# THENEED FOR SPEED



WHY IT TAKES THE EU A DECADE TO CONTROL HARMFUL CHEMICALS AND HOW TO SECURE MORE RAPID PROTECTIONS

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## Introduction Quick guide to EU chemical regulations

Chemical pollution is a growing problem globally. Global chemicals sales <u>more</u> <u>than doubled</u> between 2000 and 2017, and are expected to double again <u>by</u> <u>2030</u> and <u>quadruple</u> by 2060.

By volume, three quarters of chemicals used in Europe are hazardous, a percentage largely unchanged since 2004. Once created, chemical pollution is hard to prevent or control. Impacts are not always direct or easy to identify, but daily exposure to a mix of toxic substances is linked to rising health, fertility, developmental threats, as well as the collapse of insect, bird and mammal populations. Chemicals with dangerous properties are ubiquitous in food, drinking water, products, our homes and workplaces. Some 700 industrial chemicals are found in humans today that were not present in our grandparents. Doctors describe babies as born "pre-polluted". Scientists say that chemical pollution has passed the safe limit for humanity.

The public is right to be concerned about this situation. Europe-wide official polling in 2020 showed that 84% of Europeans are worried about the impact of chemicals present in everyday products on their health and 90% are worried about their impact on the environment. The new, environmentally conscious generation of Europeans, no longer oblivious to the danger of climate change and the risks of chemicals to their health and nature, pin their hopes for better health and a cleaner environment on visionary political commitments. The European Union prides itself on having one of the world's strictest chemical control systems. Known as the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH) is its cornerstone legislation for the assessment and management of chemicals. This set of legislative procedures entered into force in 2007 was, in large measure, intended to simplify and speed up control of dangerous chemicals after decades of fragmented and highly ineffective regulations. While REACH deals with the assessment and management of industrial chemicals, the Classification, Labelling and Packaging of chemicals law (CLP) is responsible for identifying and communicating hazardous properties of chemicals.

Both REACH and CLP work hand in hand and constitute a solid legal framework that, in theory, guarantees a high level of protection to people and the environment. But how do regulators control hazardous chemicals in Europe? They follow some logical steps:

**Identification of hazardous chemicals**, potentially requiring control measures:

<u>REACH</u> <u>Regulation</u>'s <u>Registration</u> process obliges companies aiming to manufacture, use or place chemicals on the EU market to register them and provide the European Chemicals Agency (ECHA) sufficient data to allow the authorities to assess and verify if the chemicals are safely used or if they need control. ECHA verifies the completeness (but not the quality) of the data and allows the chemical on the market by granting these a registration number;

REACH <u>Evaluation</u> mandates ECHA to verify the quality and compliance with legal obligations of the information provided by industry and the Member States (MS) to assess the potential concerns of the chemicals.

If hazards are identified:

- <u>CLP Regulation</u> through <u>Harmonised</u> <u>Classification and Labelling (CLH)</u> obliges companies to classify and label the hazardous properties of chemicals;
- <u>REACH Regulation</u>'s Candidate List of identified Substances of Very High Concern (SVHCs), is a blacklist of chemicals to be swiftly phased out. Companies must notify consumers about their presence, upon request. SVHCs are substances whose intrinsic properties and potential to damage health and the environment are so significant that their use, presence or discharge into the environment should be urgently avoided.

#### Authorities' analysis of the most adequate way to regulate hazardous chemicals, so-called Assessment of Regulatory Needs (ARN)<sup>1</sup>

#### Authorities' chemicals control measures:

REACH <u>Authorisation</u> (Annex XIV) and <u>Re-</u> <u>striction</u> (Annex XVII) - the chemicals of concern will be put forward for regulatory management measures (chemicals control measures). Authorisation is a general ban on the most harmful chemicals (unless specific authorisation is granted) and Restriction limits certain uses of harmful chemicals.

However, despite some progress in the mapping and understanding of '<u>the Chem-</u><u>ical Universe</u>', as ECHA dub it, and creating tools to regulate it, authorities have been unable to quickly and efficiently respond to the challenges posed by toxic chemicals and by the systematic delay tactics of the chemical industry, which refuses to provide reliable hazard information, as required by law, to guard against unsafe uses.<sup>2</sup>

While research continues to reveal the dangers of pushing synthetic chemicals onto the market without proper control, it takes too long for policymakers to control them. As a result, new chemicals with largely unknown safety threats are quickly given market access, while it then takes officials years of work to understand and then restrict the many dangerous substances causing so much harm. That is too late for all those blighted by cancer, infertility or collapsing ecological habitats.

REACH and CLP are set to be improved, thanks to the <u>EU Green Deal</u> and its key <u>zero pollution</u> ambition. The European Commission published on 14 October 2020 the <u>Chemicals Strategy for Sustainability</u> for a toxic-free environment (CSS) which

<sup>&</sup>lt;sup>1</sup> Formerly called Regulatory Management Options Analyses (RMOA). ARNs are not required by law although frequently used by regulators.

<sup>&</sup>lt;sup>2</sup> "EU chemicals policy must evolve and respond more rapidly and effectively to the challenges posed by hazardous chemicals. This includes ensuring that all chemicals are used more safely and sustainably, promoting that chemicals having a chronic effect for human health and the environment - substances of concern – are minimised and substituted as far as possible, and phasing out the most harmful ones for non-essential societal use, in particular in consumer products. COM(2020) 667 final, Chemicals Strategy for Sustainability - Towards a Toxic-Free Environment, page 2



foresees the revision of the main FU chemicals laws, REACH and CLP in order to help to achieve a legitimate higher level of protection of citizens and of the environment against hazardous chemicals and answers the widespread concern about the danger of chemicals by promising to rapidly phase out large families of hazardous chemicals and fundamentally shift the focus of requlation from control to prevention. This move clearly reflects the political will to act. The reform proposals of the Commission, due by the end of 2022 will be amended and finalised by the European Parliament and Member State governments through 2023 and possibly continuing after the 2024 election and into 2025. The final legal proposals are expected to roll out this much anticipated 'detox' of the European market, strengthening its REACH and CLP regulations.

Therefore, if the upcoming reforms of REACH and CLP stay true to the spirit of the Green Deal, it would give the EU's main chemical regulations a fair chance to significantly limit, sooner rather than later, the rampant chemical pollution and the prolonged exposure of people and the environment that contributes to rising rates of cancer and other serious harms.

But how long exactly does it take authorities to identify and regulate harmful chemicals in Europe? This report analyses all publicly available data for more than a thousand chemicals that have entered REACH and CLP systems since their inception. It exposes glaring flaws that allow industry to systematically 'game the system', routinely resulting in years and even decades of official inaction, even for chemicals known to be causing serious harm.

## Executive summary

The 'Need for Speed' report is the result of the first ever analysis of the length of all chemical controls by the European Commission, the <u>European Chemi-</u> <u>cals Agency</u> and Member States since entry into force of the EU's main legal instruments: REACH Regulation and its complementary Classification, Labelling and Packaging (CLP) Regulation.

All data analysed in this report comes from the European Chemical Agency (ECHA) files relating to the 1,109 chemicals regulated or currently still undergoing regulation under REACH and CLP since 2007, when REACH entered into force. Our analysis calculates the most frequent (median) time spent on each regulatory step<sup>3</sup> and identifies bottlenecks and those responsible. The results are shocking, including to officials at the heart of the process, who may not be fully aware of how long the entire regulatory process takes.

Thanks to REACH, we are increasingly aware of which products contain harmful chemicals, while CLP has improved our understanding of the hazardous nature of chemicals and their impact on our health and environment. But these successes pale in comparison to the snail's pace of regulatory action. This report reveals a stark contrast between the few short weeks it takes for companies to gain access to the European market, usually based on unreliable hazard data, and the years or even decades it takes authorities to restrict chemicals they learn are causing

#### serious harm to people or the environment.

Officials are forced to give firms permission to use chemicals within just three weeks of EU registration, but are not allowed to first study their hazards. Then it can take a decade for the officials to assess those hazards, whether the chemicals are being used dangerously and how to control them.

Harmonising the classification and labelling (CLH) of hazardous chemicals takes EU officials over five and a half years. The identification and listing of <u>Substanc-</u> es of Very High Concern (SVHCs) in the <u>Candidate List</u>, is a rare positive example of a relatively speedy REACH process, as it takes around six months on average. The process is much more efficient than CLH.

Then comes control - a step that takes additional five or nine years respectively to ban a chemical in dangerous use under REACH's Restriction process or curbing chemicals under the Authorisation process. Throughout this time, firms can legally use chemicals known to be causing serious harms until officials conclude the regulatory process.

The bottom line is that by summing up the duration of all the available regulatory steps from 1) Evaluation, to 2) Assessment of Regulatory Needs then 3) to control in neat order, **restricting** chemicals in dangerous use in **Europe takes 19 years and three months. Phasing out under the socalled Authorisation process takes 22 years and 11 months while harmonising classification and labelling takes 19 years and five months to be completed**, from start to finish.

Turning to some of the detailed control processes, this report finds that over the last decade, the Evaluation and assessment of regulatory needs (ARN) processes have triggered very few chemical controls. For example, **ARNs performed for** over 300 chemicals in the last 11 years, have resulted in three chemicals being **controlled.** This failure mainly stems from poor hazard and exposure data provided by industry. Expert groups set up to support the identification of the most hazardous category of chemicals (SVHCs) have largely failed to do so. This report finds that after ten years of carrying out Substance Evaluations, only two restrictions and one Annex XIV listing have been implemented. After ten years of PBT Expert Group deliberations, only one persistent, bioaccumulative and toxic (PBT) chemical was identified for phase out (Annex XIV<sup>4</sup>). After its eight years of existence, **Endocrine Disruptor Chemicals** the (EDC) Expert Group has failed to propel even a single chemical to a restriction or inclusion in Annex XIV.

One of the main barriers to effective chemical protection is the European Commission. After ECHA's lengthy and complex process to deliver scientific opinions, the Commission takes even longer to process these into regulatory action decisions. Almost half (45%) of all REACH and CLP decisions it is responsible for remain pending.

The Commission normally takes over three years to adopt Authorisation decisions, comprising almost two years to include SVHCs in the regulatory Annex XIV and more than one year to decide on applications for authorisation (AfAs) by SVHC users. As this report was published, a full three quarters of known SVHCs have still not been added to Annex XIV and are instead gathering dust at the Commission, while half of all the AfAs to use SVHCs remain undecided and are therefore de facto permitted in Europe.

For deciding on whether to restrict the use of harmful chemicals, the Commission normally takes one year and seven months. Even simple cases are stuck in a legal limbo without public explanation or good cause, such as decisions on harmonised classification and labelling of hazardous chemicals. This should be a mere rubber stump process, given its purely scientific nature that has already been established by ECHA, but takes an average of one year and ten months. Such are the institutional delays bedevilling consumer and environmental protections.

Advancing at such a snail's pace, with almost 2,000 substances needing to be regulated or assessed, the EU would take hundreds of years to process all outstanding dossiers and ensure all chemicals currently on the market are adequately controlled. **Throughout the time files are being processed, profit driven companies are free to use high volumes of chemicals without necessary controls and in some cases no controls at all for years.** In effect, chemicals are not properly controlled in Europe. The situation is unacceptable and must change.

According to our analysis, there are several main factors hampering REACH and CLP. Regulators are blinded from the start by the fact that in many cases, industry submits dossiers that contain dangerously inadequate and unreliable hazard and exposure data. Officials are, nevertheless, obliged to allow market access, putting the hard work of curbing dangerous use on their plates. Officials compound this problem through an ingrained tendency to over-analyse and through demand for further information, driven by the need for these data for Restriction, Authorisation, and Harmonised Classification and Labelling, as ECHA has no power to act decisively on a precautionary basis. For their part, many Member States assign too little resources to chemical evaluation and management processes, despite persistently high public concern at the growing threat from toxic chemicals shown by the EU polls. Finally, the Commission stalls a shockingly high proportion of the dossiers referred to it, dismissing almost in all cases its legal obligation to draft decisions within 3 months and delaying protections against the dangerous use of chemicals for years in a majority of cases, for no good reason.

This report concludes that REACH and CLP have failed in the <u>stated intention</u> of speeding up the control of chemicals. Upcoming legal revisions of both laws offer a once-in-a-decade opportunity to fix the problems. We should not wait though. In our view, much can already be done to speed up protections, notably by ending the chronic delays at the European Commission.

#### Conclusions: Decisions delayed are protections denied

Our analysis shows that despite some progress, REACH and CLP are failing to ensure chemical safety in Europe in a timely manner. A large number of hazardous chemicals are not properly controlled for many years, even decades, likely resulting in serious harms to human health and the environment.

The main problems identified are:

#### The absence of legally binding deadlines:

- for the Member States and ECHA to conclude whether a substance used is potentially harmful. As it is, it can take over 10 years to clarify the level of concern for a substance, from the point of registration to compliance checks and Substance Evaluation.
- for the European Commission to finalise and adopt decisions. It is alarming that the Commission spends an average of two years and sometimes over a decade, to decide on regulatory actions for known harmful chemicals.

#### The 'no data, no problem' approach.

Companies routinely submit incomplete or flawed chemical hazard and exposure data, yet they still gain market access, disrespecting the 'no data, no market' rule. This is the 'no data, no problem' trap that blindfolds officials and shifts the tremendous effort of proving whether a product is safe from the manufacturer to the regulator.

#### The lack of accountability.

National authorities are not legally bound to act on their own conclusions and recommendations.

The European Commission, on the other hand, is not held accountable on its legal obligation to provide decision proposals within three months after ECHA's scientific assessment, which leads to consistent non-compliance.

This accountability flaw in the system at both national and EU level, promotes inaction and causes further delays to the measures that need to be taken in order to prevent the harm certain chemicals could cause to people's health and the environment.

#### European Commission inaction.

Almost half (45%) of all REACH and CLP decisions remain pending. A major bottleneck is the Commission's evident maladministration<sup>5</sup> and years-long disregard for ECHA's scientific opinions and recommendations to regulate chemicals of concern. The Commission takes longer to decide than it takes ECHA to develop scientific opinions.

More detailed conclusions can be found in the different sections of each process and in chapter 8.

#### Main policy recommendations in view of the REACH and CLP reforms

To speed up the regulation of chemicals the EU should:

### Write strict and binding deadlines into law and ensure accountability.

Officials must not freeze files without just cause, particularly when serious harms are known and ongoing. The adoption of the final decisions by public authorities must be rhythmed by a binding deadline set in law. In addition, for decisions such as REACH Authorisations, to ensure that delays do not cause further harm, an absence of decision within the legal deadline must amount to a rejection.

### Apply the 'no data, no market' and 'zero tolerance to non compliance' principles.

The EU must stop firms blindfolding officials with non-compliant hazard and exposure data. A regime of harmonised and severe sanctions must uphold this commitment, as it does in other areas of EU law such as consumer protection.

#### Put protection before profits.

Use a precautionary approach and lower the level of evidence needed for authorities to identify and restrict the production and use of hazardous chemicals. Barriers to agreeing new protections should be lowered and authorities should be empowered to restrict chemicals when concerns can be justified. The burden of proof to justify derogations must be on industry.

<sup>5</sup> In the Charter of fundamental rights of the EU, Article 41 on Right to good administration states that "Every person has the right to have his or her affairs handled (...) within a reasonable time by the institutions, (...) and agencies of the Union.

### Strengthen fast-track controls and the ban of groups of the most harmful chemicals in everyday products.

Open the fast-track restriction process to additional chemical hazard categories, products and groups of chemicals. Establishing dynamic links to perform automatic bans of substances of concern in everyday products. Establishing the group approach as the default option to restrict chemicals.

#### Simplify the system.

For example, define and apply the essential use concept to reduce the number of applications for Authorisation and derogations for Restriction.

# Ensure that the revision of REACH does not introduce additional complexity and delays.

Avoid prior classification being required for SVHC identification and derogations based on exposure or use considerations for the most harmful chemicals.

More detailed recommendations can be found in the different sections of each process and in chapter 9.



# Methodology

This study analysed the length of time it took REACH and CLP processes to assess and regulate 1,109 synthetic chemicals placed on the European market between 2007 and 2022, from the moment the chemicals are authorised on the EU market, to the point authorities notified their will to regulate chemicals (registry of intentions) to the point a regulatory decision was taken. When possible, the date of entry into force of the final regulatory action was also included.

In order to have an overview on how long it would take the EU to limit the use of a hazardous chemical, this report establishes the median times of all regulatory steps in the EU chemical control process. The exception is Substance Evaluation, which officials do not track. That single missing component means that establishing how long it takes for any given chemical to go through Evaluation can only be an estimate (based on EEB's report Substance Evaluation findings). We assumed<sup>6</sup> an average of five years for compliance checks and an average of seven years for Substance Evaluation, as we did not have accurate data for all Evaluation steps. All other steps were calculated using median times of 1,109 chemicals dossiers.

We did an estimation of the total length of the process if a chemical went through all regulatory steps, from Dossier Evaluation, to Substance Evaluation, to Assessment of Regulatory Needs to control through Restriction, phase-out (Authorisation) or Harmonised Classification and Labelling. We have summed up the median duration of each step, as well as the best case scenario (shortest times for each step) and the worst case scenario (the longest records per step). Worst case estimates are made under the assumption that all REACH and CLP steps are part of the route to control.

We use publicly accessible data on REACH and CLP processes along with the legal text to unveil process flaws, make recommendations on the necessary improvements to the regulatory framework and detect the actors that undermine progress to safe and sustainable chemical use.

The data used in this report comes from the ECHA website (PACT tool, CoRAP list, etc.), data directly requested from ECHA and information available on the European Commission Decisions. The data used for the Substance Evaluation process was retrieved from <u>EEB's report</u> from 2019.

<sup>6</sup> It should be noted that the Evaluation lengths are estimations (not median times). The estimated lengths are shorter if Substance Evaluation is not part of the process or is processed in parallel to the compliance check. Also the five years of Compliance Check and the 7 years of CoRAP usually partly overlap in time. Still we consider that these are conservative estimations. SEv can take 7 to 9 years or much longer, in case data generation is needed. Same applies to Compliance Checks.

For the Assessment of Regulatory Needs (ARN) analyses, we had access only to data available from the ECHA website, the earliest of which was created in 2011. However, under REACH, ARNs have been developed before 2011, but not made public, hence unavailable for our analysis. The <u>ARN database</u> was downloaded on 28 May 2021.

Chemicals withdrawn from the CLH, SVHC, Authorisation and Restriction processes were not included in the analysis. For CLH, the analysed data considered is limited to the chemicals that included an opinion sent by ECHA to the Commission. In those ARN, Authorisation and Restriction processes where chemicals are currently awaiting a decision by the Commission, we assigned a hypothetical decision date of 01/03/2022 in order to establish a date and be able to incorporate these chemicals into our analysis. However, the hypothetical dates considered for our analysis are obviously leading to an underestimation of the true length of the processes, since, de facto, these decisions are not taken yet. It could take months or years before the Commission actually makes these decisions.

When the date of entry into force of regulatory actions was not available (for the Restriction process only), we used the median value (18 months) between the time spent by the Commission to decide (in the cases when it adopted a decision) and the entry into force of those to obtain a hypothetical date (01/09/2023) and used this for those substances without an entry into force date. This means that our calculations are an underestimation of the true length of the process and the ultimate delays are bound to be even longer.



# PART I.

Identifying chemicals of concern

# 1. The Chemical Universe

Currently, there are 23,416 substances registered in the EU under REACH.

ECHA has created a mapping tool of all registered substances called the Chemical Universe in which each substance is assigned to a data cluster or pool that indicates the regulatory actions already initiated or under consideration for that substance. It also identifies those substances for which the need for suitable regulatory actions still needs to be determined. (table 1) Yet, there are 17,126 substances not assigned to a cluster and 2,854 substances that, despite market access being granted by ECHA, still "require additional information or assessment before it is possible to identify whether further regulatory action is needed."<sup>7</sup> This means they are in use without a full understanding of their threats. Strikingly, most of these substanc-

Table 1. REACH Chemical Universe at the end of 2021 - All substances(Adapted from ECHA's regulatory strategy).8

Registration Status and Tonnage	Not yet assigned to any pool	Assessment of regulatory needs	Data generation needed	Risk manage- ment under consideration	Currently no further actions proposed	Risk management ongoing	TOTAL
> 100 tonnes per year	1,282	348	1,768	194	679	281	4,552
1-100 tonnes per year	5,944	333	737	141	446	123	7,724
Intermediate chemical <sup>9</sup>	6,172	201	192	39	230	69	6,903
NONS <sup>10</sup> - claimed active	977	28	14	4	24	14	1,061
Unclaimed NONS	1,633	33	29	13	30	40	1,778
Ceased manufacture - REACH	627	20	110	14	48	49	868
Ceased manufacture - claimed NONS	491	9	4	2	5	19	530
TOTAL	17,126	972	2,854	407	1,462	595	23,416

<sup>7</sup> ECHA, Transparent progress in addressing substances of concern -Integrated Regulatory Strategy Annual Report 2021, page 12

<sup>8</sup> ECHA, Faster action on groups of harmful chemicals -Integrated Regulatory Strategy <u>Annual Report 2022</u>, page 14

<sup>9</sup> an intermediate is a substance used in the manufacturing of another substance whereby the intermediate is itself transformed into that other substance

 $<sup>^{10}</sup>$  Notification of New Substances or previously notified substances to ECHA

es are used in the EU in large quantities: over 100 tonnes per year. Table 1 shows that 194 (4%) substances used in high quantities have risk management actions under consideration. Meanwhile, 281 (6%) have risk management ongoing, meaning that risk management measures have been implemented.

It is ECHA's goal to conclude whether they are a priority for regulatory risk management, currently of low priority for further action or are a priority for data generation by the end of 2027 for all substances registered above one tonne per year. It is clear that at this pace, it will take many more years for the EU to ensure that chemicals are adequately controlled.

To give a panoramic of the REACH process and its duration, figure 1 shows that the process starts with REACH Registration, followed by REACH Evaluation. If the registered substance presents risks to the environment or human health, an assessment of regulatory needs (ARN) may follow. The other path that the chemical typically follows is a CLH, Restriction or Authorisation process. Throughout the report, each step is further detailed.



#### Figure 1. Overview of the REACH and CLH processes and their duration.

# 2. REACH Registration

REACH requires companies to submit a registration dossier to ECHA for substances manufactured or imported into the EU above one tonne per year. REACH stipulates what information needs to be included in the dossier, information that varies depending on volume.

#### 2.1. Process

When a company submits a registration request, ECHA must carry out a '<u>complete-ness check</u>' within three weeks and provide a deadline by which to submit any missing data if a registration is incomplete. If the data provided is deemed complete (meaning some text is included in every field), ECHA<sup>11</sup> then provides a registration number to allow market access. Once market access is granted through a registration number, the legal text hampers the possibility for the market access (registration number) to be withdrawn, even in cases where the substance is proven to be dangerous.

REACH does not allow ECHA to perform an "assessment of the quality or adequacy of any data and justifications" (Article 20.2) of the registration dossier, meaning that market access can be, and often is, granted based on incorrect, inadequate and/or not reliable information (Article 20.2). Registrants mostly dismiss their obligation to keep their dossier up-to-date with any new information (Article 22), such as new studies showing the hazards of the chemical.

#### 2.2. Timeliness

REACH requires ECHA to perform a completeness check on the registration dossier within three weeks of submission by the registrant. If a registration dossier is incomplete, ECHA provides the registrants with a four-month deadline to update their submission. Most companies with complete dossiers do not update their registrations unless they are forced to, due to a decision by ECHA requesting companies to do so.<sup>12</sup> Between 2008 and 2017, 64% of registrations were never updated. When companies fail to update their registrations, no legal action follows. This shows that once a permission to be on the market is granted, companies have no incentive to update their registration.

#### 2.3. Main bottlenecks

REACH requires ECHA to grant market access to complete registrations in an extremely short time (three weeks). This forces the Agency to perform a mere completeness check. This is the 'original sin' of REACH that favours market access over

<sup>&</sup>lt;sup>11</sup> A registration is effective when ECHA provides a registration number following a completeness check. See Article 20 of REACH. A Registration decision could be appealed.
<sup>12</sup> Amec Foster Wheeler Environment and Infrastructure UK Ltd & Peter Fisk Associates Limited (2017): A study to gather insights on the drivers, barriers, costs and benefits for updating REACH registration and CLP notification dossiers.

public protection and sets up severe bottlenecks to come, as officials grapple with woefully inaccurate data when trying to determine whether toxic harm is being done and management measures are needed.

#### 2.4. Conclusions and Recommendations

Registration is the foundation of REACH. All chemical controls are based on the data provided by the companies marketing them. However, EU rules prevent officials from studying possible hazards of the chemicals registered by industry before they grant market access. Many are in fact used in uncontrolled, dangerous ways. This means that REACH favours market over protection and wrongly presumes that chemicals are innocuous rather than hazardous despite the vast evidence that proves that the opposite is true. If data is later found to be inadequate and the chemical dangerous, there is no punishment for companies irresponsibly using chemicals dangerously for years.

Regulators must have the power to strip companies of market authorisation if dossiers are not compliant or kept up-to-date. If the Commission seriously wants to implement the Chemicals Strategy for Sustainability (CSS) promise of "zero tolerance to non-compliance", today's broken completeness check must be made 'fit for purpose'. ECHA needs more time to scrutinise new registrations and must guarantee it has the high quality information it needs to warrant that a chemical is adequately controlled, before granting market access.

Our proposals to improve the situation are:

#### Apply the 'no data - no market' principle:

Force registrants to be accountable for their

products. The burden of proof to demonstrate risks are controlled should be on industry, not officials.

### Reinforce the provisions of the completeness check:

- Introduce a legal requirement in REACH, allowing ECHA to assess the quality and adequacy of registration data before market access is granted.
- Extend the legal timeframe for the completeness check beyond three weeks.
- Give ECHA retroactive powers by allowing it to revoke registration decisions in case the registrant fails to comply with legal requirements.

### Require companies to keep their dossiers accurate and up-to-date:

- All existing dossiers should be given an expiration date, after which renewal of the registration is required.
- Fees should be coupled with (re-)registration.
- Introduce mandatory annual requirements for reporting production volumes and information on use patterns, to keep this information up-to-date at all times.
- Make polluters pay, by sanctioning companies to compensate for the damage caused by their non-compliant dossiers (e.g. when a substance is identified as reprotoxicant after having been on the market for years).

Require ECHA to keep a public register of all registration decisions in full, including updates, to allow public scrutiny.

# 3. REACH Evaluation and Expert Groups

Following dossier Registration, ECHA and Member States share responsibility for an <u>Evaluation Process</u>. This is where officials evaluate the information submitted by the companies, but only after market access has been given, usually based on inadequate and unreliable hazard and exposure data.

Evaluation comprises two main processes:

- <u>Dossier Evaluation</u> (Compliance check & Examination of Testing Proposals)
- Substance Evaluation

Under the Compliance check (CCh), ECHA evaluates whether companies have provided adequate information on substance identity, substance properties and chemical safety assessment in their registration dossiers (Article 41). The Evaluation process also includes the Evaluation of Testing Proposals (Article 40), a measure that aims to avoid unnecessary animal tests, which is required when companies that register a substance want to carry out a test listed under Annex IX and Annex X of REACH. Substance Evaluation clarifies whether the use of a substance may cause harm to human health or to the environment and can require companies to provide additional information about a substance if there are concerns that a chemical may be in dangerous use (Article 44). ECHA and the Member States have created scientific expert groups to support Evaluation and to informally assess whether chemicals meet the criteria to be identified as endocrine disrupting chemicals (EDC) or Persistent, Bioaccumulative and Toxic/very Persistent and very Bioaccumulative substances (PBT/vPvB).

#### 3.1. Dossier Evaluation

In its 2018 <u>REACH review</u> the Commission acknowledged that because companies were systematically failing to provide legally required data on the most severe hazard threats and therefore a majority of substances in current use could not be considered safe, REACH protection objectives were hindered.

A Compliance check evaluates the adequacy and reliability of information in a dossier, examining substance identity, substance properties and "Chemical Safety Assessment" by companies. This information is the basis for understanding if a chemical is a threat to human health and the environment. On the other hand, non-compliance means that these chemicals may potentially harm human health or polluting the environment. Following public pressure raised by the European Environmental Bureau (EEB), the Commission raised the percentage of dossiers to be checked for compliance from a minimum of 5% to a minimum of 20% for each tonnage band (approximately 30% of all registered substances). The availability of very advanced data mining tools allows ECHA to perform many more compliance checks (e.g., focussing only on certain information-targeted checks). Yet **at the last count**, **nearly all (93%) of dossiers submitted by industry lacked critical hazard information required by law.** 

Table 2 shows the total number of registration dossiers that have gone through a Dossier Evaluation process and the number of dossiers under compliance check divided by their status. The second column shows only compliance checks for which a decision was taken by 7 May 2022. Despite being decided over three years ago, firms responsible for 27 dossiers (2%) have not yet provided the requested data, while 168 dossiers (14%) are in a follow up phase. **The earliest decision that is still in the follow-up phase was issued nearly a decade ago, in 2013.** 

#### 3.1.1. Timeliness

Compliance checks of hazard data provided by industry can take more than five years, or in worst case scenarios, over ten years.

ECHA has one year to complete a Compliance check (REACH, Art. 41(3)). However, companies get between three months and a few years (decided on a case-by-case basis) to provide missing data if ECHA decides a dossier is not compliant. If that de-

#### Table 2. Overview of Dossier Evaluation from ECHA's "<u>Dossier Evaluation status</u>" database from 2009 until 2022 (in 13 years).

Registration Status and Tonnage	All	By 7 May 2022
Dossier evaluations initiated	6,613	
Unique chemicals assessed under dossier evaluation	3,743	
Testing proposals	2,423	
Compliance checks initiated	4,190	1,212
Compliance checks concluded	2,870	1,017 (84%)
Compliance checks in follow-up	348	168 (14%)
Compliance checks for which information was requested (but not yet concluded)	573	27 (2%)
Ongoing compliance checks	206	0
Dossiers under assessment	193	0

cision is appealed, it can take a few more years for officials to receive the data necessary to understand if the substance is of concern or not. If new information is received, ECHA can issue another decision, with further time allowances given to companies to comply, potentially stretching out the process for many years.

Between 2009 and 2020, ECHA opened 3,654 compliance checks and ruled that nearly half (1,599) were not compliant. In a further 525 cases, the failings were ad-

dressed before a final decision was adopted. Of the 1,599, 69 required a second compliance check and 79 did not address the decision or addressed the decision with irrelevant data and therefore remain in breach of the law.

Table 3 shows some examples of compliance check decision-making processes, which, in the best case scenario, take a few years to resolve. Furthermore, the appeal process can add a year at least to the process. For instance, triphenyl phosphate, a flame retardant suspected of disrupting human hormones, has been under Evaluation for over ten years, but the Evaluation process remains ongoing. Therefore, regulators do not understand its threats and are unable to prevent harm to the public or the environment.

Table 3. Examples of lengthy Compliance Check decisions for four substances.Situation as of 10 September 2021.

Substance	Start of check	Decision	Due date	Appeal decision	New due date	Follow up
Triphenyl phos- phate	28/02/2011	5/04/2012	5/04/2014	10/10/2013	10/10/2015	Compliance check: con- cluded in 2015 Substance evaluation: not completed
Reaction mass of ethylbenzene and xylene	27/09/2012	21/05/2013	21/11/2013	n/a		Another compliance check was carried out with the due date July 2022. Substance Evaluation to start in 2022, despite being identified for substance evaluation in 2015
Homosalate	2017	13/03/2018	20/09/2021	18/08/2020	25/02/2024	ARN suggests waiting for completion of compliance check before including in CoRAP
Ethylenediamine	22/07/2013	07/10/2014	14/10/2015	n/a		Identified as SVHC in June 2018

#### **3.1.2.** Main bottlenecks

The main bottleneck of compliance check are **registrant companies** because they **do not provide the legally required data** in their registration dossiers. Furthermore, some companies contribute to further delays by **challenging decisions** before the <u>Board of Appeal</u>. When a registration dossier is found not to be in compliance, **companies face no consequences** for failures to comply with non-compliance decisions. Hence, **the company continues to have the right to manufacture, import and use the substance**, despite any ongoing toxic impacts on the public and environment. Companies have **no incentive** to correct the deficiencies as they would be under the potential threat of risk management measures, while the lack of information, as before REACH, provides them with a prolonged free pass to the market.

Moreover, REACH provides companies with a right of reassessment of new information, and a second decision may be needed. Also, companies may appeal the decision and buy more time as **an appeal suspends the delay to submit the data**.

Registrants that do not comply with the decisions are referred by ECHA to the State in which the company is located for enforcement. That State has the power to take action. The enforcement measures taken by the authorities differ among Member States. However, the registration remains valid and the chemical remains on the market, since **ECHA has no power to withdraw a registration number (market access)** until the national authority has taken action or until EU-wide risk management measures have been implemented.

Only when missing information is provided to ECHA, can the Agency take further action, including Substance Evaluation or risk management.

This means that only to assess if a company complies with the legal information requirements of the REACH regulation can take several years, depending on how cooperative the company is. The frequent lack of cooperation by the registrants to provide the necessary information is another major bottleneck.

Unfortunately, ECHA does not provide information about follow-ups to compliance check decisions, which makes it impossible to assess which and how many dossiers remain unreliable or how long it takes to correct them.

**ECHA helps companies** with compliance **at no additional cost**, shifting the considerable burden from profit making companies to taxpayer-funded officials.

#### **3.1.3. Conclusions and Recommendations**

The long delays are mainly caused by industry systematically misleading regulators by providing unreliable hazard data. At the last count, nearly all (93%) industry dossiers checked by ECHA lacked vital hazard and exposure data needed to assess the potential risks of cancer or other serious impacts, a high rate of illegality echoing previous years. Officials are then forced to do the lengthy and expensive work of getting the data and building cases for control measures, a process industry regularly challenges in court. The result is that officials still have little idea whether most of the 100,000 chemicals in use today pose a danger, 15 years after modern EU chemical laws went into force. This is what the EU environment agency calls the "unknown territory of chemical risks." Few firms have ever lost market access or been fined for providing misleading hazard data, despite enormous public health bills linked to chemical pollution. The EEB's proposals for improvement are:

 Require ECHA to revoke registration decisions when the companies fail to give the requested information, meaning that they still do not comply by the end of the process.

- Assess groups of substances, using read-across to fill the data gaps in a precautionary way.
- Introduce a deadline within which a dossier needs to be compliant from the date of registration in order to retain market access.
- The current 12 months deadline for issuing draft compliance check decisions should be shortened to six months.
- Tighten the deadlines for requesting more information by ECHA to companies if after the first compliance check, the information provided is not sufficient to comply. Deadlines based on test duration, should last no more than two years.
- A final decision (after consultation with company and Member States) for data generation should be adopted within one year from the start of the evaluation. Currently no deadline is specified in REACH for final decisions.
- Introduce fees for handling non-compliant dossiers.

#### 3.2. Substance Evaluation

Substance Evaluation (SEv) is the process through which concerns about chemical harms to human health and the environment are better understood. They are carried out by Member State Competent Authorities (MSCAs) under the <u>Member State</u> <u>Committee</u> (MSC). Through this process, REACH seeks evidence to prove or disprove those concerns. Substances to be evaluated because of serious concerns like e.g. carcinogenicity, reprotoxicity, persistence and bioaccumulative, or endocrine disrupting properties are included in the Community Rolling Action Plan (CoRAP). Selection of substances is based on risk considerations such as the hazard e.g. structural similarity with another known hazardous substance: exposure threat; or the aggregated tonnage. After placing a substance on the CoRAP list, the Member State evaluating the substance has 12 months to prepare a draft decision but no time limits are set for approving the decision. For example, for tris(4-nonylphenyl, branched) phosphite a draft decision was prepared in April 2014, while the final decision was only issued in 2020.

#### 3.2.1. Process

When a decision is adopted, it specifies if additional information is needed beyond the legal requirements to clarify the suspected concerns. The companies are usually given from 18 months to three years to provide the data. If a decision is appealed, it can take many years until ECHA receives the information. After the information is provided, the Member State has one year to evaluate the information (Art. 46). Then, a recommendation may be made to determine whether the chemical is a substance of very high concern (SVHC), should be part of a restriction or a harmonised classification, labelling and packaging (CLH) proposal, or be subject to other legislation (e.g. occupational exposure values).

#### 3.2.2. Timeliness

As noted by a previous EEB report<sup>13</sup>, **Substance Evaluation can take seven-nine years to conclude** if further generation of information is required. SEv is not a rapid process and lacks the ability to quickly

<sup>&</sup>lt;sup>13</sup> Loonen et al., CHEMICAL EVALUATION: Achievements, challenges and recommendations after a decade of REACH, EEB (2019).

identify and address concerns to human health and to the environment from chemicals.

#### 3.2.3. Efficiency

In the last ten years (2012 - 2022), **388** substances have been assessed. Almost **50%** (185) await a conclusion. Of the 388 substances, a restriction has been implemented for only two substances, Bisphenol A and methanol. Five substances were found to be SVHCs, but only one was included in Annex XIV (table 4). So in the course of ten years, a primary method for Member State Evaluation of suspected high-threat substances has resulted in just three being controlled.

Table 5 shows a few examples where SEv lacks the nimbleness required to address the threat posed by thousands of chemicals. It shows the importance of clear legally mandated deadlines as draft decisions must be issued within a year of the start of the process. All other steps are left to the discretion of ECHA and Member States, leading to very long delays.

#### Table 4. Status of all Substance Evaluations. Situation as of 22 June 2022.<sup>14</sup>

	Sub- stances assessed	Con- cluded	Not started	Data request to companies	SEv sus- pended	Conclusion under prepara- tion	Fol- low-up ongoing	SEv with- drawn	Ongo- ing	Number of substances regulated [RMM] <sup>15</sup>
2012-2022	388	203	23	39	9	6	21	43	34	2 [restriction] 1 [Annex XIV]

### Table 5. Examples of SEv process for four particularly slow substances(Situation as of 7 May 2022)

Substance name	CoRap inclusion	Draft decision	Decision	Info deadline to companies	SEv fol- low-up	Status	Controls
2-(4-tert-butylbenzyl) propionaldehyde	2012	22/02/2013	21/02/2014	21/08/2014	Unknown date <sup>16</sup>	Concluded on 24/02/2022	SVHC, CLH <sup>17</sup>
tris (4-nonylphenol, branch) phospho- rous acid ester (pre- viously registered as: tris(4-nonyl- phenyl,branched) phosphite)	2013	29/04/2014 (updated 08/03/2019)	10/09/2020	15/06/2021 12/12/2022	n/a	Ongoing - Not concluded	
4-tert-butylphenol	2014	3/09/2015	20/04/2016	27/01/2018		Ongoing - Not concluded	SVHC (2019)
Triclosan	2012	28/02/2013	19/09/2014	26/09/2016 Updated deadline 26/12/2018		Follow-up	

<sup>14</sup> Status <u>Substance evaluation</u> - CoRAP, retrieved from ECHA website on 22 June 2022

<sup>15</sup> Risk Management Measure

<sup>&</sup>lt;sup>16</sup> ECHA's SEv page mentions that "As an outcome of the SEv follow-up process, a second SEv draft Decision requesting further information has been sent to the Registrant(s)" and the status of this evaluation is "ongoing": <u>https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e3518</u>
<sup>17</sup> The substance CLH report for 2-(4-Tert-Butylbenzyl)Propionaldehyde mentions that part of the information generated by SEv was used to prepare the harmonised classification proposal.

#### 3.2.4. Main bottlenecks

After a Member State has prioritised a substance for Evaluation in CoRAP, **the start of Evaluation is postponed year after year for half of the substances.** According to ECHA, the main reason for these delays are **pending compliance checks.** This logjam is a massive bottleneck that in effect rewards companies with extra time to sell under-regulated substances and for providing low quality data.

After a Member State has evaluated a substance and drafted a decision, **no time lim-** its are set for the <u>Member State Com-</u> <u>mittee</u> approving the decision, leading sometimes to very long delays in concluding the process.

Routine failures by registrants to provide missing hazard information is a major bottleneck. Additionally, when a decision is adopted, companies are sometimes given three years to provide the data. **Decisions can also be appealed.** So it can take many years until ECHA receives essential hazard information and is in a position to judge ongoing threats to human health and the environment.

#### CASE STUDY: Triphenyl phosphate - A flame retardant stuck in the Evaluation process for over a decade.

No decision is yet taken

Triphenyl phosphate (TPP) is a flame retardant produced in high volumes, currently registered in the tonnage band of 1,000 - 10,000 tpa. TPP is widely used in a wide variety of products, such as foam used in upholstered furniture, children's products, cosmetics, personal care products and electronic equipment, leading to widespread exposure of humans and widespread emissions into the environment. It is also a possible alternative to decabromodiphenyl ether (also known as decaBDE), a highly regulated chemical. TPP has been subject to three Evaluation processes: Compliance check, Substance Evaluation and Test Proposal Examination.

The compliance check of Triphenyl phosphate's dossier was initiated on 28 Febru-

ary 2011 (Figure 2). After one year, ECHA concluded that the information submitted by the Registrant for registration did not comply with the requirements and requested the registrant to submit two new tests to bring the registration into compliance with the relevant information requirements. The company (Lanxess Deutschland GmbH) challenged the decision in front of the Board of Appeal who decided to uphold the decision. In 2013 the Board of Appeal adopted a decision requiring the company to submit the information within 24 months. In 2015, the registrant submitted the requested test results to ECHA and the Compliance check was concluded.

TPP was included in CoRAP with an Evaluation planned for 2014 by the UK. After several consecutive postponements from 2013 until 2017, UK submitted SEv for TPP to MSC in 2018. In 2019, ECHA issued another decision requesting another test to industry by 2020. After one year, the TPP dossier was updated with the requested results. Following Brexit, France took over this Substance Evaluation from the UK. Today, evaluation remains ongoing.

In 2020, the registrant submitted a test proposal to ECHA to perform an earthworm acute toxicity test. After ECHA decision in 2021, deadline for submitting results is August 2022. **Conclusion:** TPP has been stuck in Evaluation since 2011. The Substance Evaluation was postponed year after year, despite the concerns that the substance is a suspected endocrine disruptor. People and the environment remain exposed to TPP, as regulatory control measures are not yet planned despite being identified as a chemical of potential concern since 11 years ago.





### 3.2.5. Conclusions and Recommendations

Reaching REACH's full potential of protecting human health and the environment from the exposure to dangerous chemicals is severely hampered not only by the lack of compliance of registration dossiers but also by lengthy Evaluation procedures, low output of Substance Evaluations and lack of regulatory follow-up actions when concerns are identified.

As a result, suspected concerns remain un-

clarified for many years, while exposure of EU citizens and the environment continues and most of the substances found to pose a serious risk to human health or environment have seen no regulatory action for the time being.

As part of the upcoming REACH reform, a proper discussion at political level is needed on how to (1) truly allocate the burden of proof on industry, (2) improve the burdensome and lengthy Evaluation procedures and (3) ensure strong and proper enforcement, to speed-up the evaluation work and thereby improving the implementation of risk management measures that are urgently needed. More specific recommendations are:

- SEv should be quick. A final decision should be adopted within one year of the start of the process.
- Ordering further information should be minimised if an expert judgement can conclude that the concern for human health or the environment is real and that the risk posed by the chemicals should be managed.
- Evaluating families of chemicals should be the default approach to speed up the process, avoid regrettable substitution, reduce administrative burden and minimise test animal suffering, while not increasing the time of the evaluation.
- If SEv conclusions confirm a substance is of concern, risk management should start immediately and within clear deadlines.
- Consider merging the Dossier and Substance Evaluation processes.

#### **3.3. Expert Groups**

#### 3.3.1 Process

Expert groups provide a forum for institutions and stakeholders to discuss whether substances fulfil the ED and PBT/vPvB criteria and provide informal scientific advice to the <u>Member State Committee</u> (MSC). The groups aim to facilitate MSC discussion on whether substances meet the criteria to be identified as an SVHC.

#### 3.3.2. Timeliness

Expert groups do not necessarily prolong the SEv process. However, group discussions sometimes add an additional step to an already burdensome process. When an assessment is concluded, it seems expert groups speed up the process of SVHC identification by the MSC. However, the subsequent follow-up of management of a substance risk through Restriction or Authorisation remains terribly slow.

In 2012, ECHA established the <u>PBT Expert</u> <u>Group</u> (PBT EG). Table 6 shows that of the 225 substances assessed by the group, 92 were concluded and 133 remain under development. In summary, **in the last ten years, the PBT Expert Group has concluded 41% of chemicals Evaluations.** Out of the 24 SVHC identified by the PBT EG, 15 were referred to the Candidate List and **only one (assessed in 2012) was included in Annex XIV.** Other PBT/vPvB substances are included in Annex XIV without expert group involvement (see table 6). The PBT Expert Group is therefore rather inefficient.

Companies registering chemicals have so far self-identified 96 PBTs/vPvBs, four times more than the PBT EG. As shown in table 7, 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol, a substance used as a UV filter included in the PBT assessment list in 2012, is the only one PBT substance discussed by the PBT EG that was included in Annex XIV with a sunset date set for 2023. This means that after 11 years, this chemical will be banned from the EU market by 2023 due to its persistence and bioaccumulation in the environment, unless Authorisation is granted for specific uses.

Status	Conclusion by PBT/ vPvB EG	No. of substances	Identified SVHCs included in the Candi- date List	Risk management
Concluded 92 (41%)	PBT	4	2	0
	vPvB	12	8	
	Both	8	5	1 <sup>18</sup>
	not vPvB/PBT	59		3 <sup>19</sup> + 2 <sup>20</sup>
	Inconclusive	9		
	Ongoing	117		
Under development 133 (59%)	Postponed	16		
Total 225		225		

### Table 6. Overview of the PBT/vPvB Expert Group from 2012 to 2022 (ten years).Situation as of 6 February 2022.

### Table 7. History of the single substance in the PBT assessmenteventually included in Annex XIV.

2-(2H-benzotriazol-2-yl)- 4-(tert-butyl)-6-(sec-bu- tyl)phenol	Intention to identify as SVHC	Assessment	Identification as SVHC	ECHA Rec- ommendation for inclusion in Annex XIV	Annex XIV inclusion	Sunset date <sup>21</sup>
11 years from intention to risk management controls	2012	2015	2015	2018	2020	2023

<sup>&</sup>lt;sup>18</sup> 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328) is included in Annex XIV of REACH. However, the sunset date is foreseen on 27/11/2023.

 $<sup>^{19}</sup>$  The sunset date for the 3 substances included in Annex XIV is in 2023.

<sup>&</sup>lt;sup>20</sup> In addition to the restriction to some uses of D4 and D5, one restriction intention is listed in the pact tool for Terphenyl, hydrogenated and one restriction is under development for Dechlorane Plus

<sup>21</sup> Substance is banned from the EU market, unless authorisation is granted for specific uses. Art. 58 of REACH: "the date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted (hereinafter referred to as the sunset date)".

The Endocrine Disruptor Expert Group (ED EG) was established in 2014. Over the following eight years, it concluded only 16 (20%) of the 105 chemicals referred to it. Half of these, eight substances, were identified as SVHC and included in the Candidate List for eventual inclusion in Annex XIV. **Not a single endocrine disruptor discussed by the group has led to a Re**- striction or Annex XIV inclusion (table 8). Only one ED substance, BPA, has been included in the Restrictions list, Annex XVII though such inclusion was not due to an advice of the expert group. This restriction for BPA in thermal paper was approved before the discussion by the ED EG, hence it is concluded this restriction was not a result of the group's work.

Table 8. Overview of the Er	ndocrine Disrupt	tors Expert Group
(Situation as o	of 5 February 20	)22).

	Group assessment outcome	No. of substances	SVHC identification	Risk management implemented
	ED for human health	3	2	0
	ED for environment	5	2	0
Group review com- pleted	ED for both	7	4	1 22
21 (20%)	Not found to be an ED	4		
	Inconclusive	2		
	SEv	41		
Under development 84 (80%)	Biocides regulation	23		
	Other regulation	6		
	Postponed	14		
	TOTAL	105		

<sup>22</sup> Bisphenol A is counted only once despite having been identified as ED for human health and ED for Environment separately



#### 3.3.3. Main bottlenecks

The main bottleneck is again the **chronic lack of** essential hazard information withheld by industry. Registrant firms routinely fail to characterise hazards of their chemicals, hampering the work of expert groups. This reluctance to cooperate, at no cost to firms in terms of market access, then requires officials to begin extremely lengthy and burdensome processes to fill the data gaps in SVHC identification, principally Compliance check and SEv.

The data also shows that subsequent risk management of substances identified as SVHC is extremelly slow and inefficient.

#### 3.3.4. Conclusions and Recommendations

Expert groups offer inefficient support to the MSC on SVHC identification, in particular in relation to the 'delivery' of regulatory action. The main reason for their failure is once again the lack of information in registration dossiers. The interplay between expert groups and the MSC should be optimised. During the REACH revision, the EU should:

- Introduce a deadline within which expert groups need to conclude their assessments.
- Allow SVHC identification based on structurally related groups of chemicals.
- Update the standard information requirements for Dossier Registration under REACH, so that all data needed for SVHC identification and CLH is available, before market access is given.
- Obligate the implementation of risk control measures within one year of SVHC identification.

# 4. Assessment of Regulatory Needs (ARNs)

After a chemical is assessed and found to be a threat for health or the environment, authorities perform the <u>Assessment of Regulatory Needs</u> (ARN), previously called Risk Management Options Analysis (RMOA), to assess whether regulatory action is necessary to bring under control the substance, and to identify the most appropriate measures to do so.

ARNs are carried out by Member States or ECHA on a case-by-case basis. Although ARN discussion is voluntary, it has no legal standing, it is a pillar of ECHA's regulatory strategy. ECHA has tracked ARN discussions since 2011, a period covering 349 entries, relating to 263 unique substances or groups.

#### 4.1. Process

For ECHA, an ARN could find that the "generation of further information and assessment" is needed or that conclusions can be taken immediately. In the latter case, the following measures can be taken:

- Harmonised classification and labelling (CLH)
- Restriction: a condition on the use of chemicals (includes bans in use, import and manufacturing)
- Authorisation, which aims at the phase-out and substitution of substances of very high concern. The process includes the following steps:

- Identification as a substance of very high concern (SVHC)
- Recommendation by ECHA of SVHCs to be included in the Authorisation List (Annex XIV) by the Commission
- Inclusion in the Authorisation List by the Commission, which sets a deadline for ending the use of the SVHC if authorisation is not granted
- An authorisation process, for specific uses only (applications for authorisation or AfAs)
- Other measures, such as occupational exposure values.

#### 4.2. Timeliness

Of the 349 entries under the ARN database, the fastest ARN conclusion took less than a month. The median duration was one year and eight months and the longest was ten years and 11 months (table 9).

Shortest duration (substance)	Median duration	Longest duration (substance)
<b>Under a month</b> (1,3-propanesultone)	One year and eight months	<b>Ten years and 11 months</b> (2-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol) (not concluded)

#### Table 9: ARN timeliness<sup>23</sup>

An ARN could aid the regulation of specific substances. Of the 349 ARNs tracked by ECHA since 2011, 243 were concluded. Most concluded assessments (123 entries, 35%) took less than a year while 106 (30%) are ongoing, this is, the conclusion remains pending (figure 3).

While 106 chemicals are pending, they retain market access. Looking at the time ARNs are pending for, we have assumed the 30% ARNs that await assessment (pending) were concluded in February

2022. Most (30 entries) have been waiting for one year, but some are waiting for eight (12%, 13 entries) to ten years (3%, three entries). (Figure 4)

To carry out an ARN, can take as little as a month but in other cases, it can take years. There are 68 ARNs that started before 2020 and were not concluded by May 2021. However, the conclusion of an ARN does not mean that recommended measures will be taken in a timely manner.



Figure 3. Time between date of intention and

<sup>23</sup> For substances that still do not have a Decision from the Commission, the analysis was performed using a hypothetical decision date (01/03/2022).

The ARNs performed in the last 11 years have resulted in the restriction of two chemicals and one substance of very high concern included in the Annex XIV. It can take over ten years from an ARN's intention to the entry into force of a risk management measure (Restriction or Sunset date). The most efficient follow up process of ARNs seems to be the identification of the chemical as an SVHC (table 10).



Figure 4. On	going ARNs: Tim	ne between t	he date of	intention a	nd
h	ypothetical conc	lusion date (	(01/02/202	22)	

Table 1	10. Overv	view of the	ARN co	onclusions	Situation	as of 28	R Mav	2021
Tuble 1				sinctusions.	Situation	43 01 20	J 1110 y	2021

ARNs	Ongoing	Risk Management Measure recommended	
364	106	191	
		CLH	14
		SVHC	97
		Restriction	62
		Other risk management measures	85
		No action needed	67

#### 4.3. ARN outcomes for CLH

Table 11 shows the timing for inclusion in the CLH for the substances that underwent an ARN process. As can be seen, **out of the 14 substances for which CLH was recommended in the last eleven years, since 2011, referred to the Commission, only for one of those substances a harmonised classification came into force**.

Substance	CAS number	Date of registry of ARN inten- tion	CLH process started	CLH into force	Time since ARN (months)
2,4,6-trimethyl-2,4,6-tris (3,3,3-trifluoropropyl) cyclotris- iloxane	2374-14-3	18/07/2011	no	No	123 (10 years and 3 months)
Tris(2-methoxyethoxy)vinylsilane	1067-53-4	18/03/2013	yes	No	111
Pentasodium (carboxylatometh- yl) iminobis(ethylenenitrilo) tetraacetate	140-01-2	02/05/2013	Yes	No	103
N-carboxymethyliminobis (eth- ylenenitrilo) tetra (acetic acid)	67-43-6	02/05/2013	yes	No	103
Nitric acid	7697-37-2	10/09/2013	yes	Yes	39
[4-[α-[4-(dimethylamino)phenyl] benzylidene]cyclohexa-2,5-dien- 1-ylidene]dimethylammonium acetate	41272-40-6	10/12/2013	no	No	94
(-)-pin-2(10)-ene	18172-67-3	10/12/2013		No	94
4,4'-[2,2,2-trifluoro-1-(trifluo- romethyl)ethylidene]diphenol; bisphenol AF	1478-61-1	18/08/2015	yes	No	74
4,4'-methylenediphenol	620-92-8	18/09/2015	no	No	74
Tetrafluoroethylene	116-14-3	31/01/2017	yes	No	57
Resorcinol; 1,3-benzenediol	108-46-3	29/08/2017	yes	No	50
p-phenylenediamine	106-50-3	01/04/2015	no	No	78
Calcium cyanamide	156-62-7	14/02/2018	no	No	44
Barium chromate	10294-40-3	05/03/2018	no	No	43

#### Table 11. The time between the ARN intention and entry into force or until October 2021
#### 4.4. ARN outcomes for SVHCs

Table 12 shows the time between the ARN start to inclusion in the Candidate List. **75% of the substances recommended by an ARN to be included in the Candidate List, ended up in the list in about two years.** Although SVHC inclusion in the Candidate List is the most efficient ARN process, two years remains a rather long time, taking into account that these are highly hazardous chemicals that remain on the market.

	ARNs rec- ommending substitution	ldentified as SVHC (in Candidate List)	Average months for SVHC inclu- sion	Intention	Not started	ldentification rejected	Withdrawn by dossier submitter
all	97	73	22,9	5	15	1	3
2011	1	1	73	0	0	0	0
2012	2	2	50	0	0	0	0
2013	2	2	54	0	0	0	0
2014	13	10	30,1	0	0	1	2
2015	23	22	24,3	1	0	0	0
2016	16	13	21,5	0	2	0	1
2017	4	4	13	0	0	0	0
2018	15	14	15	0	1	0	0
2019	18	5	13,8	2	11	0	0
2020	3	1	11	1	1	0	0

#### Table 12. Summary of ARNs published by ECHA as of May 2021

#### CASE STUDY: 2-(2H-benzotriazol-2yl)-4-(tert-butyl)-6-(sec-butyl)phenol – 11 years from initial concerns to sunset date of an SVHC

2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) is a UV filter that was used in sunscreens and a UV stabiliser for plastics (such as polycarbonate and polyester). The substance was believed to be of very high concern for the environment due to its persistence and bioaccumulation. It is unclear in which products it is used and if UV-350 is used in the EU in relevant amounts. However, a large portion of UV-350 would inevitably end up as marine pollution from suncream. So Germany nominated it for the Candidate List in 2012 (figure 5). That failed, so in 2015 Germany prepared an ARN for UV-350 that confirmed the need to list it as an SVHC based on the same hazard properties. The same year, the substance was included in the Candidate List. Two years later, ECHA recommended its inclusion in REACH Annex XIV. The Commission stalled for three years until finally agreeing to the listing, with a sunset date of 27 November 2023.

This example demonstrates that even if every single process is not subject to excessive delays, the sum of all processes together amounts to a considerable 11 years, from the first intention published in 2012 to the effective ban in 2023. It demonstrates the need for a reform of REACH to speed-up the overall process.



Figure 5. Timeliness of UV-350 phase out process

#### 4.5. ARN outcomes for Restriction

Table 13 shows that out of the 59 substances that have been prioritised for Restriction by an ARN, only five substances are subject to restrictions, while 12 await entry into force. Counting from the ARN recommendation, to entry into force, **the fastest restriction on record took no less than six years, while the slowest case has taken a full decade**, as illustrated in table 14.

	Restriction recommended by ARN	Restriction Not started	Restriction agreed but pending entry into force)	Restriction into force	Restriction re- jected by the Commission	Restriction proposal ongoing	Restriction withdrawn by dossier submitter
all ARNs	59	16	12	5	1	13	13
2011	2	1	0	1	0	0	0
2012	0	0	0	0	0	0	0
2013	7	0	7	0	0	0	0
2014	6	1	1	4	0	1	0
2015	7	2	3	0	1	1	0

#### Table 13. Restriction state following an ARN recommendation

#### Table 14. Slowest and quickest restrictions triggered by an ARN process

	Substance	ARN begins Intention	ARN con- clusion(s)	Restric- tion begins intention	Restric- tion proposal	ECHA opinion	Com- mission's decision	Entry into force	Total time
Slowest	1,3-bis(1-iso- cyana- to-1-methy- lethyl)benzene (Diisocyanates group restric- tion)	July 2011	Septem- ber 2014	October 2015	February 2017	March 2018	August 2020	February 2022 / August 2023	12 years (120 months)
Quickest	Trimethoxy(3, 3,4,4,5,5,6,6,7 ,7,8,8,8-tride- cafluorooctyl) silane	April 2014	February 2015	November 2014	October 2015	June 2017	June 2019	January 2021	6 years and 9 months (81 months)



#### 4.6. Main bottlenecks

Long delays occur due to the lack of deadlines. The process is also inefficient and its implementation is unpredictable since the conclusion of an ARN does not oblige competent authorities to perform the recommended control measures, nor provide any deadline for doing so.

#### 4.7. Conclusions and Recommendations

ARNs have resulted in just three controlled chemicals out of 349 chemicals assessed in the last 11 years. The process of assessing regulatory needs has taken the authorities as little as less than a month to a decade. This means that if ARNs were fast enough, they could potentially be a useful tool to support the authorities to make the right decision on how to better control chemical threats. However, if they take several years, they become a hurdle that is slowing down the system. Moreover, the conclusion of an ARN does not mean that the recommended measures will be taken at all or in a timely manner.

Mandatory ARNs could potentially speed up the system if:

- They would be completed within six months.
- The ARN conclusions triggered an obligation for the authorities to act (which is not the case today)
- They were generic and carried out for those substances currently classified by ECHA as 'not assigned'.

# 5. Hazard identification and communication

Hazard identification is the initial process that can trigger the risk management of chemicals. It obliges companies to communicate hazards to supply chains. There are two processes under which chemical hazards are legally identified: the <u>harmonised classification and labelling</u> under Annex VI of Regulation 1272/2008 (the CLP Regulation) and the <u>SVHC identification</u> under Title VII of REACH (the Candidate List).

The two processes have different objectives. Harmonised classification helps in the trading of chemicals by providing them a harmonised system of classification which is common also outside the EU.<sup>24</sup> SVHC identification is a step towards phasing-out chemicals that, due to their intrinsic properties, are of very high concern to human health and/or the environment.

#### 5.1. Harmonised classification and labelling

The CLP Regulation aims to harmonise the way industry classifies individual chemicals or mixtures to downstream users. It establishes in its Annex VI a list of substances with harmonised mandatory classifications, labelling and packaging standards (CLH).

#### 5.1.1. Process

Industry or national officials suggest new classification of chemicals for the CLP harmonised classification list to ECHA. Entry to the list triggers automatic risk management when critical hazards have been identified by the Commission e.g. the substance is carcinogenic, mutagenic or reprotoxic (CMR) and uncontrolled or unacceptable exposure is expected, e.g. the substances are used in certain consumer products or pesticides.

Figure 6 gives an overview of the CLH process and how long it takes. The process starts with a <u>registry of intention</u>, then ECHA gives an opinion. At the end of the process, the Commission takes the final decision and dates the entry into force.



#### Figure 6 . Overview of the CLH process from the registry of intention to entry into force.

#### 5.1.2. Timeliness

The regulation has clear deadlines for ECHA to finalise its opinion. However, there is no specific deadline for the Commission to take a decision. The CLP requires it to draft a proposal "without undue delay", but only when it considers classification and labelling "appropriate". After assessing all 361 substances that have been through the CLH process since 2008, this report finds that the median time between the date of CLH intention to entry into force of Commission's decisions has been five years and nine months and the longest time was 11 vears and ten months (table 15). The median time the Commission concedes to companies to implement the CLH measures from the ATP publication until the entry into force is 21 months. This represents a disturbing failure by regulators because of health and environmental implications of such long periods of time lost.

What stands out from the table 15 and examples in table 16 is that from the date ECHA agrees a scientific opinion, **it takes the EU no less than three years and nine months to adopt a classification**, even in such straightforward files given that CLP decisions are purely based on scientific evidence, that is to say hazard factors, there is little to no room for political considerations. The Commission's failure to act in good time is not properly justified.

#### 5.1.3. Main bottlenecks

The fact that the legal text includes no deadline on the Commission to finalise decisions slows down the process considerably. In addition, the Commission also

CLP process	Shortest duration (substance)	Median duration	Longest duration (substance)	Main bottleneck	Main problem
СГН	<b>3 years and 9</b> months (tetrakis(2,6-dimeth- ylphenyl)-m-phenyl- ene biphosphate)	5 years and 9 months	<b>11 years and 10</b> <b>months</b> (CU-HDO (Bis(N-cy- clohexyl-diazeni- um-dioxy)-copper))	Commission	Delay in taking decisions and long transitional periods

## Table 16. Timeline for selected CLH processes from the date of intention toCLH proposal to entry into force

Substance name	CLH Intention	ECHA opinion	Commission decision	Entry into force	Total time
Diisobutyl phthalate	26/07/2013	04/12/2014	19/07/2016	1/03/2018	54 months
PFOA	26/06/2009	02/12/2011	02/10/2013	01/01/2015	66 months
Pitch, coal tar, high temp	11/01/2010	21/11/2011	02/10/2013	01/04/2016	75 months
Titanium dioxide	17/03/2015	14/09/2017	04/10/2019	09/09/2021	66 months
Formaldehyde	10/06/2008	30/11/2012	05/06/2014	01/04/2015	82 months

gives **exceedingly long entry into force dates, which are not justified.** Furthermore, the Commission's discretion over scientific decisions that are based on technical factors does not justify the large amount of time it takes to decide classification and labelling.

#### 5.1.4. Conclusions and Recommendations

The Commission gives firms years of extra time in which to continue using hazardous chemicals without warning downstream users about these hazards, through maladministration. It has, therefore, turned a scientific process, as defined in the law, into a political one. This 'delay policy' favours economic over human health and environmental interests.

- The ECHA's Executive Director should decide on CLH, as this is purely a scientific matter.
- Otherwise, the Commission should approve ECHA scientific opinions without delay, as this is purely a scientific matter.
- A substance or group of substances should be classified within six months of ECHA's opinion.

#### 5.2. SVHC identification

The identification of SVHCs is the first step towards the process of phasing out the most hazardous chemicals, where there are safer alternatives or where the risk of using the substance outweighs the benefits. SVHCs are CMRs, PBT or vPvB or substances with a similar level of concern to these, such as EDCs, respiratory sensitisers or substances that are Persistent, Mobile and Toxic (PMT). Once identified, a substance enters the Candidate List that will "eventually" be included in Annex XIV and be subject to the Authorisation process, meaning that they may be authorised under strict conditions and subject to a sunset clause for ultimate elimination. In addition, SVHCs must be tracked in products, and information about their presence must be disclosed in supply chains, including to consumers.

#### 5.2.1. Process

The Commission can ask ECHA to examine a substance to check if it is an SVHC, or a Member State can begin the process by preparing a dossier with the SVHC proposal. For CMR substances with a harmonised classification and labelling under CLP the dossier may be limited to a reference to the CLP entry. A 45-days consultation is carried out to collect data on whether the substance fulfils the REACH article 57 criteria for SVHC identification. If there are no objections at this stage, the substance is included directly in the Candidate List. The body responsible for SVHC identification is the <u>Member State Committee</u> (MSC) of ECHA. If the MSC reaches an unanimous agreement, the substance is added to the Candidate List. If not, the matter is referred to the Commission, further delaying the process. This means that even just one vote can prevent or delay a listing.

#### 5.2.2. Timeliness

SVHC identification is the most efficient and effective process under REACH, taking six months from the registry of intention to inclusion in the Candidate List. 224 substances are now on the Candidate List. This report notes that, with time, the process has become much quicker and every year it takes less time, on average, to conclude.

The procedure for identifying SVHCs is quick, and the consequences of being listed as a Candidate for substitution are immediate. The shortest time between date of intention to identify the chemical as SVHC to inclusion in the Candidate List is three months, the median six months and the longest case took three years and seven months (table 17).

However, by looking into the number of SVHCs added to the Candidate List per year, the process is terribly slow. In 2010,

Table 17. SVHC identification timeliness. From the date of intention of SVHC identificationto the date of inclusion in the Candidate List by ECHA

REACH process	Shortest duration (substance)	Median duration	Longest duration (substance)
SVHC identification	<b>Three months</b> (Dichromic acid)	Six months	Three years and seven months (Nonadecafluorodecanoic acid)

industry Commissioner Tajani and environment Commissioner Potočnik committed to having "all relevant currently known SVHCs included in the candidate list by 2020." The Commission in 2001 estimated that around 1,400 SVHCs (5% of registered substances) are causing serious human or environmental harms and should be curbed through the Authorisation regime. Today, two years after their deadline, only 224 are on the Candidate List<sup>25</sup>. **At the current pace of 16 SVHCs in the Candidate List per year, meeting the goal will take the EU another 73 years.** 

#### 5.2.3. Main bottlenecks

The only bottleneck in the process is the unusual case in which unanimity is not reached for the identification of a chemical as SVHC by MSC. In the past five years this happened only for one substance, while 51 substances were added to the Candidate List within the six months process, as average.

#### 5.2.4. Conclusions and Recommendations

The Candidate List is an important hazard communication tool for downstream users and consumers about the unwanted properties of these chemicals, it also helps companies to predict on the chemicals that will eventually be set for phase out. The Candidate list is also a driver of substitution, the main goal of the Authorisation process by encouraging companies to replace SVHC with safer alternatives. To better contribute to the substitution goal, the REACH reform should facilitate the process of including substances in the Candidate List. Member States and the Commission should also speed up the inclusion of SVHCs in the Candidate List.

- Where files are referred to the Commission, they should be resolved within six months of ECHA's opinion.
- Introduce a target by which all CMRs with CLH are introduced in the Candidate list.
- Consider self-classified chemicals by companies for direct inclusion in the Candidate list.
- Promote the group approach to identification of SVHCs and its inclusion to the Candidate list as the default option to increase efficiency and avoid regrettable substitution by companies substituting SVHCs by chemicals within the same chemical group, hence with similar properties.
- Commit to a minimum number of proposals of SVHC in the Candidate List. Member States with limited resources could make use of Article 59 to submit proposals of SVHC with a harmonised classification while Member States with greater resources could focus on substances of equivalent level of concern under Article 57(f) such as EDCs.
- In the upcoming revision of the REACH Regulation, avoid the introduction of additional delays. If harmonised classification is required prior to SVHC identification, the SVHC identification of EDCs, PBT/vPvB, and PMT/vPvM substances will be further delayed compared to the current situation. Therefore, we recommend keeping the current process for SVHC identification of these hazard classes with the MSC.

# PART II.

Acting on harmful chemicals

## 6. Risk Management

The main tools under REACH for reducing exposure and phasing out hazardous chemicals are the Restriction and the Authorisation processes. When a chemical is restricted through either channel, it is *de facto* recognition that a highly hazardous substance was not properly controlled at dossier registration phase, but instead given permission for unrestricted use. This is the institutionalisation of 'no data, no problem'.

Under Authorisation, SVHCs may only be permitted for specific uses. The ultimate goal of Authorisation is phase-out and substitution of SVHCs.

Restrictions aim to prohibit or limit the use or presence in goods of chemicals. They are designed to act as a safety net to manage Community-wide risks that are otherwise not adequately controlled and pose an unacceptable risk to health or the environment. Restriction can ban chemicals completely, but this has only been applied to 4<sup>26</sup> out of 71 restricted substances<sup>27</sup>. In most cases, restrictions limit a substance's use.

The restriction and phase out of the chemicals of most concern is a cost-effective process meaning that the benefits for society and the environment largely outweigh the costs<sup>28,29</sup>. Yet there remain on the market about 2,000 substances with well-known adverse effects.

#### 6.1. Overall Authorisation

The Authorisation process tries to limit the harms caused by SVHCs and aims to phase them out through the Authorisation list (Annex XIV).

#### 6.1.1. Process

Figure 7 gives an overview of the full Authorisation process. First, a <u>registry of in-</u> <u>tention for an SVHC</u> identification is triggered by Member States or ECHA on behalf of the Commission. Later it may be identified as an SVHC and added to the <u>Candidate List</u>, the Authorisation process also includes the <u>recommendation</u> by ECHA to include the SVHC from the Candidate List to <u>Annex XIV</u> accompanied by an opinion of ECHA's Member State Committee (MSC). For performing such recommendation, ECHA must prioritise substances based on a substance's intrinsic properties,

<sup>&</sup>lt;sup>26</sup> Polychlorinated terphenyls (PCTs), asbestos fibres, pentachlorophenol and its salts and esters, and monomethyl-tetrachlorodiphenyl methane
<sup>27</sup> By July 2022

<sup>28</sup> https://echa.europa.eu/documents/10162/17228/costs\_benefits\_reach\_restrictions\_2020\_en.pdf/a96dafc1-42bc-cb8c-8960-60af21808e2e

<sup>&</sup>lt;sup>29</sup> https://echa.europa.eu/documents/10162/17231/causal\_analysis\_reach\_authorisation\_en.pdf/36c6b6e9-486e-14e5-0843-5894dce69e28?t=1636465274783

wide dispersive use or production volumes. After that, the Commission decides on the inclusion of an SVHC in Annex XIV. Finally, companies can start an Application for Authorisation (AfA), ECHA gives an opinion for each AfA and only the Commission decides if they grant them an authorisation or not.

#### 6.1.2. Timeliness

Table 18 shows that **the overall Authorisation** (from SVHC intention to Commission decision for Applications for Authorisation) **lasts six years and two months in the shortest case, while the median time is nine years and three months and the longest duration can be 13 years and six months.** 

Figure 7 . Overview of the Authorisation process from the registry of intention of an SVHC identification to the Commission's decision.



### Table 18. Duration of the overall REACH Authorisation process. From the date of intentionof SVHC listing to the date of entry into force of the Commission's decision<sup>30</sup>

REACH process	Shortest duration (substance)	Median duration	Longest duration (substance)
Authorisation	<b>6 years and 2 months</b> (Bis(2-ethylhexyl) phthalate)	9 years and 3 months	<b>13 years and 6 months</b> (Sodium dichromate)

<sup>30</sup> For substances that do not yet have a Commission decision date, the analysis was conducted using a hypothetical decision date (01/03/2022)

#### 6.2. Inclusion in Annex XIV

#### 6.2.1. Process

At least once every two years, ECHA identifies substances that should be prioritised for inclusion in Annex XIV. It consults with the public for three months about the recommended substances. ECHA prepares a recommendation, considering the comments received during the consultation as well as the Agency's capacity to handle authorisation requests by applicants that must be considered, according to the legal text. The MSC prepares an opinion on ECHA's recommendation that is sent to the Commission together with the recommendation.

However, the Commission can ask ECHA to withdraw an SVHC from its recommendation list without public explanation. Once ECHA sends its recommendation to the European Commission, the Commission is responsible to make a decision. However there is no obligation from the Commission to add all proposed chemicals in the Annex XIV nor to disclose on what grounds the recommendation from ECHA is dismissed.

#### 6.2.2. Timeliness

ECHA takes a median time of 24 months for developing a recommendation on inclusion of SVHCs in the annex XIV of REACH. This report finds that **the shortest time between a recommendation and inclusion in Annex XIV was one year and one month, while the median took one year and 11 months and the longest case took 12 years and nine months** (table 19).

There are currently<sup>31</sup> 59 SVHCs included in Annex XIV in the last 13 years, since 2009 (table 20). Of the 99 SVHCs recommended for inclusion by ECHA, 40 have not yet been included in Annex XIV. At the current pace of four SVHCs in the Annex XIV per year, we will have to wait over 336 years before the estimated 1,400 SVHCs are controlled through the Authorisation regime.

Although the process for recommending substances for inclusion on Annex XIV by ECHA is smooth and straightforward, the Commission is critically delaying the decisions needed to add SVHCs in the Authorisation list. The timespan between recommendations varied between 12 to 20 months.

REACH Annex XIV	Shortest duration (substance)	Median duration	Longest duration (substance)
From Annex XIV recom- mendation (by ECHA) to inclusion in Annex XIV (by Commission)	<b>1 year and 1 month</b> (Diarsenic trioxide)	1 year and 11 months	<b>12 years and 9 months</b> (SCCP) (not concluded)

#### Table 19. Duration to include an ECHA recommendation into Annex XIV.

So far, 10 recommendations have been issued<sup>32</sup>, recommending 99 (groups of) substances for inclusion in Annex XIV. Although the Commission included only 59 in the Annex.

The Commission has demanded ECHA to exclude SVHCs from its recommendations as well as used its powers to not include in Annex XIV all substances recommended by ECHA. Lead compounds have been withdrawn from initial recommendations and remain "to be re-assessed in the following round" by ECHA for years. Lead compounds are extremely harmful chemicals that can affect every organ and system in human bodies, having particularly damaging impact on children, potentially causing behaviour and learning problems, lower IQ and hyperactivity to the children exposed. Fifteen lead compounds have been initially recom-

Date of recommendation	Number of SVHCs recommended for annex XIV inclusion	Added to Annex XIV	Delay	Substances dismissed by the Commis- sion from ECHA recommendation (not included in annex XIV)
1 <sup>st</sup> (1 June 2009)	7	1st (17 Feb 2011)	20 months	SCCP
2 <sup>nd</sup> (17 Dec 2010	8	2nd (14 Feb 2012)	13 months	-
3 <sup>rd</sup> (20 Dec 2011)	13	3rd (17 Apr 2013)	15 months	5 Cobalt salts
4 <sup>th</sup> (17 Jan 2013)	10	4th (14 Aug 2014)	18 months	DMAC
5 <sup>th</sup> (6 Feb 2014)	5		40 months	DMF, ADCA, Al-RCF and Zr-RCF
6 <sup>th</sup> (1 July 2015)	15	5th (13th June 2017)	23 months	4 borates
7 <sup>th</sup> (10 Nov 2016)	9		38 months	4 lead compounds
8 <sup>th</sup> (5 Feb 2018)	7	6th (6 February 2020)	24 months	NMP
9 <sup>th</sup> (1 Oct 2019)	18	9th (22nd April 2022)	31 months	7 lead compounds, BPA, Dechlorane Plus, HHPA, MHHPA, EGEE, EGME.
10 <sup>th</sup> (14 Apr 2021)	7	Pending		
Total	99			33

#### Table 20. Inclusion of SVHCs in Annex XIV. Situation as of June 2022

<sup>32</sup> by June 2022

mended for inclusion in Annex XIV, 11 of them are still not included.

Table 20 shows that 33 substances have been dismissed by the Commission from recommendations from ECHA such as short-chain chlorinated paraffins (SC-CPs), extremely persistent chemicals that have been excluded from ECHA's recommendation since 13 years ago. Another example is 5 cobalt salts recommended by ECHA for inclusion in Annex XIV in 2011.33 ECHA recognises that these substances cause cancer, are toxic to reproduction and put factory workers at high exposure. The Commission decided not to include these substances in the Authorisation List and committed to restrict their use. Instead of following ECHA's advice, the Commission provided a process less burdensome for the companies using the substances, at the price of public and workers health. An opinion on the restriction proposal was finalised by ECHA in September 2020, but after a year, the Commission has not yet decided on the proposal, so cobalt salts remain uncontrolled on the EU market.<sup>34</sup>

Others are likely to be permanently shielded from Authorisation by the Commission, such as Bisphenol A, a known endocrine disrupter, found in the blood of almost all Europeans on a near constant basis that was recommended for inclusion in 2019.

Figure 8 shows that of 165 SVHCs to Annex XIV (corresponding to 99 entries), 45 (27%) are still awaiting Commission approval. Of the 120 validated substances by the Commission, most of them, 48% (80)



<sup>33</sup> ECHA recommendation of 20 December 2011 for the inclusion of substances in Annex XIV, Retrieved from: <u>https://echa.europa.eu/documents/10162/22d19030-4756-4c95-b120-7c582e1335c6</u>
<sup>34</sup> The restriction timeline can be viewed here: <u>https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e181d575c8</u>

took a year before Commission approval, the rest were waiting for inclusion for two and three years. This means that **for a process that could be almost automatic since it is mainly science based, the Commission took from one to thirteen years to deliver a decision.** 

In order to assess for how long SVHCs remain in the waiting list for Authorisation from the date of ECHA's recommendation, we have established an hypothetical date (02/06/2022) of inclusion in Annex XIV (figure 9). Seven SVHCs (16%) have been waiting for less than a year but the majority (18 SVHCs, 40%) are currently waiting for two years. The other substances remain awaiting for longer, up to 13 years since the date of recommendation for inclusion in Annex XIV.

Figure 9. The time between the date of ECHA's recommendation and hypothetical date (02/06/2022) of the Commission's decision.



#### CASE STUDY. Bisphenol A, the first known endocrine disruptor, still broadly marketed.

BPA was first invented in 1891 but only in the 1930s its toxicity as an artificial oestrogen was discovered since BPA was considered as a potential pharmaceutical hormone (i.e. an intentional endocrine disruptor). But a more potent synthetic oestrogen called DES was invented in 1938, precluding the use of BPA. In what should have been a warning signal to the potential toxicity of BPA, DES was taken off the market when it was linked to reproductive cancers in babies born to mothers taking the chemical. Not suitable as a pharmaceutical, BPA was successively used by the chemical industry as a monomer in the manufacturing of polymers (eg, polycarbonate and epoxy resins).<sup>35</sup>

BPA is currently one of the world's best selling chemicals. In Europe, up to one million tonnes per year are used today. It is widely found in consumer products, including sensitive ones like toys, reusable water bottles, and food and beverage can linings. It is also present in the blood and urine of almost all Europeans. Human exposure is a widespread problem at concentrations that exceed the tolerable daily intake (of 0.04 ng per kilogram body weight per day) recently proposed by EFSA, which lowered the 'safe limit' by 100,000 times. Nineteen years ago (2003) (figure 10), before REACH, the assessment of Bisphenol A (BPA) started. In 2012, it was included in the CoRAP list. Five years later, its evaluation occurred, and BPA was included in the SVHC list due to its endocrine disrupting effects in humans and reprotoxicity. In 2018, BPA was also recognised as an endocrine disruptor for the environment.

Since the inclusion of BPA as an SVHC in the Candidate list, PlasticsEurope attempted to take BPA off this list by taking ECHA to court. PlasticsEurope has lost all appeals so far. Also the final attempt to block SVHC listing of BPA as endocrine disruptor for humans by contesting the court's decision was claimed as unjustified by the European Court of Justice. The unjustified claims made by industry cost a lot of public resources and demonstrate industry's desperate attempts to keep an SVHC on the market.

In 2019, ECHA recommended including BPA in Annex XIV. As of today, BPA's listing remains blocked by the Commission, which decided to further postpone the decision arguing that BPA will be proposed for restriction together with related bisphenols by Germany. At the current pace, it is unlikely that measures to manage the risks of BPA will be in force before 2024, 12 years after its first inclusion into the CoRAP list and more than 20 after its identification as a priority chemical for phase-out. Currently, only minor use of BPA (thermal paper) is de facto restricted in Europe. By October 2022, Germany plans to submit a restriction<sup>36</sup> for BPA and all other bisphenols.

<sup>&</sup>lt;sup>35</sup> Lessons learned from early warnings, EEA: <u>https://www.eea.europa.eu/publications/late-lessons-2/late-lessons-chapters/late-lessons-ii-chapter-10/view</u> <sup>36</sup> https://echa.europa.eu/es/registry-of-restriction-intentions/-/dislist/details/0b0236e1853413ea



#### 6.2.3. Main bottlenecks

REACH requires ECHA to recommend SVHCs for inclusion in Annex XIV at least once every two years. This is too long and slows down the system without good reason. **ECHA has demonstrated that, in practice, more frequent updates are possible.** 

Another major bottlenecks are the Commission's power to ignore ECHA recommendations, the lack of deadlines to act on the ECHA recommendation, and the absence of obligation to justify why some substances from the recommendation are ignored.

#### 6.2.4. Conclusions and Recommendations

Despite the Commission's obligation to protect human health and environment and the high costs of inaction, the Commission's failure to act results in years of unnecessary public and environmental exposure to substances of very high concern. These are substances that either persist in the environment for extremely long time, are manufactured in high volumes or are widely used in products or industrial processes. Whether intentional or not, these long delays allow the chemical industry to continue using SVHCs. The EU can address this problem, but action is needed to:

- Introduce a six months deadline for the Commission to introduce SVHCs in the Annex XIV. If this deadline is not met, substances on the Candidate list should move automatically to Annex XIV.
- Revise REACH Article 58.3 to require annual recommendations based on an MSC majority by ECHA.
- Eliminate ECHA's workload consideration for recommending SVHCs, as currently allowed by Article 58.3. Resources consideration may encourage the prioritising of substances with fewer uses and users rather than substances with a higher number of uses which are more problematic for human health and the environment. SVHCs should be prioritised for a ban regardless of ECHA's capacity optimisation.

Ensure ECHA has the resources it needs to deal with peaks in authorisation requests. ECHA could raise fees linked to Authorisation applications to ensure it has adequate resources to process them. The application of the Chemicals Strategy for Sustainability's essential use concept as a filter to directly ban non essential uses would also reduce the number of applications for authorisation. The number of AfAs can also be reduced by limiting Authorisation to one route, only for downstream users and individual or collective applications for similar uses.

#### 6.3. Applications for Authorisation

When an SVHC is added to Annex XIV, a deadline is set after which it cannot be used, unless it is subsequently authorised for use in limited circumstances.

Annex XIV substances have a sunset date, after which they are totally banned, forever. But firms can continue using them if they apply for authorisation before the sunset date and the Commission grants a use permit. Due to their highly hazardous nature, an authorisation can only be granted when there is proof than an SVHC is either adequately controlled, i.e. the exposure is reduced to as low level as possible, or when there is a societal benefit from the use of the substance. Authorisation must be refused if other suitable substitute exist.

#### 6.3.1. Process

When companies apply for authorisation (AfA) (Art. 64), ECHA starts a public consultation to seek information on less harmful alternatives for the use(s) that the applicant has solicited. Within 10 months of the application, ECHA scientific committees must finalise a draft opinion. This is sent to the applicant, which has three months to comment. ECHA then has two more months to finalise its opinion. This is then sent to the European Commission that, within 3 months, must prepare a draft decision, either refusing or granting authorisation. However, the Commission has no deadline to finalise such decisions.

#### 6.3.2. Timeliness

The 10 months framework set by REACH is reasonable and manageable. However, REACH does not clarify the duration of the public consultation on alternatives nor the timing and the procedure to ensure that an application is completed (Art. 64(3)).

Based on all publicly available records spanning 10 years, this report finds that the shortest time between an ECHA opinion and Commission decision was four months, while the median time was one year and four months and the slowest case took seven years (table 21).

REACH AfA process	Shortest duration (substance)	Median duration	Longest duration (substance)
From ECHA's opinion to	<b>4 months</b>	1 year and 4 months	<b>7 years</b>
Commission decision	(Diarsenic trioxide)		(Bis(2-ethylhexyl) phthalate)

#### Table 21. Commission's delay for Applications for Authorisation

As shown by table 22, ECHA has so far delivered in due time almost 90% of the AfA opinions while the Commission has decided on half of them.

Figure 11 shows that from a total of 225 AfAs<sup>37</sup>, a majority (fully 42%, 94) await a Commision decision. Of the 131 applications, 14% (32 entries) took less than a year, while 33% (75 entries) took a year, 6% (13) took two years, while the rest took three to four years.

In order to estimate the waiting time of 94 pending AfA decisions, we have assumed an hypothetical date (01/03/2022) of the Commission's decision for those. Figure 12 shows that most (60%, 56) of the applications are kept on hold for one year while many (28%, 26) for less than a year. The most notable example of the Commission favouring a company by not deciding is that of DEHP application, which has been pending for 7 years so far.

#### Table 22. REACH AfAs efficiency. Situation as of February 2022

REACH process	Timeline (No. years)	Number of AfAs (ap- plicants)	ECHA opinions finalised (%)	Number of decisions taken by Commision (% of adopted ECHA opinions)
AfAs	2012-2022	225 AfAs submitted	352	199
	(10 years)	(396)	(89%)	(50%)





<sup>37</sup> Situation as of February 2022





#### 6.3.3. Main bottlenecks

The European Commission is yet again the main hurdle to swift protection of public health and the environment. Because REACH only requires the Commission to prepare a draft decision for AfAs, decisions can be kept permanently in limbo.

#### 6.3.4. Conclusions and Recommendations

In the absence of Commission decisions, substances of very high concern are in effect permitted to remain in use for years, despite being recognised as the single most hazardous category of chemicals. In the meantime, applying for authorisation (before the latest application date) allows the applicant to continue using the substance normally for a year until a decision is reached, a dangerous legal limbo. REACH should be fixed so:

 The Commission is obliged to adopt AfA decisions within six months. A binding act like final adoption would open the right of interested parties to initiate a court case.

 If the Commission fails within this time period, marketing of SVHCs should be suspended once the established sunset date set in Annex XIV is reached. The current situation favours market access over hazard protection, since, in the absence of a decision, the use of a substance of very high concern is allowed, rather than taking a more protective approach to prevent exposure of potentially harmful chemicals.

#### 6.4. REACH Restriction

Restrictions are a tool to control substances that officials believe are posing an unacceptable risk to human health or the environment EU wide. Restrictions predate REACH and were formerly rooted in Directive 76/769/EEC. REACH explicitly aimed to accelerate the procedure.

#### 6.4.1. Process

A Member State or ECHA, at the request of the European Commission, can start the restriction procedure (figure 13). ECHA can make its own proposals, but only for restrictions on articles containing substances that are in Annex XIV.

A restriction proposal must be submitted to ECHA within 12 months of the process beginning (registry of intentions). ECHA checks the proposal for conformity and then consults the public for six-months. During this period, the risk assessment committee (RAC) and socio-economic analysis committee (SEAC) formulate their opinions within 12 months of the start of the first consultation on the restriction proposal. RAC evaluates "whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment" while SEAC evaluates "the suggested restrictions and the related socio-economic impact". Once adopted, SE-AC's opinion undergoes a 3-month public consultation to take into account the comments and socio-economic analyses submitted by interested parties, while RAC's opinion does not.

Both committees can be bypassed by Commission for CMRs (category 1A or 1B) used in consumer products, as per Article 68(2). The so-called '<u>fast-track</u>' Restrictions has only been used twice in the last 15 years<sup>38</sup>.



Figure 13. Overview of the Restriction process from the Registry of intention to Entry into force.

#### 6.4.2. Timeliness

Restricting harmful chemicals in Europe takes a median time of five years and seven months from date of intention to the date of entry into force. The fastest restriction on record took two years and four months while the slowest took 11 years and five months (table 23).

Instead of accelerating chemical restriction decisions, REACH has actually slowed them down. The previous and comparable restriction system limited the use of 58 substances or groups of substances over a 30 year period from 1976 to 2006. That amounts to 1.9 substances per year on average, compared to REACH's 13 new restrictions over 15 years, or 0.9 dossiers per year. REACH has also amended 22 of the previously existing restrictions, meaning that ECHA has processed a total of 35 restrictions. Table 24 shows that **23% of restriction proposals recommended by ECHA await the Commission's decision**.

Figure 14 shows that from a total of 35 REACH restriction entries amended or incorporated during REACH, **most of the substances (34%), awaited for three years from the start of the process to publication in the official journal.** 

Two notable examples of what the EEB considers illegal and unjustified delays are:

 Restriction of intentionally added microplastics in everyday products.
 EU's proposal to slash intentional microplastic pollution has been delayed by a whole year, due in May 2021.
 The delay, as revealed by an EEB and ClientEarth analysis, could have caused levels of pollution equivalent to the release of 1.6 billion plastic bottles into the environment every

Table 23. REACH Restriction timeliness from the date of the restriction
intention to entry into force

REACH process	Fastest restriction (substance)	Median duration	Slowest restriction (substance)
Restriction	<b>2 years and 4 months</b> (Cadmium and its compounds)	5 years and 7 months	<b>11 years and 5 months</b> (PFNA; PFDA; PFUnDA; PF- DoDA; PFTrDA; PFTDA; their salts and precursors)

#### Table 24. Efficiency of the Restriction process. Situation as of February 2022

REACH process	Timeline (No. years)	Number of restriction dossiers assessed	Number of restrictions waiting for conclusion (%)	Number of restrictions – decision taken
Restriction	2009-2022 (13 years)	35	8 (23%)	27 (77% of restrictions assessed)

**year**, leading to irreversible impacts on biodiversity and the environment that could potentially damage the health of Europeans.

Restriction of lead in PVC. The European Commission has put this plainly feasible and affordable restriction proposal on hold since February 2020, after the European Parliament objected to it, opposing notably the derogation

for recycled PVC in order to "protect public health and the environment". **After more than two years**, the decision remains pending. Lead is a potent toxic substance. As with other endocrine disruptors, there is no safe threshold for lead exposure. In fact, there is evidence that lead's impacts on children's neurodevelopment are greatest at the very lowest doses.



Figure 14. Commission delays in the REACH Restriction process

#### CASE STUDY. PFOA, a forever chemical allowed for 80 years with the EU as a laggard.

Perfluorooctanoic acid (PFOA) belongs to a group of thousands of highly persistent chemicals, the so-called 'forever chemicals', or PFAS (short for per- and polyfluoroalkyl substances). PFOA is widely used in all sorts of everyday products<sup>39</sup> in all EU Member States. In the 1940s (figure 15), <u>3M</u> began mass-manufacturing PFOA. In the 1950s, DuPont started production as a chemical coating (Teflon) for product applications, in particular in food contact materials. These man-made compounds are found today in almost every person that has been tested, including babies, breast milk, and umbilical cord

<sup>39</sup> such as surfactants, in detergents, lubricants, textiles, carpets, fire-fighting foams, in creams and cosmetics, and in food packaging

blood. Unborn children are particularly at risk. Scientists say PFOA poisoning in Europe is a "potentially <u>serious public</u> <u>health problem</u>" after finding "<u>alarming</u>" levels in children, often at higher levels than adults due to its bioaccumulative property.

Thousands of studies over the past 40 years show that PFOA endangers the planet and public health. It is linked to <u>health impacts</u> such as kidney and testicular cancer, lower birth weight and size, weaker immune systems in children, reduced hormone levels and delayed puberty, impaired thyroid function, liver damage, increased cholesterol, obesity, decreased fertility in men and women, and possibly also breast cancer and miscarriages. Following a 1998 US Environmental Protection Agency alert on the health hazards of toxic fluorinated chemicals, including PFOA, the industry declared a voluntary phase out starting in 2000.

In Europe, PFOA went through a CLH procedure in 2009, was listed on the Candidate List in 2013 and restricted in 2020, three years after a ban in Canada and listing in the Stockholm convention. Excluding some prior regulatory steps, it took EU officials a total of 11 years to ban a chemical that industry had already decided to voluntarily phase-out 20 years ago, 22 years after powerful US government health warnings and 40 years after scientists started raising the alarm. It is safe to assume that countless suffering has been caused by the EU's broken chemical controls.



Figure 15. PFOA timeliness

#### 6.4.3. Main bottlenecks

One delay factor is the **high burden of proof required by authorities before they can restrict harmful chemicals.** Regulators are obliged to demonstrate "unacceptable risks at EU level" while the information provided by chemical manufacturers to substantiate this proof is shockingly poor. Alarmingly, **companies do not need to prove safety before their chemicals are allowed on the market.** 

Another important hurdle is the **lack of obligation by regulators to act,** once a danger has been identified, or even when the need for regulatory action has been acknowledged through ARNs.

Finally, the **Commission's lengthy indecision** adds years to the regulatory process. Just one in five (20%) of restrictions were processed in two years, while a majority have been waiting four years now for Commission adoption. The failure was noted in the 2018 <u>REACH Review</u>: "the restriction and authorisation processes still need to be implemented more efficiently and with quicker decision making"<sup>40</sup>. Yet nothing has changed. Deadlines on the Commission are badly needed.

#### 6.4.4. Conclusions and Recommendations

In the last 13 years, the EU has been unable to speed up restriction of the most harmful chemicals on the market under REACH. However, more group restrictions<sup>41</sup> entered into force compared with the previous system, allowing more chemicals being regulated in 'one go'. **Grouping has been proven to be an effective tool for accelerating chemicals control.**  EEB recommendations to accelerate restrictions are:

- Restriction proposals undergo considerable vetting, so the Commission should have an obligation to present the proposed restriction to be voted on by Member States within six months of ECHA's final opinion.
- The Commission or Member States should submit a restriction proposal to ECHA within 12 months of ARN conclusion.
- Extend the fast-track restriction route established for CMR substances (under article 68.2) to additional hazard categories and beyond consumer products alone and by granting Member States the right of initiative of this route.
- Insert group restrictions in the legal text as the default option in order to incentivise the restriction of chemical groups that are functionally the same, to reduce bureaucratic burden, avoid regrettable substitution and speed up safety protections.
- Apply the <u>"essential use" concept</u> to reduce the number of derogations.
- Reduce the burden of proof on authorities by changing the benchmark to begin restrictions from demonstrating 'unacceptable risk' to justifying 'high concern'.

<sup>&</sup>lt;sup>40</sup> COM(2018) 116 final

<sup>&</sup>lt;sup>41</sup> Such as the restriction of over 4,000 hazardous chemicals found in tattoo inks and permanent make-up

# 7. Culture of inaction at the European Commission

After ECHA's lengthy and complex process to deliver scientific opinions, the Commission takes even longer to process these into regulatory actions, as long as years in some cases. The median time for SVHC inclusion in Annex XIV is 23 months while for restriction decisions the median is 19 months. Seemingly asleep on the job, only a quarter of the known SVHCs have been added to Annex XIV in the last 9 years, while decisions remain pending for a full half of applications for authorisation. All the while these substances of concern remain in dangerous use causing potential harm and suffering.

An overview of the median times for Member States/ECHA submitting RMM proposals, ECHA developing opinions and recommendations and the Commission to make decisions:

#### **Restriction:**

- Member States/ECHA takes 12 months to submit Restriction proposals
- ECHA takes 17 months to process<sup>42</sup> restrictions.
- The Commission takes a further 19 months to approve<sup>43</sup> restrictions.

#### Authorisation:

 Member States/ECHA takes 6 months to submit SVHC proposals

- ECHA takes 24 months to recommend SVHCs in annex XIV.
- The Commission takes 23 months to include<sup>44</sup> SVHCs in annex XIV.
- ECHA and its committees take 10 months to develop<sup>45</sup> opinions on AfAs.
- The Commission takes a further 16 months to decide.

#### CLH:

- Member States take 14 months to submit<sup>46</sup> a CLH proposal.
- ECHA takes 12 months to develop<sup>47</sup> CLH opinions
- The Commission takes a further 21 months to adopt<sup>48</sup> decisions and these entering into force.

<sup>&</sup>lt;sup>42</sup> From submission of a restriction proposal to final opinion

<sup>&</sup>lt;sup>43</sup> From opinions sent to the Commission and date for Official Journal publication

 $<sup>^{44}</sup>$  From ECHA recommendation of Annex XIV amendment to the Commission Annex XIV amendment

<sup>&</sup>lt;sup>45</sup> From the date of receipt of an application for authorisation (payment date) until submission of final opinion to the Commission

<sup>&</sup>lt;sup>47</sup> From the date of receipt of the final dossier to ECHA's final opinion

<sup>&</sup>lt;sup>48</sup> From the date of submission of the ECHA opinion to the date of Adaptation to Technical Progress (ATP) publication until the entry into force

# CASE STUDY: DEHP - A decade of de facto authorisation for an everywhere chemical.

Phthalates are a family of man-made chemical compounds first introduced in the 1920s (figure 16). In 1931, the wide use of <u>di(2-ethylhexyl)</u> phthalate (DEHP) began to be used as a plasticizer of <u>polyvinyl chloride</u> (PVC). It is still used globally in the manufacture of plastics, solvents, and personal care products.

In 1994, a <u>Canadian study</u> found that children's exposure to phthalates is greater than that of adults and that DEHP was harmful to human health. The Canadian government quickly banned their use in cosmetics and restricted their use in other products.

The EU has restricted DEHP in children's toys since 1999. Following a growing number of studies showing adverse effects, in particular to young infants, **DEHP** was in 2008 among the first batch of substances to be given the status of very high concern (Candidate List), due to its reprotoxic properties. Later, its endocrine disrupting properties were added to the reasons for inclusion in the Candidate List, in 2014 for its ED properties for human health and in 2017 for its ED properties for the environment.



Figure 16. DEHP timeliness

In 2012, DEHP was added to Annex XIV with a sunset date of 2015. This meant that from February 2015, DEHP was banned unless given authorisation for specific uses. DEZA a.s., a Czech company owned by Mr Andrej Babiš (second richest man in the Czech Republic and former Prime Minister) applied to continue using DEHP in everyday products in 2013, alongside other two companies. The other two applicants for authorisation ceased production of DEHP. Today, 9 years after applying for authorisation, DEZA is still allowed to manufacture DEHP because no decision has been taken by the European Commission. The chemical has been in a legal limbo for nearly a decade as the Commission favours a powerful industry player.

## 8. Conclusions

Scientists recently declared that chemical pollution has <u>passed the safe limit</u> for humanity. Daily exposure to a mix of toxic substances is linked to rising <u>health</u>, <u>fertility</u>, <u>developmental</u> threats, as well as the collapse of <u>insect</u>, <u>bird</u> and <u>mammal</u> populations.

A draft study for the European Commission, set to be published in the coming weeks, found that 1,300 chemicals, used in volumes of 23 million tonnes per year in Europe, are linked to cancer, infertility, stunted development in children and other serious health impacts and will be banned from all products in the coming years. Of those, over 600 chemicals totalling 5 million tonnes a year, go into consumer products.

There is an urgent need to act. However, EU chemical controls are skewed in favour of market access, forcing officials to allow chemicals on the EU market in no more than three weeks, without even a basic understanding of their hazards. It then takes officials:

- Five years to check the quality of the data provided by chemical manufacturers
- Seven years to evaluate a substance
- One year and eight months to assess the regulatory needs

- Five years and seven months to restrict the dangerous chemicals under REACH
- Nine years and three months to phase out SVHCs through Authorisation under REACH
- Five years and nine months to adopt harmonised classification and labelling at EU level under CLP

#### Until officials conclude the regulatory process, firms can legally use chemicals known to be causing serious harms.

Only assessing the hazards of chemicals can take 12 years<sup>49</sup>. Then comes regulatory action, assessing and adopting control measures using the Restrictions route took seven years and three months, phasing out through Authorisation 10 years and 11 months while adopting CLH, seven years and five months (table 25). Taking an extremely conservative approach, this report can reliably conclude that **it takes officials around a decade to control chemicals that are in dangerous use**, taking

 $<sup>^{\</sup>rm 49}$  Assuming 5 years for CCh and 7 years for SEv

into consideration all regulatory steps from Evaluation, to ARNs, to Restriction, Authorisation or CLH.

The conservative nature of this estimate becomes clear when concluding how long it would take considering all regulatory routes together. **Restricting hazardous**  chemicals in dangerous use can take officials 19 years and three months to conclude. Phasing them out under the so-called Authorisation process can take them 22 years and 11 months, while harmonising classification and labelling can take 19 years and five months to be completed, from start to finish (figure 17).

#### Figure 17. Overall timeliness from Registration to phase out.



a.) From Registration to Restriction

#### b.) From Registration to general ban (Authorisation)



c) From Registration to CLH



This report also establishes the shortest and the longest chemical control cases excluding the Evaluation process (table 25):

The best-case scenario for controlling any newly recognised chemical threat, takes over two years through the Restriction process. The slowest takes over 22 years.

Phasing out substances of very high con-

cern under the so-called Authorisation process would never be achieved in under six years, while the slowest case on records equals to over 24 years.

Things are little better under the harmonisation of classification and labelling route, with the fastest controls taking no less than three years, while the slowest takes 22 years.

Table 25. Timeliness of overall regulatory processes starting by Assessment of Regulatory Needs until a Risk Management Measure is adopted (Authorisation) or entered into force (Restriction and CLH).

Risk Management Measure	Best case scenario (Shortest duration of ARN <sup>50</sup> and RMM <sup>51</sup> processes)	Median duration of ARN <sup>52</sup> and RMM <sup>53</sup> processes	Worst case scenario (Longest duration of ARN <sup>54</sup> and RMM <sup>55</sup> processes)
<b>Restriction</b> From ARN to entry into force	2 years and 5 months (29 months)	7 years and 3 months (87 months)	22 years and 4 months (268 months)
Authorisation From ARN to AfA decision by COM	6 years and 3 months (75 months)	10 years and 11 months (131 months)	24 years and 5 months (293 months)
<b>CLH</b> From ARN to date of entry into force	3 years and 10 months (46 months)	7 years and 5 months (89 months)	22 years and 9 months (273 months)

This report shows that, despite some progress<sup>56</sup>, REACH is failing to protect the public and environment from a rising tide of hazardous chemicals. Officials are clearly aware of serious health impacts and suffering as well as grave environmental impacts, but are forced to run chemicals through a long list of meandering legal processes before finally taking action. In the case of the European Commission, officials regularly sit on files for years, allowing serious ongoing harms to continue. The result is that many chemicals in dangerous use remain stuck

 Routine gaming of the system by industry. Firms submit hazard data to officials that is unreliable in almost all cases that officials check (<u>93% at the</u> <u>last count</u>). This would be considered gross negligence, except the EEB believes it is deliberate, since acknowledging hazards invites unwanted reg-

<sup>&</sup>lt;sup>50</sup> Shortest case of ARN was 1 month

<sup>&</sup>lt;sup>51</sup> Shortest cases for Restriction: 28 months, Authorisation: 74 months, CLH: 45 months

<sup>&</sup>lt;sup>52</sup> Median of all cases of ARN was 20 months

<sup>&</sup>lt;sup>53</sup> Median of all cases: Restriction: 67 months, Authorisation: 111 months, CLH: 69 months

<sup>&</sup>lt;sup>54</sup> Longest case of ARN was 131 months

<sup>-</sup> Longest case of ARN was 131 months

 $<sup>^{55}</sup>$  Longest cases were: Restriction: 137 months, Authorisation: 162 months, CLH: 142 months

<sup>&</sup>lt;sup>56</sup> 224 substances identified as SVHC and added to the Candidate List; 59 substances added to Annex XIV (Authorisation List); 27 restrictions entered into force; 4,440 compliance checks completed; 194 substance evaluations completed

in the EU system. All the while, **as officials dither or stall protections, firms are free to continue using high volumes of hazardous chemicals despite the known harms.** This report identifies four main problems:

ulatory action. REACH obliges officials to grant market access before checking dossier quality, lumbering them with the major task of proving chemicals are in dangerous use. The situation is compounded by a culture of resistance by industry, with firms routinely challenging ECHA decisions through vexatious cases, even over basic hazard data that is supposed to be the foundation of market access. Moreover, registrations are valid indefinitely, regardless of their level of compliance. Only a cancellation, argue ECHA and the EU Commission, could truly implement the REACH principle of "no data, no market" sustainably. The outcome: the legal maxim of 'no data, no market' has become 'no data, no problem' and firms have de facto permission to use chemicals dangerously in consumer and other products for a decade, even where officials are fully aware of serious harms being done.

 The lack of deadlines. The European Commission has the legal obligation to draft decisions within three months, but no obligation to adopt final decisions. That loophole results in decisions being stalled for years, *de facto* granting industry ample amounts of extra time to continue uncontrolled and therefore dangerous use of hazardous chemicals. In fact, this report finds that the Commission is the ultimate bottleneck. All chemical control roads ultimately lead to the Commission for approval. Its offices are an elephants' graveyard for many dossiers that routinely gathers dust for years. This even though ECHA has painstakingly established the facts and recommends the controls needed. Quick decisions are perfectly viable, though the Commission shies away from showing resolve in its decision-making. It thus tips the balance in favour of industry, and against public health and the environment. Officials in other institutions also sit on files and. all in all, after a chemical is given market access, it can take officials over ten years to go through compliance checks and substance evaluation alone, and a further ten years for hazard controls to be agreed and enter into force. Years of public poisoning are the fault, ultimately, of a lack of clear deadlines written into law.

The lack of accountability by Member States and by the Commission to protect the EU citizens and environment by taking timely action against harmful chemicals. Member States are not obliged to finalise an Assessment of Regulatory Needs (ARN) or implement their control recommendations. If an ARN indicates the need for a Restriction or Authorisation process, it indicates that a serious risk to society exists. It should be acted upon immediately. On the other hand, the Commission in almost all cases fails to meet its obligation to draft decisions in three months. However, there is no justification provided to EU citizens for such delay. If the Commission fails to act, there should be transparency and legal consequences for maladministration and inaction.

At the end of the day, it is significantly easier and faster for industry to market unsafe chemicals than for the authorities to take them off the market. Officials understand the serious harms being done, but take a decade to control them. In the meantime, people and the environment are unnecessarily exposed.

## 9. Recommendations

Write strict, binding deadlines into law. Officials must not freeze files without just cause, particularly when serious harms are known and ongoing. There should be legal consequences such as market suspension when deadlines are not met. In particular, we propose REACH is reformed so that it introduces:

- A six months deadline for ECHA to issue draft compliance check decisions.
- A three year deadline by which all industry dossiers need to be compliant from the start of compliance check.
   ECHA must be granted the power to revoke registration licences if this deadline is not met.
- A maximum two years deadline on test duration to registrants.
- A one year deadline from the start of Evaluation for ECHA/MSCA to adopt a final decision (after consultation with company and Member States) for data generation.
- A six months deadline for ECHA/ MSCA developing ARNs.
- A one year deadline for ECHA/MSCA to submit a risk management proposal when SEv or ARN concludes that risk management measures are needed.
- A 2027 target by which all CMRs with CLH are introduced in the Candidate list.

- A 2030 target by which the most harmful chemicals are banned from consumer products.
- An obligation to perform ECHA's annual recommendations of SVHCs in Annex XIV based on an MSC majority by ECHA.
- A one year deadline for the Commission to implement risk management measures after SVHCs are added to the Candidate list.
- An automatic inclusion of CLH decisions in CLP Annex VI by the Executive Director of ECHA. Otherwise, a maximum six months deadline for CLH decisions.
- A six months deadline for the Commission to adopt final decisions for chemicals control. If this deadline is not met, substances on the Candidate list should move automatically to Annex XIV. For applications for authorisation decisions, the absence of a decision within the legal deadline should be treated as a rejection (implicit negative administrative decision, following the model for access to document requests in the EU). In other words, SVHCs could no longer be used, to end the current situation of *de facto* authorisation by failure to act.

Apply the 'no data, no market' and 'zero tolerance to non compliance' principles. The EU must stop firms blindfolding officials with non-compliant hazard and exposure data.

- Fix the 'original sin' and force companies to prove their products are safe. Revise REACH so ECHA can evaluate the quality and adequacy of hazard data before allowing market access (granting a registration number).
- Introduce a mandatory requirement for annual dossier updates in relation to tonnages and use patterns.
- Implement a 'dossier expiration date' so the registration validity would automatically terminate when the company in question does not meet its obligation to update the registration or provide the data requested by the ECHA.
- Give ECHA the power to revoke registration numbers and to sanction companies when registrants fail to comply with the law. With the power to require the payment of large fines from companies that submit unreliable or misleading data, regulators would quickly dissuade the culture of impunity that currently exists and would quickly reverse today's widespread non-compliance.

#### Put protection before profits.

Use a precautionary approach and lower the level of evidence needed for identifying and regulating hazardous chemicals.

 Introduce the Generic Risk Management approach as the default option for controlling substances of concern.

- Apply the precautionary principle by lowering the legal benchmark for chemical controls from proving "unacceptable risk" to justifying "high concern", with a right to trigger control measures on the basis of lack of data. Officials should not get lost in the details and paralysis by analysis when considering action against toxic chemicals. If companies do not prove absence of hazards, chemicals should be presumed hazardous rather than safe.
- The burden of proof to justify derogations must be on industry.

## Speed up the regulation of hazardous chemicals.

- Establish automatic bans of groups of substances of concern in everyday products, for example by setting up dynamic links between the Candidate List and CLH to trigger automatic restrictions under REACH.
- Extend the fast-track restriction route (Art 68.2) to endocrine disruptors, persistent and bioaccumulative, and persistent and mobile chemicals as well as for professional uses. Also by opening this route also to Member State competent authorities.
- Make a group approach the default option in REACH for restricting chemicals, instead of one-by-one.
- Add additional SVHC categories to tackle dangerous blindspots, such as endocrine disruptors and persistent, mobile and toxic/very persistent very mobile chemicals.



#### Simplify the system.

- Reduce Authorisation to one route, the adequate control route, only for downstream users and individual or collective application for similar uses.
- Apply the EU's new 'Essential Use' concept to screen out clearly non-essential uses such as luxury and decorative uses and greatly reduce the number of applications for authorisation and derogations for restriction.
- Allow ECHA to perform compliance checks and substance evaluation concurrently, to prevent years of delay.
- Introduce a legal framework that allows Evaluation and testing strategies based on group considerations.

## Ensure that legal revision makes REACH faster, not slower.

- Avoid prior classification being required for SVHC identification.
- Avoid a derogation system based on exposure or use considerations for the most harmful chemicals, in particular in everyday products.
#### Annex I. REACH and CLP processes timeliness summary table

REACH/CLP process <sup>57</sup>	Shortest duration (substance)	Median duration	Longest duration (substance)	Main bottleneck(s)	Main Problem(s)
REACH REGISTRATION completeness check	< 3 weeks data not available	3 weeks data not avail- able	3 weeks data not available	REACH legal text	Too short deadline for ECHA to grant regis- tration numbers Legal text preventing ECHA to assess the quality of the data in the Registration phase
REACH EVALUA	TION <sup>58</sup>				
Compliance check (CCh)	data not available	data not avail- able	> 5 years (not concluded yet)	Industry	Lack of cooperation by the registrants to provide the necessary information Industry possibility of challenging ECHA's decisions
Substance Eval- uation (SEv)			7-9 years	Member States Industry	Substance evaluation paired with compli- ance checks Lack of cooperation by the registrants to provide the necessary information Industry possibility of challenging ECHA's decisions
ARN	Less than a month (1,3-propanesul- tone)	1 year and 8 months	10 years and 11 months (2-(2H-benzotri- azol-2-yl)-4-(1,1,3,3-te- tramethylbutyl)phenol) (not concluded) <sup>59</sup>	Industry Member States/ECHA	Lack of cooperation by the registrants to provide the necessary information Lack of deadlines for Member States to finalise SEv or obliga- tion to trigger control measures

<sup>57</sup> From the date of intention to the date of Commission's decision/publication in the official journal/entry into force or inclusion in the candidate list by ECHA (in case of SVHCs identification)

<sup>58</sup> Substance evaluation can take from 7 to 9 years from their inclusion in CoRAP, and if further data generation is needed.

<sup>59</sup> For substances that do not yet have a date on the Commission's decision. The analysis was conducted by using a hypothetical decision date (01/03/2022) for substances with different transitional periods. The latest date was considered as the entry into force. When the date of entry into force was not available we used the median between the Commission decision and entry into force to obtain a hypothetical date (01/09/2023) and extrapolate it to those substances without an entry into force date.

REACH/CLP process <sup>57</sup>	Shortest duration (substance)	Median duration	Longest duration (substance)	Main bottleneck(s)	Main Problem(s)	
HAZARD IDENT	HAZARD IDENTIFICATION					
CLH	3 years and 9 months (tetrakis(2,6-di- methyl- phenyl)-m-phenyl- ene biphosphate)	5 years and 9 months	11 years and 10 months (CU-HDO (Bis(N-cy- clohexyl-diazenium-di- oxy)-copper))	Commission	Delay in taking decisions	
SVHC identifi- cation	3 months (Dichromic acid)	6 months	3 years and 7 months (Nonadecafluorodecano- ic acid)	Legal text	Obligation to reach unanimous decisions by MSC	
RISK MANAGEMENT MEASURES						
Annex XIV inclusion (by Commission)	1 year and 1 month (Diarsenic trioxide)	1 year and 11 months	12 years and 9 months (SCCP) (not concluded)	Commission	Commission's fre- quent inaction and delays in making decisions	
Authorisation	6 years and 2 months (Bis(2-ethylhexyl) phthalate)	9 years and 3 months	13 years and 6 months (Sodium dichromate)	Commission	Commission's fre- quent inaction and delays in making decisions	
Restriction	2 years and 4 months (Cadmium and its compounds)	5 years and 7 months	11 years and 5 months (PFNA; PFDA; PFUn- DA; PFDoDA; PFTrDA; PFTDA; their salts and precursors)	Commission	Commission's fre- quent inaction and delays in making decisions	

## Annex II.

Efficiency of the REACH and CLP processes to identify and regulate chemicals of concern-summary table

REACH / CLP process	Timeline (No years)	Number of substances assessed	Number of substances waiting for assessment conclusion (%)	Number of sub- stances recom- mended for RMM (%)	Number of sub- stances regulated – decision taken [RMM]
Dossier evaluation (compliance check)	2009 - 2022 (13 years)	6568 (4165)	2128 (32%)	data not available	data not available
Substance Evaluation	2012-2022 (10 years)	388	195 (50%)	50% of conclud- ed SEv	2 [restriction] 1 [Annex XIV]
ARN/RMOA	2011-2022 (11 years)	349	106 (30%)	173	2 [restriction]
PBT assessment	2012-2022 (10 years)	225	133 (59%)	92	1 [annex XIV]
ED assessment	2014-2022 (8 years)	105	84 (80%)	15 (14%)	0
CLH	2011-2022 (11 years)	361		14	1[1] [CLH]
Restriction	2009-2022 (13 years)	35	8 (23%)		27 (77% of restric- tions assessed)
Annex XIV		223 SVHC	169		59 included in annex XIV (24% of SVHC)
Authorisation decisions	2013-2022 (9 years)	248 AfAs submitted by companies		352 ECHA opin- ions finalised	199 decisions by Commision (56,5% of adopted opinions by ECHA)

### Annex III.

Median times for ECHA developing opinions and recommendations and the Commission to make decisions

REACH/CLP process	Shortest duration (Substance)	Median duration	Longest duration (Substance)
<b>CLH</b> From date of submission to ECHA's final opinion	4 months (nicotine (ISO); 3-[(2S)-1-methylpyrroli- din-2-yl]pyridine	12 months	2 years and 1 month (triflusulfuron-methyl; methyl 2-({[4-(dimethyl- amino)-6-(2,2,2-trifluoroe- thoxy)-1,3,5-triazin-2-yl] carbamoyl}sulfam- oyl)-3-methylbenzoate)
<b>CLH</b> From date of ECHA's final opinion to Commission decision (ATP publication)	1 year and 3 months (Tetra- fluoroethylene) 1 year and 10 months		5 years and 5 months (Galli- um arsenide)
<b>SVHC</b> From date of submission to MSC Agreement	2 months (Silicic acid, lead salt)	4 months	4 months (Phenol, tetrapropylene)
<b>SVHC</b> From date of MSC Agreement to Inclusion in candidate list	Less than a month (Phenol, dodecyl-, branched)	Less than a month	2 years and 6 months (2,4-di-tert-butyl-6-(5-chlo- robenzotriazol-2-yl)phenol)
Authorisation From Annex XIV recommenda- tion (by ECHA) to inclusion in Annex XIV (by COM)	1 year and 1 month (Diarsenic trioxide)	1 year an 11 months	12 years and 9 months (SCCP) (not concluded)
Authorisation From date of AfA submission to ECHA's opinion	5 months (Diarsenic trioxide)	1 year and 1 month	3 years (Chromium trioxide)
Authorisation From ECHA's opinion to Com- mission decision	4 months (Diarsenic trioxide)	1 year and 4 months	7 years (Bis(2-ethylhexyl) phthalate)
<b>Restriction</b> From date of submission to ECHA's opinion sent to Com- mission	11 months (formaldehyde and formal- dehyde releasers)	1 year and 5 months	2 years (4,4'-isopropylidenediphenol (Bisphenol A))
<b>Restriction</b> From opinion sent to Commis- sion to Journal Publication	6 months (Cadmium and its com- pounds)	1 year and 7 months	3 years and 10 months (Lead and its compounds)

## Annex IV.

#### Main bottlenecks and recommendations- summary table

	Decisions (includ- ing in progress)	concluded	Problem identified	Bottleneck	Recommended
Dossier evalua- tion (compliance check)	3,959	2,762	Lack of a legally binding deadline to complete the process after the information is requested. Lack of transparency	Industry / ECHA	Withdraw regis- tration Transparency on compliance Maximum time to complete No incentive to provide compliant registrations
Substance eval- uation	384	170	Lack of deadline to approve the draft decision No deadline to com- plete the process	Industry / ECHA	Include RM and time limit; Integrate dossier and substance evaluation
ARN	268		Lack of accountabil- ity as process is not legally binding No timeline for com- pleting ARN and lack of implementation strategy	MS + ECHA	Max time limit
PBT assessment			No time limits	All	Deadlines
ED assessment			No time limit	All	Deadlines
Substitution – Annex XIV			Substance's selec- tion is determined by ECHA's workload; Lack of deadlines for Commission's deci- sions; Commission can ignore scientific advice without motivation	Commission	MSC to decide and COM max 3 months; COM to motivate why it doesn't follow ECHA's recommendation more power for MS (direct listing in an- nex XIV by MSC by qualified majority

	Decisions (includ- ing in progress)	concluded	Problem identified	Bottleneck	Recommended
Restriction			Lack of deadlines for Commission's deci- sions;	Commission	Mandatory 6 months deadline for approval by the Commission
SVHC			Substances are included only after a lengthy evaluation process	none	Automatic inclusion of CLH CMRs and adoption by quali- fied majority instead of consensus
CLP			Substances are included only after a lengthy evaluation process No deadlines for the Commission to decide; Commission can make	Commission	Executive Director of ECHA decision in lieu of Commission decision
Authorisation decisions			No deadlines for the Commission to decide;	Commission	3 months for final decision - consid- ered rejected if Commission doesn't decide

# Glossary

REACH	Regulation No 1907/2006 on the Registration, Evalu ation, Authorisation and Restriction of Chemicals
CLP	Regulation No 1272/2008 on the Classification, La belling and Packaging
CSS	Chemicals Strategy for Sustainability
ECHA	European Chemicals Agency
PBT	Persistent, Bioaccumulative and Toxic chemical
vPvB	very Persistent and very Bioaccumulative
ED	Endocrine Disruptors
SVHCs	Substances of Very High Concern
ARN	Assessment of Regulatory Needs
RMOA	Regulatory Management Option Analysis
EEB	European Environmental Bureau
SEv	Substance Evaluation

MSCA	Member State Competent Authorities
CoRAP	Community Rolling Action Plan
TPP	Triphenyl phosphate
BPA	Bisphenol A
CLH	Harmonised Classification and Labelling
AfAs	Applications for Authorisation
CMR	Carcinogenic, Mutagenic and Reprotoxic
PFOA	Perfluorooctanoic acid
PFAS	Per- and polyfluoroalkyl sub stances
RAC	Risk Assessment Committee
MSC	Member State Committee
PMT	Persistent, Mobile and Toxic
SEAC	Socio-Economic Analysis Committee
PVC	Polyvinyl chloride
DEHP	di(2-ethylhexyl) phthalate



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