On all PFAS, "the universal restriction".

This necessary and promising improvement has, regrettably, been plagued by overlaps, re-evaluations, dithering and delaying.

⁵⁴ See <u>NGO contribution</u> to the public consultation on the Annex XV Dossier.

⁵⁵ See Restrictions Roadmap, Pool 1.

⁵⁶ <u>'Forever pollution': Explore the map of Europe's PFAS contamination (lemonde.fr).</u>

FIGURE 3



As shown in figure 3 (blue area), essentially all PFAS foams in use, and certainly all PFAS currently sold, are of the C6 type. The scientific committees' opinion on the PFHxA restriction, adopted in 2021, proposes clear action. Nevertheless, ECHA started a procedure for a separate ban of "all PFAS" in fire-fighting foams, with all re-evaluations and re-negotiations leading to substantial weakening.

The PFHxA restriction, on its own, has been plagued by delays: despite a relatively fast opinion adoption, it took ECHA five months to publish the text after its committees had agreed on the opinions. Worse, the Commission still has not prepared the legal text based on the ECHA committees' opinion despite a legal deadline of three months.

Overlaps and re-evaluations also risk delaying, or derailing, parts of the new 'universal' PFAS restriction that was proposed by five Member States in February. This restriction is supposed to ban the remaining uses of PFAS, with some exemptions and transition times, and the proposal guarantees that no earlier decisions will be weakened. However, as long as the C6 restriction is not a decision yet, those affected by the PFHxA opinion can still hope for a renegotiation that will be more favourable to them. For sure, they will not rely on hope alone.

The early stages of universal PFAS restriction have shown a solid, clear and well-researched dossier. Its focus on persistence means that all PFAS are covered, including fluorinated gases and fluoropolymers. This broad scope of course means that an analysis of a very large and diverse number of applications have been assessed technically and for economic impacts of the ban. Likewise, the dossier contains a high number of exemptions with transition times of six or twelve years.

Overall, regulatory action on PFAS under REACH has mostly focussed on banning niche substances or doomed substances. Successful regulatory action on relevant substances for current production and use is still in the realm of the future. Good proposals generally do not exit the opinion- and decision-making process unscathed.



2. Finding: too little ambition across the board

In this second part, we build on the evidence from the first section's table and two case studies to assess the achievement of the three objectives of the roadmap so far.

OBJECTIVE 1: The Restrictions Roadmap enables effective and efficient management of the risk posed by the most hazardous groups of substances.

The table and case studies above showed that the effectiveness of the restrictions to tackle the risks is, overall, expected to be low. The lack of efficient processes contributes to typically slow restrictions. Legal deadlines are almost always breached. A series of shortcomings have been identified.

Limited grouping

Most restriction proposals largely fail to grasp the tremendous opportunity of restricting through wide grouping by only including a few substances from the problematic chemical group. Out of the 14 ongoing restrictions, 12 focus on a small fraction of the substance group (e.g., only five bisphenols from the broad bisphenols group including 148 chemicals with most uses of controversial BPA set to continue); do not consider a ban (DMAC and NEP); or cover the substance in a specific use only (e.g., lead 'in ammunition', lead 'in PVC', PAHs 'in clay targets'). The universal PFAS proposal is the only promising ban in this regard. Some of these restrictions were initiated before the publication of the roadmap and the implementation of the grouping approach. However, for many, the narrow scope could have been corrected as part of the ECHA process or by the Commission who has broad discretion when it comes to the adoption of final restrictive measures.⁵⁷

Narrowly defined restrictions clearly leave a majority of pollution impacts unregulated. Such piecemeal regulation also increases headaches for governments, industry and the general public by increasing the complexity of the legal landscape. It also perpetuates the widespread abuse of regrettable substitution by industry, where one banned chemical is easily swapped for one of the many other unregulated substances from the same chemical family that is often just as harmful.

Use of exemptions is the norm

The Chemicals Strategy pledged that "all uses" of target chemical groups should be restricted - unless proven essential for society.⁵⁸ To fulfil that objective, the roadmap commits to address a wider range of uses - industrial, professional, consumer uses and uses in articles (products). Unfortunately most of the restriction proposals that fol-

⁵⁷ Article 73 REACH states that the Commission final restriction decision may diverge from the initial proposal or from the ECHA opinion, as long as it is explained why.
⁵⁸ Chemicals Strategy for Sustainability, p. 10.

lowed contain major derogations, including for non-critical uses, meaning that significant volumes will remain in use and/or polluting the environment. This has therefore effectively emptied the roadmap of its ambition for Pool 0 substances by removing most of its scope. A notable case is terphenyl⁵⁹, for which both the main use by volume and by emissions will continue unregulated. In many cases, information gaps are wrongly used to justify exemptions, such as the free pass proposed to be given to PFAS fire fighting foams at Seveso plants. ECHA in its restriction proposal for MCCPs highlighted the lack of cooperation of various industrial sectors concerned by the ban, while rewarding this behaviour by the metalworking sector by considering a regulatory exemption.60

Since the objective is to ban most harmful substances across sectors, exceptions should be rare, i.e., for well justified critical uses for which there are no alternatives.⁶¹ This is not what has happened so far, as the table above shows. Part of the problem stems from a chronic lack of information shared by industry, which often withholds data that is essential for regulatory action, leaving authorities with the heavy burden of proving their case. But also, the leniency of the ECHA evaluation towards industry requests has led the committees, and in particular SEAC, to support non properly justified derogations.

Unjustified transitional periods

Officials regularly gift industry with transitional periods before bans become effective, regulatory holidays that are not always justified, or are way too long when alternatives are known to exist, turning them into quasi exemptions. For example, the use of PFAS in portable extinguishers gets a 5-year transition time under the fire-fighting foams proposal, despite alternatives already in use. The lead in ammunition restriction proposal also includes a transition period of 5 years for the use of lead shot in hunting although non toxic shot is available on the market.⁶²

Regulatory delays

Several restrictions have been blocked for years as they sat gathering dust at ECHA and/or the European Commission, such as protections against lead and PFHxA. Previous restriction proposals, not mentioned in the roadmap, have been similarly waiting for a decision by the Commissions for years, including, for example, the restriction of skin sensitising substances (sitting at the Commission's desk already fo two and a half years), D4-D5-D6 which are highly persistent and bioaccumulative chemicals (three years delay by the Commission), the use of calcium cyanamide in fertilisers (two and a half years delay by the Commission). The restriction of intentionally-added microplastics has been discussed for more than a year now by the Commission and Member States - meanwhile 42,000 tonnes of microplastics (intentionally used) continue to wash into rivers and seas. These delays, arguably not driven by the intention to make the most protective risk management rules possible, are not only illegal, but of course allow serious pollution to continue.

⁵⁹ Annex XV Report for terphenyl, hydrogenated - c0cb9178-9bc7-b4f3-1c25-0fda75b81fb1 (europa.eu).

⁶⁰ See <u>Annex XV Dossier</u> for a restriction MCCPs, p. 97.

⁶¹ See ClientEarth <u>Demand 4</u> for the REACH Reform: A coherent approach to continuous use of the most harmful substances.

⁶² <u>Annex XV Dossier</u> for lead in ammunition, p. 10.

OBJECTIVE 2: The Restrictions Roadmap provides visibility on the use of authority resources.

The Restrictions Roadmap provides transparency on the prioritisation of chemical phase-outs, and therefore how authorities' resources are to be spent. It is however unclear whether that visibility can in turn support more appropriate and efficient management of those resources.

First, a considerable amount of resources are spent on restrictions which have either of very limited scope compared to the initial objective (e.g. lead in PVC) or have limited impact. The lead in ammunition restriction followed a former restriction adopted in 2021 that only banned the use of this ammunition in wetlands. Dechlorane Plus, for example, is not produced in the EU any longer and will be subject to international measures. Bisphenols are another striking example of poor management of public resources. The Commission is already considering another bisphenol restriction covering the human health impacts, doubling the work and resources that could have been allocated to a single file.

Second, the roadmap does not address nor alleviate the particularly high burden of dossier preparation and evaluation, which mostly falls on ECHA and Member States. The restriction proposal's preparation involves compiling, analysing and presenting information on emissions, uses and risk associated with a particular substance group use in a structured dossier ('Annex XV report'). It is known to be incredibly resource intensive and challenging for authorities, especially as the data they rely on is usually withheld by industry. The current roadmap shows that only a few large states (e.g. France, Germany) propose restrictions, while those with fewer resources seem unable to initiate the process. The next step of ECHA scrutiny is also resource intensive. It is made particularly burdensome when large numbers of industries contribute to the process as they tend to flood the RAC and SEAC with derogation requests and, sometimes, contradictory information.

OBJECTIVE 3: The Restrictions Roadmap provides transparency to the various stakeholders.

The Roadmap undoubtedly provides clarity on the different proposals in the regulatory pipeline, the authorities involved and, in some cases, the expected date of submission of the restriction proposal to ECHA, which is only informative if upheld.

However, important information is missing for various stakeholders, in particular companies trying to develop safer chemicals, making it harder for them to anticipate and provide authorities information on alternatives.

Notable information missing is:

- The expected year of entry into force of the restriction, which would indicate when obligations start applying;
- Any foreseen delays, during the ECHA procedure, or the political decision process once the restriction is in the hands of the Commission. For most dossiers, the Commission has failed its threemonth legal deadline.
- The scope of the proposal. The roadmap merely states if the ban is a "group" restriction or the number of substances to be restricted, without further indication. This makes it difficult for stakeholders to anticipate what the scope of a restriction will look like in practice.



Conclusion: let's get the real detox started.

The Restrictions Roadmap does part of its job well. It provides a clear list of the chemical bans that will be scrutinised in the coming months and years in the EU. In that sense it allows visibility on the use of public resources (objective 2) and regulatory priorities (objective 3), even if full transparency of the different processes may be improved.

What is most preoccupying is that the roadmap fails to fully meet its first objective, which is to support the elimination of the most harmful groups of chemicals. Albeit making clear that some of the most hazardous groups are under consideration, including bisphenols, PFAS, phthalates, and flame retardants, our report shows that most of these substances are likely to continue to be manufactured and used in the EU, to the detriment of our health and that of ecosystems, our economy and the broader state of the environment.

The current legal framework in fact enables nearly all types of bans, but the implementation practice by the Commission and ECHA makes it very hard in practice. The burden of providing information on uses and emissions of hazardous chemicals is put on authorities instead of companies; derogations are granted even when information that justifies their need is missing; uncertain risks are treated as acceptable; and the Commission can stall the process for years with no consequence.

These amount to significant breaches of the REACH text.⁶³ Until the revision of REACH,

that is expected to ease regulatory processes⁶⁴, policy makers need to radically upgrade their ambition in line with existing REACH provisions and political commitments.

As highlighted in this report, beyond the REACH text, there are factors that significantly slow down the implementation of the Chemicals Strategy for Sustainability:

- The burden on authorities to present a perfect restriction proposal not prescribed by REACH and contrary to its underpinning precautionary principle⁶⁵
 is extremely high in practice, and inappropriate, considering the general lack of public information on uses of chemicals. This does not encourage dossier submitters to propose broad bans, because it might be hard for them to justify based on the available information.
- In the context of scientific uncertainties, ECHA is both strict with the dossier submitter when information is missing, and lenient towards industry requests for derogations. At the end of the process, the strongest restrictions end up with a thin skin.

⁶³ In particular Article 1 which sets that REACH provisions are underpinned by the need to ensure a high level of environmental and health protection, the precautionary principle, the prevention of harm and the burden of proof put on industry. Articles 68.1 and 73 also give broad discretion to the Commission to interpret the unacceptability of the risk, and the legal timelines are clarified in the Restriction chapter (Articles 68-73).

⁶⁴ See Demand #3 for REACH reform: A systemic approach to risk management by authorities | ClientEarth.

⁶⁵ Article 1(3) REACH.

- The Commission lacks political leadership: REACH gives the Commission the power to frame the final decision, which might involve not following the ECHA opinion or taking a precautionary approach when required by the circumstances. This never happens in practice, as shown by the chemicals in nappies' restriction example.
- The repeated and unexplained regulatory delays hinder urgent action against serious pollution for which there have been early warnings. These delays also call into question the suitability of the REACH processes to urgently address the huge environmental and health concerns posed by hazardous chemicals.

The Restrictions Roadmap is no trivial list it has the potential to be a strong guide and support to the CSS detoxification ambition. If not, there might be grave implications in terms of health and environmental damage unaddressed, and related costs for society.

Until the REACH revision happens, the current approach must be reviewed, and the bar of political ambition set high enough:

 Substances must be restricted by groups as a rule and derogations should be exceptional, case by case and upon strict proof that the derogated substances are not harmful.

- All uses of the most harmful substances must be banned unless they are critical uses lacking alternatives.
- The "unacceptable risk" must be assessed in the light of the precautionary principle. That means in the presence of uncertainties, the strictest measures should be considered out of precaution.
- The roadmap must showcase more precise timelines, in particular with a view to avoid unacceptable delays at the decision-making stage and to provide predictability on the time of entry into force. Authorities must also inform about the reasons for delays to legal deadlines.

Such an ambitious approach has already been applied to the universal PFAS restriction proposal and, if not weakened during the decision-making process, it might contribute to significantly reducing PFAS pollution. The Pool 1 restrictions, some of them already under investigation by ECHA such as PVC and its additives⁶⁶ and carcinogenic, mutagenic and toxic for reproduction (CMRs) chemicals in childcare products⁶⁷, are the next opportunity to expand this approach. It is time the real detox gets started.

⁶⁶ <u>a860fd87-4231-5ed4-157b-f6cda1ee5832 (europa.eu).</u>

⁶⁷ <u>ccdf4a10-dea1-68e3-5ce2-5c210e8cd74d (europa.eu).</u>



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