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Protecting humans and wildlife from harmful chemicals

Waiting for REACH:

The negative impacts of delaying reform of EU chemical laws

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A report by the EEB and CHEM Trust

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Zakia Khattabi, Belgian Federal Minister for Climate, Environment, Sustainable Development and the Green Deal

“All lights are green! The last hurdle for the Commission to publish the long-awaited revision of the REACH regulation has been cleared! The Regulatory Scrutiny Board has given a favorable opinion on the Commission's impact assessment. I therefore once again call on the Commission to publish the REACH revision as soon as possible.

The Commission has already proven that it can achieve high ambitions in climate and environmental policies when it delivers on the promises of the Green Deal. It is now time to deliver on one of the crucial dossiers and take important steps to further ensure a high level of protection to the environment and health and to accompany chemical companies on their way to the green and digital transition.”

Martin Hojsík, Member of the European Parliament, Renew Europe Group

"We urge the Commission to not to delay publication of REACH 2.0. beyond June 2022 as there would be no time left to finalise this long-awaited reform of the chemical legislation. It seems that some in the Commission do hear us, but the expectations on the Parliament's side are great. The European industry needs a policy framework that will incentivize transition to safe, circular and less energy intensive chemicals. If we want the industry of tomorrow, we have to start with ambitious changes today. The REACH 2.0. will ensure that it stays a global leader in safe and sustainable chemistry and that it is resilient in times of crisis. It will ensure an effective phase out of the most harmful chemicals to keep our activities within the planetary boundaries and to protect the health of every individual."

Patrick ten Brink, Secretary General of the European Environmental Bureau (EEB)

“EU officials’ hard work in delivering a transformative Green Deal legislative roadmap is bogged down by last-minute political decisions coming from top-level Commissioners. This unjustified self-sabotage only responds to political and industry pressure. People are asking for bold policies to speed up the pace of change towards a clean, resilient and toxic-free future. By prioritising short-term profits over people and the environment, the EU risks losing citizens’ trust and risk compromising long term competitiveness and resilience. Furthermore, any delay in the REACH revision will undermine Ursula von der Leyen’s Green Deal legacy. A ‘person-on-the-moon-moment’ risks being missed.”

Sylvie Lemoine, Executive Director of the European Chemical Industry Council (CEFIC)

“The new REACH should support our industry in the unprecedented double twin transition. It should ensure we can innovate and invest with confidence in the materials of tomorrow, help boost circularity, step up enforcement, streamline regulatory procedures, remove bottlenecks, give a thrust to alternatives to animal testing and create markets for safe and sustainable

chemicals. We need a REACH that does all these things to move further along the Transition Pathway to 2050".

Monique Goyens, Director General at BEUC

"Consumers need much more certainty that the products they use daily do not contain harmful chemicals. In 2020, the European Commission itself called for a toxic-free environment but it has yet to turn this political ambition into concrete actions. A reform of the EU's flagship REACH legislation is overdue as it is the only way to help authorities act against harmful chemicals before their use becomes widespread in consumer products.

We should avoid the situation we have today where national authorities are proposing a general PFAS ban long after these harmful chemicals have become common in clothing, cleaning agents and food packaging. Better chemicals legislation should mean that such chemicals never make it to market in the first place."

Anne-Sofie Bäckar, Executive Director at ChemSec

"REACH revision is the most important part of making the Chemicals Strategy reality. Industry is already adapting, and investors are relying on it. It is urgent to phase out of the most harmful substances from products and this will unlock the market for alternative providers and boost innovation. The message we get is clear; publish the REACH revision by June."

Michael Warhurst, Executive Director, CHEM Trust

"People and the environment continue to be exposed to hazardous chemicals, including endocrine disruptors, and the longer the REACH revision takes the longer this exposure continues due to the ineffectiveness of current procedures. We need the new REACH to set a target to phase out the most harmful chemicals by 2030, and we need that new legislation to be in force as soon as possible"

Tony Musu, Senior Researcher for the European Trade Union Institute (ETUI)

"Work-related cancers are the first cause of death at work with more than 100 000 deaths per year in the EU – these cancers are preventable, they are due to bad working conditions with carcinogens. Most of the time, workers don't know they are exposed".

1 Executive Summary

Confronted with climate disruption, environmental degradation and the acceleration of biodiversity loss, the European Commission presented in late 2019 the European Green Deal. A symbol of the commitment of the Commission and its President, Ursula von der Leyen to the prioritisation of climate and environmental issues, it also promised to be inclusive, leaving no one behind. This represented a fundamental shift towards a greener Europe for a more sustainable and fairer society.

One of the Green Deal's most important chapters to contribute to the zero-pollution ambition is the Chemicals Strategy for Sustainability (CSS). The CSS was published in 2020 and foresaw the revision of REACH, the EU's main legislation on chemicals.

REACH entered into force in 2007 and after 16 years in operation, numerous studies point at an urgent need to reform REACH and fix major shortcomings that had been identified to increase its level of protection and further strengthen the competitiveness and innovativeness of European industries.

Yet, the EU Commission failed to table its proposal for a targeted revision of REACH by the deadline of 2022 set in the CSS. Instead, it is planning to publish it in the last quarter of 2023. A mere one year, though the consequence of this delay is important: the current Parliament would have no chance to finish its first reading before the elections in 2024, significantly delaying the REACH revision even further, damaging the Green Deal legacy and creating huge uncertainties about the direction the EU chemicals industry should move toward, just at times when clarity is needed the most.

In addition, a delay in the REACH reform causes a high level of uncertainty for the industry as the regulatory framework remains unclear and no clear signal is sent to the market and investors regarding the phase-out of hazardous substances and the direction in which innovation will need to go.

If the revision of REACH is further delayed:

- **There will be a continuation of the current pollution status quo**, where hazardous substances are often not identified or managed effectively, posing a risk to human health and the environment. This will have negative impacts on several health and environmental goals of the European Green Deal, including those related to the protection of biodiversity, air and water quality, zero pollution and human health.
- **The development and resilience of the EU chemicals industry and SMEs will also be hampered**, due to a lack of a clear direction at the moment when it needs to invest in the transition, **while frontrunner companies that have already invested in the substitution of hazardous substances will be penalised**. If new manufacturing methods are going to be developed and implemented (potentially with support from EU taxpayers) it is essential that they are making the right chemicals for the long term.
- **European companies, SMEs, and frontrunners will lose competitiveness and innovation capacity, and stay behind the global market** on sustainable and safe chemicals. Also, investors would not finance companies within the EU due to high litigation risks of the use of hazardous chemicals.

- **The EU's transition towards a sustainable and circular economy will be hindered**. By promoting the development and use of safer and more sustainable chemicals and products, the REACH Regulation can support the EU's goals related to waste reduction, resource efficiency, and sustainable production and consumption.
- **The CSS efforts to create a toxic-free environment will be undermined** by prolonging the use of hazardous substances and delaying the development and implementation of safer alternatives.
- **The EU is unlikely to ensure toxic-free products by 2030** jeopardising several product policy areas including ecodesign, ecolabel, and sustainable textiles.
- **Put the achievement of the global Sustainable Development Goals and EU's climate and social targets goals at risk**, with far-reaching consequences for the EU and the world.

A delay or the cancellation of the REACH reform would mean that the shortcomings of the past would continue to exist, in particular:

- **A lack of hazard data** that prevents the identification of hazardous substances and their proper risk management, coupled with a lack of due regard to the fact that we are all exposed to mixtures of chemicals, not single chemicals
- **Slow and ineffective regulatory measures** to limit the use of substances of high concern in products and industrial processes
- **A lack of information and regulation** of (hazardous) polymers
- **A lack of data on the uses of chemicals**, hampering (targeted) risk assessment, (regulatory) risk management and risk communication

All the above shortcomings result in an insufficient level of protection of humans and the environment. Increasing exposure levels have been demonstrated in human biomonitoring and environmental monitoring, e.g. as recently published by the 'Forever Pollution Project'[1] for PFAS across the EU.

Therefore, REACH regulation should be reformed as soon as possible. In particular, the following improvements are vital:

- Increased information requirements on hazards and uses. Including registration of polymers and a requirement to assess chemical safety for low volume substances
- Introduction of a mixture assessment factor into risk assessments to ensure that the reality of our exposure to mixtures is considered
- Improve restrictions and extend the operation of the generic approach to risk management to ensure the phase out of the most harmful chemicals from consumer products by 2030, supported by clear and strict rules for exemptions
- Improvement of the authorisation process

[1] Le Monde (France), NDR, WDR and Süddeutsche Zeitung (Germany), RADAR Magazine and Le Scienze (Italy), The Investigative Desk and NRC (Netherlands). 'The Forever Pollution Project', 2023. Available at: https://foreverpollution.eu/

- Introduction of a system to ensure that the most hazardous chemicals can only be used where the use is essential
- Stepping up the enforcement of the REACH provisions.

The continuing delay in the REACH reform is a failure of the Commission. We know it is under pressure from parts of the chemical industry who are trying to uphold a status quo that is harmful to people and the planet, but the Commission must see through their vested interests and lobbying and do the right thing by supporting the publication of a strong and effective REACH proposal without delay.

We call on the Commission to publish the REACH proposal as soon as possible, and at the latest by June 2023, in order to ensure that the regulatory process is advanced to a state that can be concluded swiftly after the start of the new Commission's mandate.

In order to simplify the process, the Commission should consider splitting the REACH reform into the revision of the main legal text and a revision of the Annexes.

2 Background

2.1 The story of the REACH Delay

Environmental and climate crises prompted the adoption of the European Green Deal back in 2019. The European Commission (EC) and its president, Ursula von der Leyen, presented a roadmap to follow through on the Green Deal, confronting these existential threats and thereby transforming the EU into a modern, resource-efficient and competitive economy.

The COVID-19 pandemic started in Europe in early 2020. The world experienced a human catastrophe, with lives lost, widespread sickness, unprecedented social hardship, and job insecurity. The impact on poorer countries with weak health systems and a high number of people working in the informal sector without any social protection could not even be foreseen at that stage.

Concerted efforts to opportunistically use the pandemic emergency to undermine legislation emerged. For example, in the US, the Environmental Protection Agency (EPA) used the COVID-19 outbreak as an excuse to grant a 'free pass' to polluters[2] and relax the enforcement of environmental regulations and fines. The European Green Deal and the Chemicals Strategy for Sustainability (CSS) that was under development and consultation with the EU institutions, also came under attack. Some European chemicals industries stated in March 2020 that "the pandemic showed that without chemistry we are completely helpless" and that they needed

[2] The Guardian, "Trump administration allows companies to break pollution laws during coronavirus pandemic," March 27, 2020, accessed March 2, 2023, https://www.theguardian.com/environment/2020/mar/27/trump-pollution-laws-epa-allows-companies-pollute-without-penalty-during-coronavirus.

similar measures to those put in place by the EPA, temporarily "relaxing the requirements[3] that would increase production capacity or transport of goods".

Fortunately, the CSS' ambitious vision was repeatedly endorsed by EU member governments[4], and the von der Leyen Commission withstood the pressure to put on hold EU chemical policy reform. The Commission presented in October 2020 the Chemicals Strategy for Sustainability, showing that Europe stays true to the European Green Deal, including its zero pollution and toxic-free commitments. The CSS is a truly transformative agenda that can drive detoxification and decarbonisation of our economies, while creating jobs and economic opportunity. The CSS includes more than 80 actions to protect people and the environment from the impacts of hazardous chemicals, and to transition the chemical industry into a green and sustainable one.

Yet, in the beginning of 2022, Russia's unrightful invasion of Ukraine started. This resulted in an energy crisis, with very high gas, electricity and fuel prices and an overall increased cost of living.

Against this new backdrop, many industries started to heavily lobby the European Commission to drop some of the objectives and planned policies to make the green transition a reality. Their argument was that any changes in policy at the moment could be deeply detrimental for European Industry. The German industry associations (VCI and BDI), rallied in May 2022 to lobby against the revision of REACH, arguing that there was "no time for experiments"[5] in response to the looming recession, even though EU sold production of chemicals continues to increase[6]. The EU chemicals industry has grown its sales in the past ten years by €232bn, reaching a peak of €769bn in 2021. This is far above expectations, ensuring that profits will keep running despite the war. In fact, the largest German chemical companies, BASF and Bayer reported record sales and profits in the 2nd quarter of 2022 and issued promising forecasts[7], showing that profits will keep running despite the war.

In its position, the German chemicals industry federation, VCI, argues that the European Commission's pursuit of the Green Deal is negligent and call for postponing legislation aimed at fighting pollution, like the Chemicals Strategy, industrial emission controls and carbon taxation, in order to "ease their regulatory burden" to be able to "better cope with the impacts of the war in Ukraine".

The German industry associations' idea of a moratorium has been championed by MEPs Esther de Lange[8] (the Netherlands, EPP) and Christian Ehler[9] (Germany, EPP). In September

[3] Teraz Srodowisko, "How is the chemical industry doing in conditions of higher necessity?," accessed March 2, 2023, www-teraz--srodowisko-pl.translate.goog/aktualnosci/przemysl-chemiczny-pandemia-Zielinski-8464.html?_x_tr_sl=pl&_x_tr_tl=en&_x_tr_hl=pl#xtor=EPR-1.

[4] Council of the European Union, "Council conclusions on chemicals," June 26, 2019, accessed March 2, 2023, www.consilium.europa.eu/en/press/press-releases/2019/06/26/council-conclusions-on-chemicals/#:~:text=12%3A05-,Council%20conclusions%20on%20chemicals,endocrine%20disruptors%2C%20nanomaterials%20and%20pharmaceuticals.

[5] https://newslettertogo.com/bgjtcqk7-ruj0kro0-rkuuv702-2nw

[6] Eurostat, "Record high shares of renewable energy in electricity and heat production in 2021," September 21, 2022, accessed March 2, 2023, https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20220921-1.

[7] ChemSec, "Don't believe everything you hear – European chemical industry is doing fine," January 30, 2020, accessed March 2, 2023, https://chemsec.org/dont-believe-everything-you-hear-european-chemical-industry-is-doing-fine/.

[8] ENDS Europe, "MEPs split on EU green goals as commission proposes Russian oil ban," October 20, 2021, accessed March 2, 2023, www.endseurope.com/article/1754888/meps-split-eu-green-goals-commission-proposes-russian-oil-ban.

[9] https://twitter.com/EPPGroup/status/1572141012197277696?s=20&t=9r1nT70eG84uSHRNrf7BEA

2022, the EPP group called in its position paper for a “regulatory moratorium of REACH”[10]. This paper called for the EU to immediately ease the burden on businesses by invoking a regulatory moratorium and delay those acts that “would unnecessarily increase costs for businesses already under strain (including REACH)”. Business Europe voiced ‘sympathy’[11] for this moratorium on green laws.

Following news that the revision of the EU’s centre piece for chemicals safety, REACH, was missing from the Commission’s draft 2023 work programme, to be published in October 2022, a wave of support for the Chemicals Strategy for Sustainability emerged in September.

Leading Members of the European Parliament’s[12] Environment Committee called on the three Executive Vice-Presidents of the European Commission to adopt the REACH proposal as soon as possible. In their letter, the chair of the Environment Committee, Pascal Canfin, and the coordinators of S&D, Renew, Greens/EFA, and The Left said they wanted to be able to achieve results within this Parliament term.

Environmental and health NGOs[13] also called on the European Commission President von der Leyen to stay on track and to publish the REACH revision by March 2023 at the latest.

At the beginning of October, just before the European Commission’s publication of the 2023 work programme, a group of EU governments, including Germany, wrote a letter[14] to remind the European Commission of the "importance of a timely implementation of the ambitious the Chemicals Strategy for Sustainability" and of "revising REACH".

The following day, the European Parliament rejected[15] calls for a regulatory moratorium on REACH in its resolution on the increase in energy prices in Europe. Initially, this call was put forward by the EPP in its motion for a resolution[16] and was then carried forward by the ECR[17] for the final vote in plenary.

On 10 October 2022, while the European Commission was still discussing whether and when the REACH revision was to come, the Socialists and Democrats group in the European Parliament (S&D) joined the wave of support for the revision of this centrepiece legislation and urged[18] President von der Leyen to not delay the revision any further, saying it must be included in its 2023 work programme.

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[10] European People's Party Group in the European Parliament, "EPP Group position paper on fighting inflation and tackling the rise of energy and living costs," accessed March 2, 2023, www.eppgroup.eu/newsroom/publications/epp-group-position-paper-on-fighting-inflation-and-tackling-the-rise-of-energy-and-living-costs.

[11] EURACTIV, "EU business group voices sympathy for moratorium on green laws," October 21, 2021, accessed March 2, 2023, www.euractiv.com/section/energy-environment/news/eu-business-group-voices-sympathy-for-moratorium-on-green-laws/

[12] https://twitter.com/pcanfin/status/1575420095446368256?s=20&t=_VyQVYKs8kylamZ57bFtew

[13] European Environmental Bureau, "NGO letter to Ursula von der Leyen on REACH and CLP reform," September 21, 2022, accessed March 2, 2023, https://eeb.org/wp-content/uploads/2022/09/NGO-letter-to-Ursula-VDL-on-REACH-and-CLP-reform-1-1.pdf.

[14] Danish Ministry of the Environment, "Joint letter on REACH and the importance of a timely implementation," accessed March 2, 2023, https://mim.dk/media/233841/joint-letter-on-reach-and-the-importance-of-a-timely-implementation.pdf.

[15] European Parliament. (2022, February 10). Motion for a resolution on the situation in Kazakhstan. Retrieved from www.europarl.europa.eu/doceo/document/RC-9-2022-0416_EN.html

[16] www.europarl.europa.eu/doceo/document/B-9-2022-0416_EN.html

[17] www.europarl.europa.eu/doceo/document/RC-9-2022-0416-AM-017-026_EN.pdf

[18] Socialists and Democrats Group in the European Parliament, "S&Ds urge President von der Leyen: REACH reform should be part of next Commission work programme," October 26, 2022, accessed March 2, 2023,

On 17 October, civil society and several MEPs sent the last call[19] to von der Leyen's Commission "not to drop chemicals law reform as a gift to polluters".

The media[20] exposed some of the internal discussions that were taking place within the College of Commissioners, suggesting Commissioners Breton and Vestager were the main opponents of the revision of REACH.

On 18 October 2022, the European Commission caved into the chemical industry's pressure[21] and announced in their 2023 work programme[22] a delay of one year for the publication of the REACH revision proposal, moving it to the fourth quarter of 2023. A one-year delay would make it impossible for the current Parliament to conclude the revision, causing uncertainties about the toxic-free pillar of the EU Green Deal.

The delay was met with criticism from many stakeholders, governments and political parties. The Commission tried to offer reassurance that it was standing firm on its Green Deal commitments. Vice-President Šefčovič answering[23] a question about the REACH delay from the Co-President of the Greens stated that *"once this file is ready, we will not hesitate, we will present it to the Parliament and to the Council".*

The Belgian Federal Minister for Climate, Environment, Sustainable Development and the Green Deal, Zakia Khattabi, expressed her disappointment and warned that she will no longer wait for Commission's decision on certain chemical files, and will instead take national action.

The European chemicals industry association (CEFIC) and Eurometaux called for the revision to be introduced as soon as possible, for clarity and predictability reasons.

In the meantime, the REACH revision file was still moving forward. DG GROW and DG Environment submitted the impact assessment to the Commission's Regulatory Scrutiny Board in October, which gave the green light to the REACH revision on 15 November 2022.

At the beginning of 2023, energy prices in Europe fell significantly, below what they were when Russia launched its full-scale invasion of Ukraine. In the energy markets of Germany, Belgium and France, the average January price was the lowest since August 2021, in Italy, the lowest

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www.socialistsanddemocrats.eu/newsroom/sds-urge-president-von-der-leyen-reach-reform-should-be-part-next-commission-work.

[19] European Environmental Bureau, "EU Commission to drop chemical regulation as a gift to big polluters," October 25, 2021, accessed March 2, 2023, https://eeb.org/eu-commission-to-drop-chemical-regulation-as-a-gift-to-big-polluters/.

[20] Information.dk. "EU-Kommissionen bøjer sig for industrispres og udvander indsats mod farlig kemi" (2022, October 12). Retrieved March 9, 2023, from www.information.dk/udland/2022/10/eu-kommissionen-boejer-industripres-udvander-indsats-farlig-kemi#:~:text=EU-Kommissionen%20b%C3%B8jer%20sig%20for%20industripres%20og%20udvander%20indsats%20mod%20farlig%20kemi,-Inden%20%C3%A5rets%20udgang&text=En%20af%20de%20s%C3%A5kaldte%20PFAS,k%C3%B8er%20og%20mennesker%20i%20omr%C3%A5det"

Le Monde. "Les lobbys de l'industrie chimique ont gagné : la Commission européenne enterre le plan d'interdiction des substances toxiques pour la santé et l'environnement" (2022, October 19). Retrieved March 9, 2023, from www.lemonde.fr/planete/article/2022/10/19/les-lobbies-de-l-industrie-chimique-ont-gagne-la-commission-europeenne-enterre-le-plan-d-interdiction-des-substances-toxiques-pour-la-sante-et-l-environnement_6146397_3244.html

[21] European Environmental Bureau, "Commission's 2023 Work Programme caves under chemical and farm industry pressures," October 13, 2022, accessed March 2, 2023, https://eeb.org/commissions-2023-work-programme-caves-under-chemical-and-farm-industry-pressures/.

[22] European Commission, "Commission Work Programme 2023," accessed March 2, 2023, https://commission.europa.eu/strategy-documents/commission-work-programme/commission-work-programme-2023_en.

[23] "Commission's green chemicals goal unchanged despite REACH delay" (2022, January 11). ENDS Europe. Retrieved March 9, 2023, from www.endseurope.com/article/1802606/commissions-green-chemicals-goal-unchanged-despite-reach-delay

since September 2021. Germany probably will not need the complete €200 bn earmarked by the government to protect households and businesses from the impact of a sharp rise in energy prices. The EU is already preparing its own response to support investment in green industry. Nevertheless, despite evidence that the arguments supporting a moratorium are no longer valid, the future of the REACH reform remains uncertain.

2.2 Scenarios on the level of delay

The revised REACH legislation will need to go through the EU's ordinary legislative process, with co-decision by Parliament and Council. The length of time it takes to complete the EU this process can vary depending on the complexity of the proposed legislation, the time the institutions take for establishing their positions, and other factors such as changes in the political landscape or the priorities of the institutions.

In general, **the EU co-decision process takes between one and two or more years**, from the time the European Commission submits a legislative proposal to the time the European Parliament and the Council of the European Union approve a final text.

To better understand the scenarios of the level of delay, we summarise the stages of the co-decision process[24], each of which may take a variable amount of time:

1. First reading: The first reading begins when the European Commission, the executive body of the EU, submits a legislative proposal to the European Parliament and the Council of the European Union. The institutions then have the opportunity to propose amendments to the Commission's proposal. There is no time limit on the first reading in the Parliament and Council. However, the first reading typically takes around six to nine months.

Potential first reading agreement: Parliament and Council may try to speed up the legislative process by making an agreement before the formal vote on their first reading positions. These **inter-institutional negotiations** (often referred to as 'trilogues'[25]) are a series of informal negotiations between representatives of the European Parliament, the Council of the European Union, and the European Commission, with the aim of reaching a compromise on the final text of the proposed legislation. These negotiations can take several months to complete, but if they succeed then the final text is voted through at first reading.

2. Second reading: If the first reading does not yield a compromise, then a second reading will focus on the differences between the Parliament and Council positions. This will result in a second reading agreement – if an agreement is possible at this stage. In this case, the European Parliament and the Council of the European Union will adopt the final text of the proposed legislation. The second reading must be done within three months from when it is formally started, with a possible extension of one month. Typically, it takes around three to six months.

[24] Council of the European Union, "Ordinary legislative procedure," accessed March 2, 2023, www.consilium.europa.eu/en/council-eu/decision-making/ordinary-legislative-procedure/.

[25] Definition of trilogue available here: https://eur-lex.europa.eu/EN/legal-content/glossary/trilogue.html#:~:text=In%20the%20context%20of%20the%20European%20Union%E2%80%99s%20ordinary,of%20the%20European%20Union%20and%20the%20European%20Commission

Conciliation: If the European Parliament and the Council of the European Union cannot reach an agreement during the second reading, then a **conciliation committee** is convened to resolve the issues and find a compromise solution. The Committee has six weeks to reach a compromise agreement, which must be approved by both the European Parliament and the Council of the European Union in order to become law.

3. Final adoption: Once the European Parliament and the Council of the European Union have found a political agreement, the final draft text is sent for a check by the lawyer-linguists, following which it is formally adopted by both institutions, signed and then published in the European Official Journal. This finalisation typically takes several months.

If either institution rejects the proposal at any stage of the procedure, or the Parliament and the Council cannot reach a compromise, the proposal is not adopted and the procedure ends. A new procedure can start only with a new proposal from the Commission.

Overall, the EU co-decision process can be lengthy, particularly if the legislation is complex. However, the process is designed to be flexible and adaptable to different circumstances, and there are formal and informal mechanisms in place to manage disagreements and find compromises, which can help to speed up the process in certain cases.

2.2.1 Mechanisms that could accelerate the co-decision process:

European Council general approach

At an early stage of the legislative process (during the first reading stage), before the European Parliament delivers its opinion, the Council of the European Union may adopt a 'general approach'. This sets out the main elements of the Council's position on the proposed legislation. It is not legally binding, but it represents a strong political commitment by the Council to its position on the proposed legislation.

It provides a basis for negotiations between the Council and the European Parliament allowing to enter into negotiations without a formal common position. It also allows the Council to move forward with its mandate, even if the Parliament is not sitting due to elections (as will be the case in 2024).

Splitting the revision of REACH into two processes, co-decision and implementing act

Certain parts of EU laws can be modified by implementing acts, a non-legislative process which is generally more rapid than co-decision.

This is a possible option for REACH, where the amendment of the annexes could be done through a comitology procedure via an implementing act. This can be done as long as the amendment falls into the scope of the Commission’s empowerment. Changes to the main text of REACH would still go through co-decision.

The length of time it takes to complete an implementing act procedure can vary depending on a number of factors, such as the complexity of the issue and the level of agreement between Member States.

The Commission has been granted implementing powers by REACH, with implementing acts permitted for amendments of the REACH annexes. In practice this would mean all changes related to adding a Mixtures Assessment Factor (MAF)[26] and additional information requirements on low volume chemicals; endocrine disruptors; persistent chemicals; neuro and immuno-toxicants; and polymers (except for the explicit exemption in the core legal text of REACH) could fall under comitology.

The implementing act does not require co-decision by the EU institutions, but the involvement of the comitology committee (REACH committee), composed of representatives from all EU countries -in the form of a vote, on the Commission's proposed measures. In addition to the vote in the REACH committee, the Commission's implementing powers are also subject to the right of information and right to scrutiny by the European Parliament and Council.

Parliament and/or Council can object to the proposed implementing act if it exceeds the Commission's powers defined in the initial act or if the draft is not compatible with the aim or the content of the basic instrument or does not respect the principles of subsidiarity or proportionality.[27] The Commission is then obliged to review its proposed act in the light of this input and decide whether to maintain, amend the proposal or present a legislative proposal in the terms of the Treaty.

2.2.2 Conclusions on timeline and scenarios

Considering the co-legislation and comitology processes, and assuming the Commission will not submit its proposal for the REACH revision before June 2023, in practice, **it will not be possible for the current EU institutions to conclude a co-decision process of REACH**. Four scenarios for the REACH revision publication are considered:

SCENARIO 1

REACH proposal published in June 2023: With the Commission proposal published by June 2023, at the beginning of the Spanish Presidency of the Council of the EU, the European Parliament could adopt its position for first reading by April 2024, though this would require a rapid process of discussion. Council could be discussing its position in a similar time period and could reach a general mandate by June 2024. Negotiations for an early second reading could begin in autumn 2024, provided that the committee in charge accepts the plenary position of the previous Parliament as basis for negotiations. An early second reading agreement could then be reached by the end of 2024 or in the first half of 2025.

SCENARIO 2

September 2023: This scenario is largely uncertain. Typically, there would not be time for the European Parliament to reach the first reading stage since it typically takes 6 to

[26] In this case the empowerment given to the Commission would allow such an amendment of the Annex.

[27] According to article 5a, §3(b)(PRAC) of decision 1999/468/EC: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01999D0468-20060723

9 months. However, only a plenary vote can be carried over to the new Parliament. Progress could only be made on the Council side, which could negotiate a General Approach by June 2024, and the European Commission could move forward with an implementing act via comitology for amending the annexes, thus simplify the scope of the co-decision procedure. If Council adopts a general approach then it is unlikely that an incoming Commission would try to use the principle of 'Political Discontinuity' to withdraw the REACH proposal. However, problems could emerge if the new Parliament has substantially different priorities from the outgoing Parliament.

SCENARIO 3

October-December 2023: This scenario means that there would be no time for a substantive discussion of the text in the current European Parliament. Council discussions could move forward though, with a possibility that Spain could start discussions if publication is in October, then on to Belgium in the first half of 2024. There would be a slim chance of Belgium managing to reach a general approach or at least a partial general approach by Summer 2024, but it is more likely that discussions would continue into the Hungarian presidency. The new Parliament could start the co-legislative process in autumn 2024 provided that the new Commission does not withdraw the proposal.

SCENARIO 4

No REACH revision. The European Commission could fail to publish a REACH revision proposal, and it also has a right to withdraw proposals, though this right is not unlimited.[28] In particular, once there is a formal position in Council, then a proposal cannot be withdrawn. The REACH revision proposal could also get stuck in the first reading – where no deadlines apply – due to lack of effective discussion and decision-making in Parliament and/or Council.

Suspending the REACH revision over the European Parliament elections in 2024, will create significant uncertainties about the direction EU chemicals policy will take.

We believe that this scenario is less likely to happen, but we have seen efforts[29] from some industry and MEPs of the German EPP (European People's Party) to not have a revision of REACH at all, claiming that it would add too much burden to European industry and add to the economic crisis.

[28] www.europarl.europa.eu/RegData/etudes/BRIE/2021/689364/EPRS_BRI(2021)689364_EN.pdf

[29] https://twitter.com/MEP_Ehler/status/1620767791002550272?cxt=HHwWgIDQ4f_tj_4sAAAA

Considering these scenarios:

Under none of the scenarios will a co-decision process of REACH be concluded.

Scenario 1 would provide some predictability and certainty that the new REACH would stick to its commitments related to the environmental and human health protection as well as increased competitiveness, as it would provide a possibility for a first reading under the current European Parliament and the achievement of a general approach by the next two presidencies of the Council of the EU.

Scenario 2 could allow for a Council general approach during the term of the current Commission, but not allow for Parliament to effectively vote in first reading.

Scenario 3 would be similar to scenario 2, but would create even more uncertainty, as work in Council could only take place in 2024, and it would be unlikely for Council to achieve a General Approach before the end of the Commission mandate.

Scenario 4 would create maximum uncertainty, as the political orientation of the new Commission is unknown, so there may not be a proposal to revise REACH at all.

2.3 Aim of this report

The report attempts to qualitatively describe the gains expected from the REACH reform regarding an increased level of human health and environmental protection and improved innovation and competitiveness of the European industry.

It provides information on how the immediate gains translate into further benefits in other legal areas, including via better information and transparency. It thereby highlights the losses in the fields of occupational safety and health (OSH), consumers, the environment, the circular economy, and the industry/economy. The report describes the benefits of the REACH reform qualitatively but can only provide a limited level of detail because of several uncertainties mainly regarding:

a) the details of the Commission's REACH proposal regarding the issues addressed
b) the possible length of the delay; i.e. which of the scenarios will actually take place (cf. Section 2.2 above)
c) the reactions of market actors to legislative changes.

The report does not consider the costs or burdens the REACH reform may add to the various actors because it is assumed that the benefits will by far outweigh the risks, in line with previous

reviews[30] by the European Commission of the REACH regulation. In order to keep this report concise and focussed, only the major aspects of the REACH reform are addressed.

2.4 Methodology

For this report, we compiled available information on the REACH reform and the types of gains that it would bring. Then, we analysed how the gains from REACH would improve the implementation of chemicals and other policies in order to contribute to the goals of the Chemicals Strategy for Sustainability (CSS), the European Green Deal and the broader Sustainable Development Goals (SDGs). We provided some quantitative information from impact assessments or other studies to illustrate the gains or damage prevented.

The potential REACH amendments analysed here are the ones considered by the Commission, as indicated by the Chemicals Strategy for Sustainability, its Work Programme, the Impact Assessment process (consultations, workshops etc.) as well as discussions in CARACAL[31] and other fora.

Due to the lack of reliable, transparent and quantitative data on the benefits of chemicals legislation in general, and the envisaged changes under REACH in particular, for most aspects it is difficult to quantify the benefits in terms of e.g. prevented cancer cases or prevented environmental damage and related medical care or remediation costs. This is a pervasive problem in chemicals policy, where impacts often occur years after exposure and are not identified until it is too late. For example, we are all contaminated with PFAS and there is no way of removing this contamination, even if regulators demanded that the chemical industry pay for it.

On the other hand, cost estimates of implementing certain actions under REACH, like the development of registration dossiers, or the reformulation of a mixture to replace a hazardous chemical, have been developed for impact assessments, restriction proposals or authorisation applications. However, this information is difficult to verify and has been criticised.

One example is the most recent impact assessment published by CEFIC[32] on the impacts of the Chemicals Strategy for Sustainability, including the Generic Approach to Risk Management (GARM, also known as GRA). CEFIC's assessment has been criticised by the EU Commission, DG GROW, as overestimating the costs of the implementation of the GARM, by assuming a very rigid approach of the Commission's future actions, i.e. prohibiting all

[30] European Commission (2013): REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS in accordance with Article 117(4) of REACH and Article 46(2) of CLP, and a review of certain elements of REACH in line with Articles 75(2), 138(2), 138(3) and 138(6) of REACH. COM(2013) 49 final. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013DC0049&from=EN

European Commission (2017): COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE. COM(2018) 116 final, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0116&from=EN

[31] Competent Authorities for REACH and CLP: https://ec.europa.eu/environment/chemicals/reach/competent_authorities_en.htm

[32] https://cefic.org/app/uploads/2021/12/Economic-Analysis-of-the-Impacts-of-the-Chemicals-Strategy-for-Sustainability-Phase-1.pdf

substances in the scope of the GARM in all their uses.[33] Additional criticism about the study include that cost estimates are extrapolations based on (limited) industry data which cannot be checked by "outsiders". Further, neither are changes in the market and benefits for alternative providers taken into account, nor are the effects on the downstream user industries considered. However, according to the study it had become evident that many products do contain substances of (high) concern and might pose risks to human health or the environment.

The lack of balance between (quantified and) detailed cost estimates and the (hardly quantifiable) benefits has been frequently discussed, amongst others in the Socio-Economic Analysis Committee in the context of REACH restrictions, as well as in the context of applications for authorisation. This has been one of the reasons, why the Essential Use Concept (EUC) has been suggested for introduction under REACH, and horizontally.

Consequently, this report does quote cost and benefit figures, where available and considered reliable and relevant. However, they should be regarded as additional and illustrative information rather than firm evidence.

3 Expected gains from the REACH Revision

3.1 Increased level of protection of human health and the environment

All legislation on chemicals considered in this report aims at increasing the level of protection of human health (workers and consumers) and/or the environment through the reduction of risks from chemicals. This aim requires the reduction of exposures to the hazardous chemicals, which can be achieved via:

- Eliminating the most hazardous chemicals, with the exception of essential use, starting with the most hazardous substances, mixtures or chemicals in products that could be used by consumers and professionals
- Applying technical, organisational or personal measures (risk control measures) to minimise emissions of and exposure to all hazardous chemicals
- Improve transparency on the occurrence of hazardous chemicals to enable all users of chemicals (in products) to take informed decisions
- Developing safe and sustainable by design alternatives

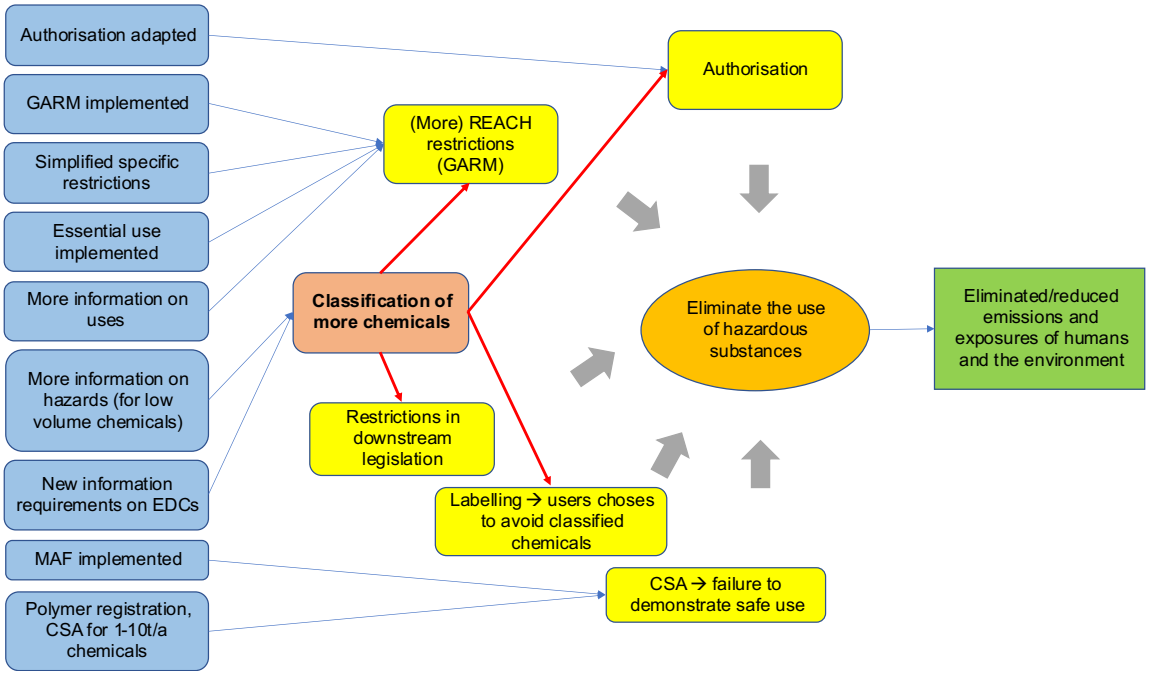
The **elimination of the most hazardous chemicals** can be a result of REACH restrictions (Annex XVII) or a failure to apply for or receive an authorisation. Downstream legislation, e.g. the Toy Safety Directive or the Cosmetics Regulation, may also restrict the use of substances either via a reference to classification (e.g. CMRs) or based on a specific risk assessment (requiring hazard information). Uses can also be eliminated when registrants fail to demonstrate safe use in their chemical safety assessment (CSA), when the use is not identified

[33] https://chemicalwatch.com/426447/cefic-overestimates-impact-of-reach-revision-says-commission-expert

in the safety data sheet (SDS) or is classed as 'use advised against'. Transparency on the occurrence of chemicals in products may result in the elimination of uses via market demand, i.e. the will of the consumer.

Figure 1 shows how the proposed changes of REACH are linked to the elimination of unsafe uses of chemicals resulting in an increasing level of protection and economic benefits.

Figure 1: Changes in REACH supporting the elimination of uses

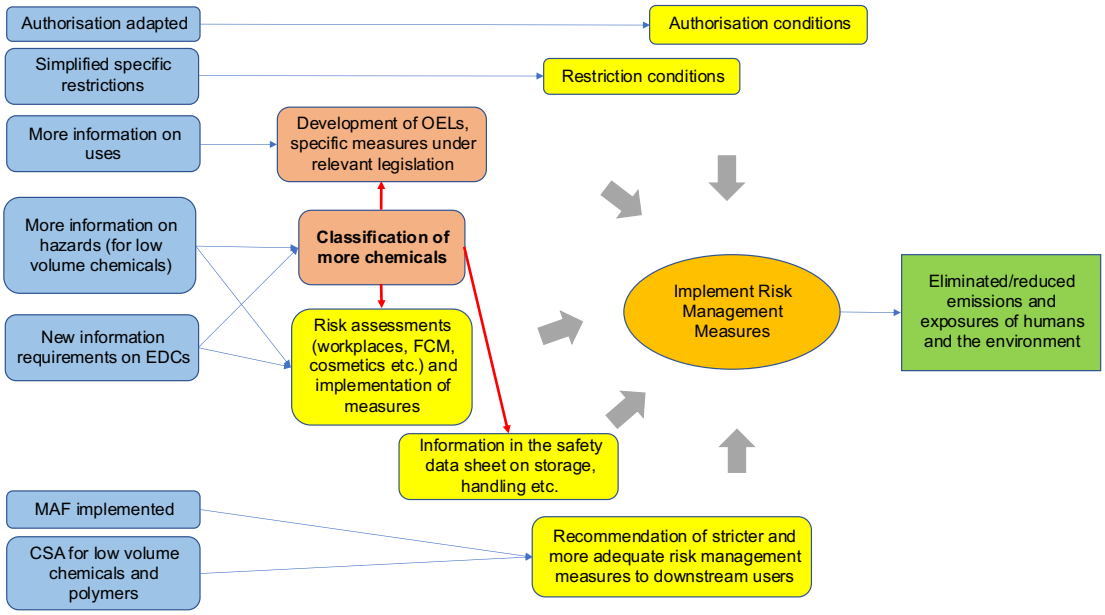


The level of protection can also be increased by **limiting emissions and exposures** from processes to workplaces and the environment through the application of technical or organisational measures or the use of personal protective equipment. Emissions and exposures products can mainly be reduced by concentration limits. Risk management measures can be triggered by conditions in authorisations, restrictions or specific OSH, product or environmental legislation, including Occupational Exposure Limit Values (OELs) or Environmental Quality Standards (EQSs).

The classification of a chemical and/or (new) hazard information may trigger specific measures, such as consideration in workplace risk assessments or derivation of specific migration limits in food contact materials legislation. Also, general risk management information in safety data sheets influences the handling, emissions and disposal of chemicals (in products), contributing to exposure reduction.

Finally, (better and more) chemical safety assessments result in improved recommendations for risk management measures, which should be implemented by downstream users. The following figure illustrates how the REACH changes would lead to the implementation of improved risk management measures:

Figure 2: Changes in REACH supporting improved emission and exposure controls

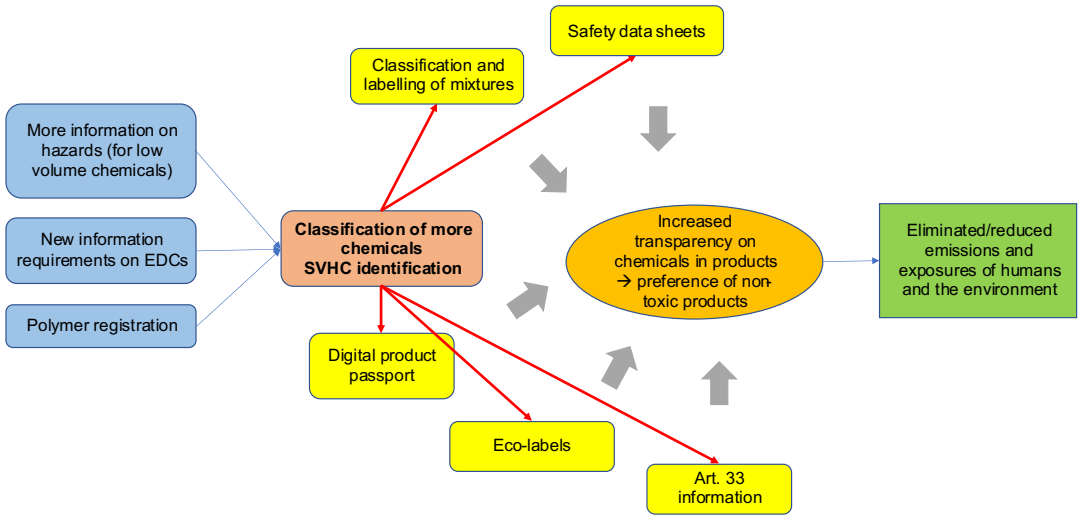


Currently, information on the **occurrence of chemicals is not transparent**, in particular in consumer articles. If chemicals users and consumers had more information, they could decide to choose non-toxic products (if available) and thus, market forces would contribute to the increase of protection level.

Transparency in the supply chain would increase if more chemicals were classified. This information would not only be passed in the supply chain via the safety data sheets but could also feed into other legislation, such as the digital product passport planned under the sustainable products regulation.

Figure 3 illustrates how increased transparency would reduce emissions and exposures to chemicals and support competitiveness and innovation of the European industry:

Figure 3: Changes in REACH supporting transparency on chemicals in products



The availability of safe and sustainable by design (SSbD) alternatives is essential to allow the phase out of hazardous chemicals or to allow choosing between different products. The development of such chemicals is supported by the recently adopted Commission's SSbD framework[34] but would also receive significant impetus by a clear and strict REACH regulation that indicates what chemicals are unwanted in the future and would be restricted or subject to authorisation.

If there is no guarantee that the unsafe or unsustainable (and probably cheaper) chemical will be removed from the market, then there is no certainty that better (but probably more expensive) chemicals would have a good market. Furthermore, a strong and comprehensive REACH providing a clear and predictable regulatory environment would ensure investments are directed into sustainable solutions and that downstream industries cooperate in innovation activities.

3.2 Enhanced competitiveness and innovation of the European Industry

Enhanced competitiveness and innovation of the European industry can be achieved by:

- Transitioning the chemicals sector towards a sustainable, climate-neutral industry that supplies the economy with safe and sustainable chemicals
- Incentivising the development of safer chemical and non-chemical alternatives to the use of substances of concern, by clearly signalling to the market that these chemicals will be restricted in the (near) future
- Promoting the use of safer alternatives though more transparency on the uses and hazards of chemicals and encouraging industry actors to cooperate along and across supply chains
- Transforming the global chemicals industry and markets by working towards the adoption of European legislation as a global standard

The European industry acts in a global context and is subject to a competitive market. The CSS states that the "EU Green Deal […] has set the EU on a course to become a sustainable climate neutral and circular economy by 2050."[35] According to the CSS, the EU's comprehensive and protective legal framework is predictable and becoming a safety standard worldwide.

[34] COMMISSION RECOMMENDATION of 8.12.2022 "Establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials. Available at: https://research-and-innovation.ec.europa.eu/system/files/2022-12/Commission%20recommendation%20-%20establishing%20a%20European%20assessment%20framework%20for%20safe%20and%20sustainable%20by%20design.PDF

[35] EU Commission (2020): COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. COM(2020) 667 final. Brussels. Available at: https://environment.ec.europa.eu/strategy/chemicals-strategy_en

The Transition Pathway for the Chemical Industry[36] outlines actions that should support its green and digital transition. Its implementation by the chemical industry is said to "[…] *improve its own resilience, sustainability and circularity.*" It further specifies that "*to strengthen the competitiveness of the chemical industry it is necessary to […] continue enhancing the safety and sustainability of chemicals and materials […].*" It relates to the concept of safe and sustainable by design which specifies that SSbD chemicals should not have properties of high concern.

The implementation of the Transition Pathway will be supported by public and private investments into chemical producers and users. The REACH reform is a once-in-a-lifetime opportunity to ensure that these investments are directed not only towards carbon neutrality and decreased dependency on 'external supply chains' but to also and equally to ensure that the safety of chemical products is considered.

The Transition Pathway is vague regarding the quality of the chemical industry's products, hence a clear and predictable legal framework is needed. If the REACH revision is implemented now, this predictable legal framework would exist. If REACH is delayed, the industry will be left with a high degree of uncertainty as to which parts of the REACH reform will be implemented and as to when to expect a loss of the incentives to develop alternatives that are safe and sustainable by design, creating the 'market pull' the Transition Pathway posits as necessary.

The implementation of the REACH reform would reward front runner companies that have already invested in the substitution of hazardous substances, following the goals of the CSS. In particular, a strong incentive for the substitution of hazardous chemicals from everyday (consumer) products would be generated due to the implementation of an improved authorisation process which would in turn result in fewer authorisations being granted. This would be due to the application of an assessment on whether to qualify the use as essential, as well as due to the implementation of the GARM.

Substitution would then reduce costs associated with educating workers, waste handling, emissions control, and health costs for workers, ultimately improving the overall performance of the industry. These REACH risk management measures would also put European companies, innovators and SMEs in a pole position in the global market for sustainable and safe chemicals.

4 Links between REACH changes and expected gains

Overall, the projected amendments of REACH would considerably improve the capacity of public authorities and companies to increase the level of protection by:

[36] EU Commission (2023): Transition Pathway for the Chemical Industry. Available at: https://ec.europa.eu/docsroom/documents/53078

- **Securing an information basis** that would allow to identify the hazards of chemicals more completely than now and to classify them or to identify them as SVHCs, which would trigger further (regulatory) risk management measures
- **Enabling quicker and more effective restrictions**, more responsive to the evolution of our understanding of chemical pollution and less resource-intensive for public authorities
- **Creating a more resource efficient way to decide** when and why some hazardous chemicals may be allowed a transitional period to be phased out
- **Increase the compliance with existing rules**, to ensure a level playing field and a better protection

4.1 Increased visibility of the chemicals' universe through new and adapted information requirements

The REACH revision envisages several changes that aim to improve the availability of information on chemicals.

The availability of hazard information is a pre-condition for the classification of chemicals and/or the identification of SVHCs. The classification and/or SVHC identification is the initial trigger for regulatory and voluntary risk management. Therefore, hazard information is essential for starting new or enhancing existing risk management processes.

Information on uses is essential for the authorities to prioritise chemicals for risk management, to assess potential risks and select appropriate control instruments under REACH or other legislation. Therefore, use information indicating exposure patterns and exposure levels, is essential for an efficient and effective risk management process.

Better information on hazards and uses would mean:

- **More hazardous chemicals can be identified, and hence classified or introduced in the REACH Candidate List as SVHCs:** If more hazard information is generated for more chemicals, more substances can be classified for more endpoints either by the manufacturers and importers (self-classification), or by the authorities (harmonised classification). More chemicals would be introduced in the Candidate List as SVHCs.

  This impacts on:

  - **Workers health**: classified and very high concern substances must be considered in the employers' workplace risk assessment and derivation of risk reduction measures, including for occupational carcinogens, mutagens and reprotoxicants. For classified substances as well as Candidate List substances, information must be provided via safety data sheets. Employers and workers can use them to ensure the safe handling of chemicals. Classified substances are more likely to be prioritised for further risk management at workplaces than non-classified ones, e.g. via the development of occupational exposure limit values (OELs), or specific restrictions. SVHCs trigger information requirements

throughout the supply chain (Article 33.1) which trigger more protective measures.

- **Consumer protection**: a CMR classification (almost) automatically restricts the use in consumer chemicals (Annex XVII) and other downstream legislation, such as the Toy Safety Directive or the Cosmetics Regulation. If the GARM is implemented (cf. Section 4.3), classification would speed up this process. Classified substances are also more likely to be prioritised for risk management, e.g. under the Food Contact Materials Legislation.
- **Environmental protection**: the effects of classification and SVHC listing on consumers and workers would also impact on environmental exposures. Moreover, waste containing hazardous chemicals (classified under CLP) would be considered as hazardous waste with strict waste treatment rules.

- **Improved identification of risks**: More data on the hazards and uses of (low volume) chemicals and polymers would allow regulators to assess and identify risks more efficiently and comprehensively. This would allow for better prioritisation of chemicals for regulatory risk management and determining the appropriate level of control.
- **Better decision-making on risk management**: The improved risk assessments would allow regulators to decide about the risks and benefits of different chemicals, whether or not, and under which conditions, to allow their use and which regulatory instrument would best suited to manage risks.
- **Increased innovation**: Better and more information on hazards and uses would support the assessment of safer alternatives (higher certainty about the absence of hazards), and encourage innovation in the development of new, safer chemicals.
- **Greater transparency and change of market demands**: Increased information would promote greater transparency on the occurrence of hazardous substances in products within the supply chain and for consumers and other stakeholders, allowing them to make more informed decisions about the products they use and the companies they support.
- **Better management of resources**: Information on hazards and uses of chemicals would support the implementation of a non-toxic circular economy, because waste treatment and recycling processes could consider chemicals in their input materials (wastes), generate more and cleaner secondary materials and separate wastes containing toxic chemicals from the economy.
- **Improved monitoring**: Better use of information would enable regulators to develop more effective monitoring programs to detect and respond to environmental contamination, reducing the risk of long-term harm to the environment.
- **Enhanced public awareness**: Increased information would raise public awareness about the potential risks associated with chemical use and promote greater environmental responsibility among businesses and consumers.

4.1.1 Registration of low volume substances

Current situation

Companies must register all substances they manufacture or place on the market in quantities above 1 tonne per year. The required information depends on the tonnage of the chemical produced or marketed.

In the current situation, very limited information[37] is required for the chemicals registered between 1 and 10 tonnes per year. The lack of information on e.g. repeated dose toxicity and on long-term toxicological and ecotoxicological endpoints, including carcinogenicity, persistence and bioaccumulation potential prevents an adequate identification of the hazardous properties of the low volume chemicals. Whereas a Chemical Safety Assessment (CSA) and Chemical Safety Report (CSR) is required for chemicals registered >10 tonnes per year, such CSA/CSR is not required for chemicals registered between 1 and 10 tonnes per year.

The European Chemicals Agency's (ECHA) assessments of regulatory needs is currently hampered by the lack of use information, e.g. for the prioritisation of which substances should be suggested for harmonised classification, for substance evaluation or for restrictions, and to determine which substances might be better regulated under other legislation.

Changes expected in the REACH reform

The CSS identified the need to increase the information requirements for substances at all tonnage levels to enable the identification of critical hazard properties, such as carcinogenicity and to enable companies to perform a CSA and prepare a CSR for low volume chemicals registered between 1 and 10 tonnes per year.

The upcoming revision of the information requirements should ensure that the registration dossiers must contain all necessary information for the hazard identification of low volume chemicals by companies and authorities. The update of the information requirements should facilitate the self-classification by companies as well as harmonised EU classification by authorities. Clearly a balance would have to be found between the necessity to provide more information for protection of human health and environment with the reduction of animal tests, as the EEB and CHEM Trust already agreed[38] in other public positions, for instance by implementing the use of the precautionary principle and by working towards a gradual transition to hazard identification based on new approach methodologies (NAMs) in the future.

It is expected that the proposal for an update of the REACH Annexes includes several changes to the information requirements for low volume chemicals. Several scenarios have been discussed, but it is not yet known what the final proposal will look like. Scenarios discussed include to merge Annex VII and Annex VIII, which would enhance the information available for

[37] The current information requirements for low volume chemicals allow the hazard identification of mutagenicity, genotoxicity, skin and eye irritation, skin sensitisation, acute (oral) toxicity, aquatic toxicity for only one species, growth inhibition of aquatic plants and ready biodegradability.

[38] European Environmental Bureau, "Letter to Frans Timmermans and relevant Commissioners on need to update the REACH information requirements," February 27, 2023, accessed March 8, 2023, https://eeb.org/wp-content/uploads/2023/02/20230227-EEB-letter-to-Timmermans-and-relavant-Commissioners.pdf.

the lowest tonnage chemicals to the level of information currently required for substances registered between 10 and 100 tonnes per year.

The envisaged CSA/CSR will require manufacturers and importers to provide information on the uses of their chemicals according to the current use descriptor system. This will enhance the knowledge base on chemical uses for prioritisation and risk assessment of authorities. In addition, the CSA/CSA will form the basis for recommending (improved) risk management measures at the workplace along the supply chain through the SDS.

Overview of lost benefits due to a REACH delay

A delay in the implementation of increased information requirements for low volume chemicals would mean that no additional hazard and use information is available and no chemical safety assessments must be performed. As a result, the mechanisms leading to an increased level of human health and environmental protection, including via downstream legislation could not be realised.

Almost 10,000 substances are registered at the lowest tonnage band of 1 - 10 tonnes per year. A recent report estimated that between 99 and 139 low volume chemicals potentially meet the Substances of Very High Concern (SVHC) criteria, hence a priority for phase out, but remain unnoticed due to the lack of crucial hazard information[39]

The extent of the impact (of a delay) depends on the specific measures that are proposed and eventually accepted in the REACH revision. The more stringent the information requirements are implemented, the better the information basis for regulatory risk management will be. On the other hand, the costs for implementing the information requirements for industry will also increase. It is clear however that benefits for society would by far exceed the costs to industry. In fact, the generation of information is also an investment that would be 'worth the money in the end' to help companies to promote innovation in the chemicals sector and bring safer products to the market, as recognised by BASF in 2012, referring to the REACH registration costs.[40]

At a qualitative level, the current challenges regarding the lack of basic toxicity data and a chemical safety assessment will remain, continuing the delay in managing risks of the substances of most concern, the related inefficiencies in processes and the lack of abilities to monitor policy progress and target enforcement campaigns.

[39] European Commission, Directorate-General for Environment, Footitt, A., Postle, M., Vencovska, J., et al., Gather further information to be used in support of an impact assessment of potential options, in particular possible amendments of REACH Annexes, to modify requirements for registration of low tonnage substances (1-10t/year) and the CSA/CSR requirement for low tonnage substances with or without CMR properties in the framework of REACH : final report, Publications Office, 2020, https://data.europa.eu/doi/10.2779/37609

[40]Euractiv, 3 September 2012: 'REACH chemical law 'worth the money in the end', says BASF. Available at: www.euractiv.com/section/sustainable-dev/news/reach-chemical-law-worth-the-money-in-the-end-says-basf/

4.1.2 Polymer registration

Current situation

People and the environment are widely exposed to polymers, the main constituents of plastics. The number of polymers on the EU-market is estimated as 70 000 – 400 000, being 200,000 the best estimate.[41] These chemicals continue to build up in terrestrial and ocean ecosystems and production is predicted to continue increasing, resulting in emissions to our waterways of up to 53 million tons (Mt) per year by 2030. Apart from plastics, polymeric substances are present in many other materials, products and applications, including but not limited to silicones, coatings, paints, detergents, household and personal care products, agricultural fertilizers and wastewater treatment, often leading to direct releases into the environment.[42]

Although polymers are manufactured and used in Europe in extremely high quantities (e.g. plastic production in Europe has been above 65 million tonnes per year over the last years[43]), no systematic public information is available today on identity, hazards, quantities, uses, and exposure of the polymers produced and marketed in Europe. There is partial information on many monomers (e.g., BPA, styrene) and additives used in plastics, like phthalates, but we have little to no information on polymers, while there are many concerns about their environmental and human health impacts.

Polymers were exempted from registration when the legal text was approved back in 2006, although Art. 138 requested the Commission to present a legislative proposal as soon as a practicable and cost-efficient way of selecting polymers for registration could be established and after following a report on the risks of polymers compared to other substances and the need, if any, to register certain types of polymers. Since then, the Commission has requested three studies, in 2012[44], 2015[45] and 2020[46]. CARACAL established a stakeholders expert subgroup[47] to provide advice to the Commission called CASG-polymers.

All three studies showed that the societal benefits of registering all polymers outweighed its costs. The impact assessment included two options, one presented by ECETOC and industrial stakeholders and another proposal from ECHA. Both options include notification obligations for all polymers although the data to be provided differs and both options also fluctuate on the number of polymers to be registered (based on their potential hazard) and timeline.

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[41] European Commission: https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/b97e285c-2454-499c-84cd-3d11efd57f4c/details

[42] Statement on the registration of polymers under REACH Authored by and signed by members of the scientific community, April 2021. Available at: https://eeb.org/wp-content/uploads/2021/04/Statement-on-the-registration-of-polymers-under-REACH-_v250421.pdf

[43] PlasticsEurope, 2020

[44] Review of registration dossiers for chemicals: Study on the review of the operation of REACH by the European Commission." (2012). Available at: http://ec.europa.eu/environment/chemicals/reach/pdf/studies_review2012/report_study10.pdf

[45] European Commission. "Study on the Evaluation of the Application of the Definition of 'Polymers' in the REACH Regulation." (2017). Available at: http://ec.europa.eu/environment/chemicals/reach/pdf/FINAL%20REPORT%20POLYMER%20SI671025.pdf

[46] European Commission. "Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Chemicals Strategy for Sustainability Towards a Toxic-Free Environment." (2020). Available at: https://op.europa.eu/en/publication-detail/-/publication/1cc811ff-d5fc-11ea-adf7-01aa75ed71a1.

[47] CASG_polymers

Changes expected in the REACH reform

Registration will provide basic information on the identity, quantities, uses, hazards and risks posed by polymers. A 2020 study[48] estimated that there are 200,000 polymers on the EU market and up to 30,000 may require registration. However, given the reduced scope of the polymers that may require registration criteria, we estimate that only 12,000 (6%) out would have to run safety checks.

Ahead of the registration phase, a mandatory notification of polymers was agreed in CASG-polymers as necessary for all polymers.

Six notification purposes are identified:

1) Information for authorities as to how many polymers are marketed that require registration (PRR) and non-PRR
2) Information for the public as to how many PRR/non-PRR are marketed
3) Information for companies to facilitate the forming of joint registrations and grouping of PRRs
4) Information for enforcement authorities to check process conditions linked to precursor status
5) Information for authorities to check the conclusion on non-PRR status, in case of concern arising

   Additionally: information on available hazard data for authorities
6) Information for ECHA to develop grouping criteria

As a second step, companies would be required to provide additional information through the REACH registration process.

Overview of lost benefits due to a REACH delay

The notification of polymers would provide the authorities with an overview of which polymers are used in the market and might be useful for further regulatory action, e.g. in the context of the Plastics Strategy.

The registration of (certain) polymers would be the first step in regulatory risk management. As with other chemicals, the information provided would be used to prioritise polymers for further assessment and potential risk management activities. Polymer manufacturers would have to prepare a CSA, resulting in the identification of uses that cannot be supported because no conditions of safe use can be identified. Furthermore, polymer manufacturers would have to provide hazard, use and risk information along the supply chain, thus enabling downstream users to protect themselves at their workplace, prevent environmental emissions and design their (consumer) products based on information.

[48] Scientific and technical support for the development of criteria to identify and group polymers for registration/evaluation under REACH and their impact assessment. Final report, European Commission. Available at: https://op.europa.eu/en/publication-detail/-/publication/1cc811ff-d5fc-11ea-adf7-01aa75ed71a1

Further gains that would be postponed if the polymer registration is delayed due to a delay in the REACH reform are:

- **Circular economy**: Information on the composition, biodegradability and potential hazards of polymers could help to identify materials that are more suitable for recycling or reuse and support the development of more effective and efficient recycling technologies. In addition, the information could help to improve the environmental performance of polymers throughout their life cycle, from production to disposal. This would support the implementation of the Plastics Strategy and the transition to a more circular and clean economy.
- **Competitiveness and innovation**: the availability of information on polymers could help to increase transparency and trust in the market, which in turn could benefit companies that are already producing safer and more environmentally friendly polymers (meaning degradable and non-toxic), as they could use the information to differentiate their products and gain a competitive advantage.

  The registration process could also encourage the development of safer and more sustainable polymers, create opportunities for new players to enter the market and highlight areas for research and development, which could support the emergence of new technologies and business models.

  Registration of polymers ensure that all substances are subject to the same standards and requirements (level playing field), thereby preventing unfair competition and providing greater certainty for companies that are already producing safer and more environmentally friendly polymers.

The consequences of a failure to require the registration of polymers in the REACH reform is that polymers will not be accessible to risk management under REACH and other legislation. Due to the lack of basic information on this group of chemicals, no prioritisation, no risk assessment, and no regulatory risk reduction measure will be implemented. This will also have an impact on the circular economy and industry competitiveness and innovation; ultimately this will result in a continued exposure of people and the environment to hazardous chemicals and a less competitive industry.

4.1.3 Information requirements for the identification of EDCs

Current situation

Under REACH, endocrine disrupting chemicals (EDCs) can be identified as a SVHCs according to REACH Art. 59 on a case-by-case basis by assessing if they fulfil the criteria of REACH Art. 57(f) (if sufficient data is available, e.g. from scientific literature) or via a substance evaluation according to Title VI (if information is missing and must be requested from the registrants). The process of identifying e.g. BPS as an endocrine disruptor started in 2012 (registry of intention) and ended in January 2023 with the inclusion in the Candidate List due

to ED properties (11 years). According to the EEB report Need for Speed[49], 105 substances were assessed for endocrine disrupting (ED) properties during the years 2014-2022. Of these, 84 are still awaiting a conclusion. A substance evaluation, which is needed to get registrants to generate data in case the available information is insufficient to allow a conclusion regarding the ED properties of a substance, is specified to last between 7 and 9 years.

Until now, ECHA's ED expert group has only 'identified' 18 EDCs since it was established, and in total, the EU competent authorities have, over the last 16 years, identified 22 substances/substance groups as EDCs included in the Candidate List. This rate of identifying a mere two EDCs per year would, if extrapolated to the future, leave many EDCs unidentified and therefore risks improperly managed.

A (harmonised) classification as an EDC is currently not possible. However, the Commission adopted a delegated act[50] to amend the Regulation on the Classification, Labelling and Packaging of Substances and Mixtures[51] (CLP) to introduce, amongst others, new hazard classes for EDCs to human health and EDCs to the environment, including 2 hazard categories: Category 1 for known or presumed EDCs and Category 2 for suspected EDCs. [52] An upcoming guidance document will specify the details regarding the evidence needed for classifying chemicals according to the new hazard classes. The new hazard classes are a milestone in the implementation of the CSS as they establish a horizontal approach to EDC identification, which has been criticised as lacking in the fitness check of the regulatory measures as regards EDCs.[53]

The CLP Regulation requires chemicals suppliers to use the available data for the classification of their substances and mixtures, but it does not require them to generate new data on the hazardous properties of substances. The type and extent of information requirements under REACH[54] determine the extent of the functioning and effectiveness of the CLP regulation.

The current information requirements under REACH are not sufficient to allow the classification of EDCs according to the new CLP hazard classes, which require both information on a substance's adverse effects and its endocrine mode of action.

Changes expected in the REACH reform

Additional information requirements under REACH have an immediate impact on the ability to classify substances as EDCs. The classification may then be a trigger for further requirements

[49] The European Environmental Bureau (2022): The Need for Speed. Available at: https://eeb.org/need-for-speed-on-chemical-protections-in-europe/

[50] Commission Delegated Regulation (EU) …/... of 19.12.2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures

[51] REGULATION (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures

[52] EU Commission (2022): Annexes to the Commission Delegated Regulation amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures. C(2022) 9383 final annexes 1 to 4, Brussels.

[53] Commission Staff Working Document Executive Summary of the Fitness Check on Endocrine Disruptors of the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and The Committee of the Regions. SWD(2020) 225 final (ED Fitness check)

[54] In addition, the Biocidal Products Regulation and the Plant Protection Products Regulation require the suppliers of active substances to generate and provide information on the hazardous properties of the substances, but these are not subject of this report.

in downstream legislation aimed at reducing exposure and risks to these substances. Therefore, the impacts of the REACH reform regarding information on EDCs are considered in close relation to the CLP regulation.

According to the Chemicals Strategy's EDCs Action Plan[55], the REACH Annexes should be adapted to "[…] allow the identification of endocrine disruptors in relevant legislation […]". We therefore expect that any data requirements under REACH will have to be aligned with the information needs for classifying substances under CLP as well as identifying SVHCs under REACH. According to the proposed amendments of the CLP regulation, any suitable and appropriate information may be considered in a weight of evidence determination to decide if a substance is to be classified as an EDC.

We expect the new REACH information requirements to cover data on adverse effects and on the endocrine mode of action. This would include literature data and information from in vitro tests for the substances registered in volumes from 1-10 t/a to allow initial conclusions on the potential existence of ED properties and trigger further testing.[56]

Overview of missed gains due to a REACH delay

As outlined in the introduction, the main missed gain from the REACH revision delay would be that the information basis to classify EDCs or identify them as SVHC would be missing. This will have two types of consequences:

- SVHC identification/harmonised classification has to rely on available data, which will have to be identified and evaluated by the authorities (impacting on the efficiency of the process). If no data is available from public sources:
  - Substances will not be identified as SVHC or classified as EDC; or
  - First a substance evaluation will have to be started to generate new data. This might delay the ED identification for some 7-9 years (cf. above).
- Authorities will have to rely on QSARs and read across therefore continue to have difficulties and uncertainties in prioritising substances for regulatory action, including harmonised classification or SVHC identification.

As a consequence, the speed of EDC identification/classification will be extremely low.

If no/few EDCs are identified as SVHC/classified, no further actions will be triggered (cf. list of measures depending on classification, SVHC identification and hazard information). Unidentified EDCs will continue to be used (unknowingly) and not be adequately controlled, resulting high exposures of workers, consumers and the environment.

[55] EU Commission (2020): Annex to the communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. COM(2020) 667 final, Brussels.

[56] CHEM Trust and HEAL submitted detailed comments to the Commission's proposals on the information requirements to identify ED properties.

Studies with pregnant **workers** that had been exposed to EDCs at the workplace showed that their children have an increased risk of congenital anomalies of the kidney and the urinary tract[57] or a risk of lower birth weight[58]. In one study, it was derived that 11% of the women participating in the study were exposed to EDs at the workplace[59]. Hence, it is possible that as a minimum 10% of the workforce are currently exposed to EDCs without even knowing it.

In a publication of 2016[60], a group of scientists estimated the **costs of exposure to EDCs** in the EU. They found that EDCs can be associated with (> 20% causation), amongst others, IQ loss, autism, attention-deficit hyperactivity disorder, male infertility and obesity. Accounting of the 20% causation probability, they calculated the related costs of being at least 109 billion euros per year, only for those substances that were included in the study. In an update of that study[61], they included further adverse effects on women's health and increased their cost estimates to a median of 163 billion euros per year.

Another study by the University of Utrecht[62] estimates socio-economic health costs associated with exposure to EDCs ranging between 46 and 288 billion euros per year, noting that the figures should be handled with care in view of the uncertainties related to the causality of EDCs and health related costs.

The Nordic Council[63] estimated societal costs related to endocrine effects on male reproductive health and extrapolated the results to the EU28 based on population size. Allocating 20% of the health-related costs to EDC exposure, the total costs are estimated at 592 million euros per year for male reproductive disorders alone.

The state-of-the-art report on endocrine disruptors[64] in 2011, provides an extensive overview of the evidence about **adverse effects of EDCs on wildlife**, indicating that EDCs in the environment can cause significant damage. This includes impacts on biodiversity from endocrine related adverse effects on behaviour, reproduction or the immune system. The scale of effects in relation to exposure is challenging to predict, due to low-dose effects, non-linear dose response relationships and the dependence of effects on the time of exposure. The current bisphenols restriction does not calculate any environmental impacts at all but specifies exposure reduction as an appropriate proxy for risk reduction.

Knowledge of which substances are EDCs is a pre-condition to implementing a non-toxic circular economy. Examples of gains that would be delayed if EDCs are not identified are:

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[57] https://academic.oup.com/humrep/article/37/1/142/6422201

[58] www.ncbi.nlm.nih.gov/pmc/articles/PMC5089886/pdf/EHP208.pdf

[59] www.ncbi.nlm.nih.gov/pmc/articles/PMC5089886/pdf/EHP208.pdf

[60] Trasande L, Zoeller RT, Hass U, Kortenkamp A, Grandjean P, Myers JP, DiGangi J, Bellanger M, Hauser R, Legler J, Skakkebaek NE, Heindel JJ. (2015): Estimating burden and disease costs of exposure to endocrine-disrupting chemicals in the European union. J Clin Endocrinol Metab. 2015 Apr;100(4):1245-55. doi: 10.1210/jc.2014-4324. Epub 2015 Mar 5. PMID: 25742516; PMCID: PMC4399291. OII

[61] L. Transande (2016): Burden of disease and costs of exposure to endocrine disrupting chemicals in the European Union: an updated analysis. https://doi.org/10.1111/andr.12178. Available at: https://onlinelibrary.wiley.com/doi/full/10.1111/andr.12178

[62] Ingrid Rijk et al. (2016): Health costs that may be associated with Endocrine Disrupting Chemicals. Available at: www.uu.nl/sites/default/files/rijk_et_al_2016_-_report_iras_-_health_cost_associated_with_edcs_3.pdf

[63] Ing-Marie Olsson et al (2014): The Cost of Inaction A socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health. Available at: http://norden.diva-portal.org/smash/get/diva2:763442/FULLTEXT04.pdf.

[64] A. Kortenkamp et al. (2011): STATE OF THE ART ASSESSMENT OF ENDOCRINE DISRUPTERS Final Report. Available at: https://ec.europa.eu/environment/chemicals/endocrine/pdf/sota_edc_final_report.pdf

- Decrease of waste products with EDCs (due to phase-out) resulting in less contaminated waste streams and secondary materials
- Better separation of EDC-containing wastes resulting in clean(er) secondary materials
- Consideration of EDCs in waste classification (as hazardous) ensuring regulatory control of the waste treatment processes and the use of more protective technologies,
- Information provision on EDCs (identified as SVHC) in products via the SCIP database

If the REACH reform is delayed and EDCs are not classified/identified, the current situation of (unknowingly) recycling EDCs will continue, resulting in costs due to human and environmental exposure to EDCs and losses in resource efficiency due to the uncertainty about the content of EDCs (and other toxic chemicals) in wastes.

Competitiveness and innovation would also benefit from more information: Without knowledge about ED properties of substances, market actors are unable to act but face a high level of uncertainty about the (future) compliance of their products, as well as related business risks from the use of these substances.

4.1.4 Neurotoxicity and immunotoxicity

The current registration information requirements do not allow the identification of neurotoxic or immunotoxic chemicals. Neurotoxic chemicals can affect brain development after prenatal exposure, and lead to learning disabilities, mental retardation and behavioural disorders in the offspring at later stages in life[65]. Immunotoxic effects include immunosuppression, which can reduce resistance to infections and tumours, and the capacity to respond to vaccines. Immuno-active chemicals are also linked to causing allergies, and increased vulnerability to autoimmune diseases like diabetes. Effects on the proper functioning of the immune system continue to be discovered due to exposure to chemicals.

The CSS proposed a revision of the requirements for registration in order to ensure an effective identification of the substances with critical hazard properties, which may affect the nervous and immune systems. The purpose of this revision is to assist companies and authorities in the hazard identification and subsequent implementation of risk management measures.

Failure to revise the information requirements in a timely manner would lead to a delayed identification of chemicals with neurotoxic or immunotoxic properties under REACH and other legislations, resulting in prolonged exposure of people and wildlife to these toxic chemicals, as none of the improvements that depend on additional hazard information can be implemented.

The impact on other legislations will be similar to the effects of the delay of the REACH reform regarding the update of information requirements for EDCs (cf. Section 4.1.3).

[65] https://chemtrust.org/brain/

4.1.5 Information on the environmental footprint of chemicals

The current REACH legislation fails to include any provision on the environmental footprint of chemicals. However, considerations on environmental impacts of the use of chemicals may be included in socio-economic analyses in the context of restrictions and authorisations.

The CSS mentions minimising (as a condition for SSbD) and reducing the environmental footprint of chemicals and calls for information requirements to be introduced under REACH. The concept of environmental footprint includes different elements of sustainability, certainly including greenhouse gas emissions, but not excluding resource use, impacts on ecosystems and biodiversity as well as the lifecycle perspective.

The new information requirements under REACH on the environmental footprint of chemicals could help identify areas of concern and prioritize actions to reduce the environmental footprint of chemicals. They could support efforts to reduce greenhouse gas emissions and thereby contribute to achieving broader environmental objectives, such as the reduction of the carbon footprint of industrial processes and the transition to a low-carbon economy, in turn positively affecting climate change mitigation efforts.

If companies use the newly generated information on the environmental footprint, this may have positive economic impacts, such as triggering innovation, reducing production costs, and increased market opportunities for companies that adopt more sustainable practices.

4.1.6 Information on uses and exposures

Current situation

At present, information on uses and exposures should be provided by the registrants in their registration dossiers. However, they are frequently not aware of the (end-)uses of their chemicals and, as the current supply chain communication does not work ‘upstream’, they have little means to improve their information basis. Hence, registration information on uses and exposures is very ‘basic’.

Details on quantities applied ‘per use’ are mostly missing and the reliability of information is low. In addition, registration volumes are not regularly updated. Therefore, the demonstration of safe use in the registrants’ CSA can be questioned and the authorities lack data for their work. As they have no information about the identity of companies using substances, their work has to be performed based on insufficient data.

Changes expected in the REACH reform

It is expected that the proposal for a reformed REACH includes several changes to the information requirements on uses and exposures, but it is yet unclear how they will be designed in particular. The adaptation of registration tools and guidance as well as some clarifications of terms are possible without any changes to the REACH Regulation and are therefore not discussed in this report. The following changes to the information requirements are expected:

- Registrants may be required to update information on the volumes they manufacture, export and supply for use as intermediates on a regular basis (different intervals are possible)
- Registrants may be required to provide more information on use for the most hazardous substances
- Downstream users may be required to report on their use of substances and options include:
  - only formulators reporting on the amounts of SVHCs they use of in mixtures and the intended use of these mixtures as such, in further mixtures or in articles
  - formulators and end-users reporting on the amounts of any classified substance in their own products (mixtures and articles) and the intended end-use of these products
- Registrants and downstream users may be required to provide information on substances that are earmarked for regulatory action, e.g. by inclusion on the REACH Candidate List, the Community Rolling Action Plan etc. For registrants this could mean updating their registration dossier, and for downstream users providing data directly to the authorities, i.e. ECHA.

Overview of lost benefits due to a REACH delay

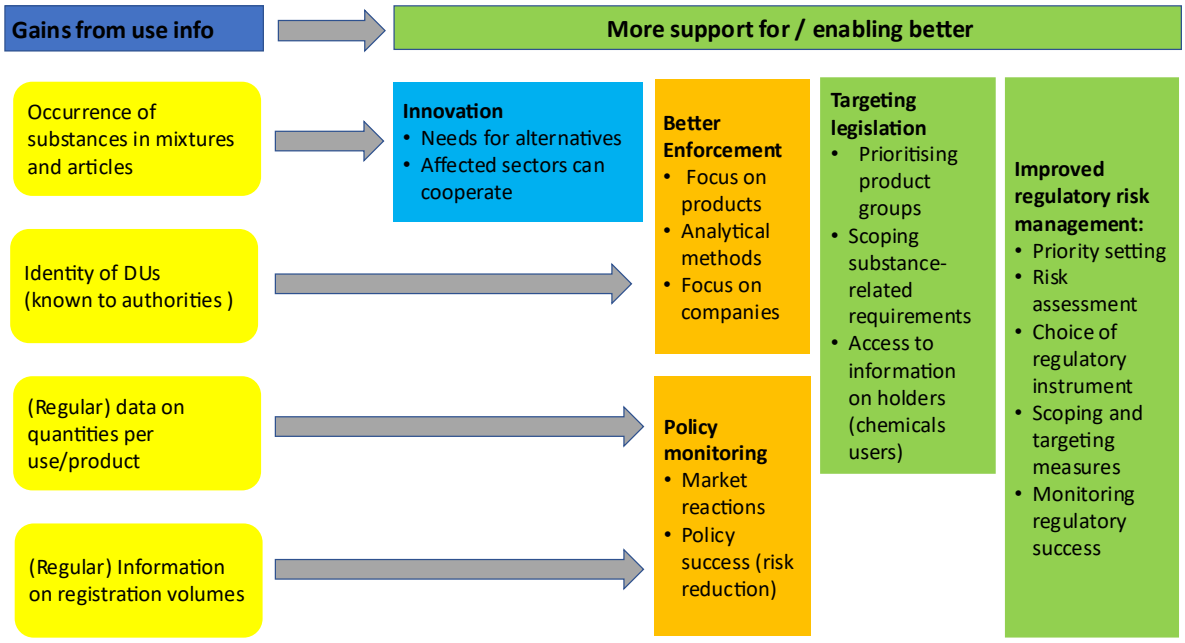
If authorities continue to lack adequate information on use, they will continue to face problems in their risk management work, including for the prioritisation of chemicals for action, the selection of the appropriate risk management instrument the risk assessment and design of regulatory measures (cf. list of actions depending on use information from REACH). This may result in insufficient, ineffective and inefficient risk management, e.g. because:

- Substances that are in practice irrelevant are prioritised for risk management, while relevant ones remain unidentified
- Inappropriate regulatory instruments are selected, e.g. those addressing a minor use, under REACH or other legislations
- The scope of regulation may be wrongly defined or exemption needs are wrongly evaluated
- Authorities lack access to user companies to gather information (high resource use for information gathering)
- Policy impacts cannot be properly monitored due to a lack of time trend data and identifying changes in use, exposure and risk brought about by regulatory actions

The extent of the impact (of a delay) depends on the specific measures that are proposed and eventually accepted in the REACH reform. The more stringent the implementation of the information requirements, i.e. the more frequently and detailed registrants and downstream

users are to report information, the better the information basis for regulatory risk management will be.

Figure 4: Gains from information on uses and exposures



Similar to the lack of hazard information, a lack of information on substance uses hampers the implementation of the circular economy, in particular because no overarching management of material streams can be planned, which means that investment decisions in technologies for sorting and treatment that ensure non-toxic secondary materials are delayed.

A lack of use information would also disable an important innovation driver, as it is not transparent in the market for which products/uses safer alternatives are needed. Alternative providers would face higher challenges to enter (new) markets and possibilities to enhance cooperation in the market to replace hazardous substances are lost (shared costs).

4.1.7 Moving towards grouping approaches

The grouping of substances for risk assessment and risk management is currently possible under REACH but is not yet specifically promoted for the registration process by the REACH text or its Annexes.

The Commission proposed in the CSS a revision of the registration requirements to promote the use of grouping approaches. By clarifying how to use group assessments, the assessment processes by companies and authorities can be made simpler, faster and less burdensome for companies and authorities.

The revision of REACH should facilitate the use and acceptance of grouping approaches as the basis of regulatory control and hazard identification under REACH, CLP and other legislations.

The delay of the REACH revision may slow down the gradual transition from assessing and regulating chemicals one by one to regulating them by groups, continuing the current situation where companies often move from one chemical to a similar one, then having to reformulate again when this chemical is phased out.[66] This is not only very inefficient for companies but also means people and the environment continue to be exposed to hazardous chemicals.

4.2 Essential Use Concept

Current situation

The Essential Use Concept (EUC) does not exist in the current legal framework of REACH. The current restriction and authorisation processes involve applying a socio-economic analysis (SEA) to determine if the benefits of regulation outweigh the costs. This process is resource-intensive and biased towards costs for industry, making it challenging for authorities to make informed decisions, particularly regarding the availability of alternatives.

Changes expected in the REACH reform

The CSS foresees the introduction of EUC under REACH to support the restriction and authorisation procedures and expects it would be applied across different EU legislations, e.g. the Biocidal Products Regulation (BPR), the Cosmetics Regulation, the Medical Devices Regulation and others. In all these legislations manufacturers must demonstrate that their substances are safe for use and, therefore, can benefit from the application of EUC.

The EUC in the upcoming REACH revision should offer a mechanism for quickly identifying essential uses of chemicals and exempting them from bans under the restriction or authorisation title. On the contrary, non-essential uses may not be eligible for applying to authorisation or a restriction derogation.

The CSS remains vague on what the approach will involve in practice. The result of the Commission's work[67] – hence whether it will be improving the level of protection or not – depends very much on the details of how it will be applied. Several scenarios are on the table. In a best-case scenario, an essential use approach will have the following gains:

- **Empower the EU institutions and States to ban non-essential uses** without spending large resources on justifying why they must be banned (for example by developing a socio-economic assessment, a full risk assessment etc.)
- **Accelerate the decisions** on the uses that are manifestly essential, and which may be allowed a longer substitution period if they can prove that there is no alternative,

[66] https://chemtrust.org/toxicsoup/

[67] European Commission. "Workshop Report: Essential Use under the EU Regulation on Persistent Organic Pollutants (POPs)." (2022). Available at: https://environment.ec.europa.eu/system/files/2022-05/Essential%20Use%20Workshop%20Report%20final.pdf

that the emission/exposure is minimised and that credible and ambitious substitution efforts are in place

- **Identify the uses in the grey zone**, on which more analysis might be needed to identify the right decision
- **Increase predictability** by clarifying to all actors the rationale behind the choices made by public authorities on which uses may continue, when others must go immediately
- **Encourage societal and industry debate and heightened awareness** on the fact that the most hazardous chemicals must, by default, be phased out, and it is only by exception, and with a good reason, that continuous use may be acceptable and allowed

Moreover, by emphasising the need for only necessary uses of chemicals, the EUC simplifies or even replaces the SEA process, making economic cost assessments unnecessary. Additionally, the availability of alternatives becomes a knock-out criterion, incentivising alternative providers to participate in consultation processes and promote innovation towards safer alternatives.

Therefore, a swift revision on REACH would help to tackle all the gaps on the essential use concept, making its application effective and aligned with REACH primary goals towards protection of health of citizens and environment.

4.3 Restrictions, including Generic Approach to Risk Management (GARM)

Current situation

REACH defines two types of restrictions procedures: a specific approach (Art. 68.1 or 69.2 for articles containing SVHCs on authorisation list[68]) and a generic approach (Art. 68.2). Restrictions may also be passed under product legislation, such as the Toy Safety Directive or the Cosmetics Regulation.

Specific restrictions

Authorities prepare a restriction proposal including a risk assessment, an argumentation of the need for community-wide action, a socio-economic assessment (SEA) and an assessment of alternatives. A specific restriction is only considered justified if:

- an unacceptable risk from the use of a substance/or substance group to humans and/or the environment is demonstrated
- there is a need for community-wide action
- the socio-economic benefits outweigh the costs of the restriction

[68] Article 69.2 specifies that after the sunset date of SVHCs on the authorisation list ECHA is to assess the need for a complementary restriction in articles.

Restriction proposals are publicly consulted, and the Risk Assessment Committee (RAC) and the Socio-Economic Analysis Committee (SEAC) prepare opinions on them. These opinions are also subject to a public consultation. Finally, the Commission consults with the Member States' comitology committee (the REACH committee) and decides on the restriction based on the restriction dossier and the committee opinions.

Restrictions may completely ban the manufacture, import and use of chemicals or impose conditions such as define concentration limits in products, impose labelling or training requirements or prescribe the implementation of risk management measures.

The development of a restriction dossier is very complex and resource demanding.[69] The lack of information on uses and exposures severely hampers a proper risk assessment, the socio-economic analysis and the alternatives assessment.

A report from the German Environment Agency found that restrictions under the simplified procedure reduce the workload of authorities, in particular due to avoiding the need to demonstrate an unacceptable risk.[70]

Generic restrictions

REACH Art. 68.2 empowers the Commission to propose restrictions for substances meeting the criteria for classification as CMR Cat. 1A or 1B[71] as such, in mixtures or in articles that could be used by consumers. A 'simplified' restriction follows a committee procedure (REACH Art. 133) and does not require a restriction dossier. It is based on the assumption of an inevitable exposure from consumer uses and a resulting risk (generic risk assumption).

The responsibility for risk management is placed on the market actors, as one cannot rely on consumers implementing any exposure reduction measures, i.e. a generic risk management using bans or concentration limits are considered the most effective.

Restrictions of CMRs Cat. 1A/B as such or in consumer mixtures have been implemented via the entries 28 to 30 of REACH Annex XVII. Two group restriction of CMRs Cat 1A/1B in consumer products (articles) have been passed on in the last 16 years of REACH: a) a prohibition of placing on the market of 33 CMRs in consumer clothing and associated accessories and b) concentration limits for eight PAHs in consumer products.

[69] In the inception impact assessment it says "*The current restriction process is too slow to sufficiently protect consumers and professional users against risks from the most hazardous substances. The normal restriction procedure, through specific risk assessment, puts a high burden on authorities to document unacceptable risk for health or the environment.*" Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment_en

[70] O. Wirt et al. (2021): Advancing REACH – The Restriction Procedure. Available at: www.umweltbundesamt.de/sites/default/files/medien/5750/publikationen/2021-04-12_texte_54-2021_reach_ap_5.1.pdf

[71] In practice, this means "substances with a harmonised classification as CMR Cat. 1A or 1B

Changes expected in the REACH reform

The REACH reform is expected to extend the scope of the Generic Approach to Risk Management under Art. 68.2 with regard to:

- the covered hazards: PBT/vPvB, EDCs, STOT, neurotoxic substances, immunotoxic substances, respiratory sensitisers and PMT/vPvM
- the covered user groups: professional uses that are similar to consumer uses[72] will be included

Generally, only uses that are considered essential to the society may be exempted. This creates a close link to the Essential Use Criteria (EUC, c.f. Section 4.2). It is unclear whether the Commission's proposal will introduce a new possibility for industry to ask for derogations based on proving the essentiality of a use.

Another factor that will affect how effectively and fast the REACH revision will provide gains for human health and the environment is the timeframe for the implementation of the GARM.

Options that have been discussed range from automatic restrictions based on classification as a first immediate step to staggered approaches starting with mixtures and including articles only later in the process, with the most likely option somewhere in between the two extremes.

Overview of lost benefits due to a REACH delay

The extension of Art. 68.2 to more hazardous properties and to professional uses would increase the total number of restrictions and result in more restrictions being implemented via the GARM than via the specific restrictions route. Consequently, more substances would be restricted with a broader restriction scope, increasing the level of human (consumers and workers) and environmental protection due to reduced emissions and exposures along the entire lifecycle.

If the GARM is not implemented or significantly delayed, this important regulatory instrument to achieve a toxic free environment is not used to its full potential. If REACH is delayed, the specific restrictions process is likely to remain the main restrictions route, continuing to create high burdens for the authorities to restrict a substance.

By accelerating the phase-out of hazardous substances in products, the GARM would also contribute to non-toxic material cycles, improved waste management and increased resource efficiency as more wastes can be recycled.

According to ECHA's report[73], 22 restriction proposals have been decided between 2010 and 2020 – an average rate of only 2.2 proposals per year.

In the nine case studies analysed in the German study[70] about the restrictions process, it took 40-50 months from the announcement of the intention to restrict a substance and the finalisation of RAC/SEAC opinion. Furthermore, the Commission normally took more than one year to take a final decision. This corresponds to the analysis of the EEB on the duration of risk management under REACH, which identified the median of the time needed for a restriction as 5 years and 7 months.

[72] Professional uses that resemble industrial applications are not foreseen to be covered.

ECHA assessed the costs and benefits of restrictions passed in the years 2016 to 2020. A key finding is that "restricting the use of hazardous chemicals under REACH generates at least four times more benefits to society than what they cost."[73] The report also states that both the costs and the benefits of restrictions have been increasing compared to ECHA's first assessment.

The Nordic Council estimated the costs to society due to inaction[74] in restricting the use of PFAS. Examples of annual health costs they specify are:

- occupational exposure to PFAS increases the risk of kidney cancer, resulting in health-related costs on the order of EUR 12.7 to EUR 41.4 million in the EEA countries
- exposure of persons located near production plants in relation to increased risk of mortality, may cause between 41 and 49 billion EUR annually in the EEA countries
- low-level exposure to PFAS in adults may cause costs of 10.7-35 billion EUR annually due to hypertension

The Nordic Council report also includes cost estimates for environmental cost, including for water treatment and soil remediation. These range from 82,1 million EUR to 170,8 billion EUR annually for the EEA countries.

If the REACH reform and therewith the GARM is delayed, predictability of the regulatory framework will be lost, and the business environment will remain uncertain with regard to future substitution needs. Companies that have already invested in safer products will not be rewarded and will have to continue competing with the long-established but toxic chemicals they could replace.

4.4 Amendment of Art. 57

Current situation

The authorisation process starts with the identification of a chemical as an SVHC. The current Article 57 of the REACH legal text identifies the following categories of SVHCs:

- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A or 1B of the CLP regulation (Article 57 a – c)
- Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to Annex XIII. (Article 57 d – e)

[73] ECHA (2021): Costs and benefits of REACH restrictions proposed between 2016-2020. Available at https://echa.europa.eu/documents/10162/17228/costs_benefits_reach_restrictions_2020_en.pdf/a96dafc1-42bc-cb8c-8960-60af21808e2e

[74] Nordic Council of Ministers (2019): THE COST OF INACTION - A socioeconomic analysis of environmental and health impacts linked to exposure to PFAS. Available at: http://norden.diva-portal.org/smash/record.jsf?pid=diva2%3A1295959&dswid=-7345

- On a case-by-case basis, substances that cause an equivalent level of concern as CMR or PBT/vPvB substances. (Article 57f)

Neither endocrine disruptors nor persistent, mobile and toxic chemicals (PMT) or very persistent and very mobile chemicals (vPvM) are *per se* considered as SVHCs. Rather, the identification of EDCs, PMTs or vPvMs can currently only take place under article 57f and requires an assessment of the level of equivalent concern to SVHCs identified according to art 57 a– e. The assessment of the equivalent level of concern is considered problematic and labour-intensive for authorities.

Changes expected in the REACH reform

One of the actions defined in the CSS proposed to amend REACH Article 57 to add EDCs, PMTs and vPvMs to the list of substances of very high concern. This means that the equivalent level of concern assessment will not be needed for the identification as SVHC of EDCs, PMT and vPvM substances, which is a simplification of their SVHC identification process.

A simplification of the SVHC identification process could mean faster recognition and inclusion in the candidate list of priority chemicals for phase-out, which has a positive substitution effect.[75] Candidate listing also brings immediate obligations for the registrants regarding the safety data sheet communication on safe use and notification to ECHA of articles containing the SVHC above 0.1% (w/w).

Although this change could make the SVHC identification process faster theoretically, it should also be recognised that if there was a requirement of pre-classification under CLP, this would make the SVHC identification process much longer.[76]

Overview of lost benefits due to a REACH delay

With the delay of the REACH reform, the requirement for authorities to perform the equivalent level of concern assessment for EDCs, and PMT and vPvM substances would remain. This means delays in the SVHC identification of EDCs and PMTs, vPvMs, leading to subsequent delays:

- in the candidate listing
- In the substitution effect of candidate listing
- In further risk management measures, including bans under the authorisation process or restrictions

The consequences of these delays are described in Section 4.3 (restrictions) and Section 4.5 (authorisation).

[75] European Chemicals Agency, 'Impacts of REACH restriction and authorisation on substitution in the EU', July 2020. Available at: https://echa.europa.eu/documents/10162/24152346/impact_rest_auth_on_substitution_en.pdf/7c95222f-5f84-57f7-4cba-65b8463c79d4

[76] European Environmental Bureau, "The Need for Speed: Executive Summary," accessed March 7, 2023

4.5 Authorisation

Current situation

Authorisation under REACH is a unique process in the global regulatory framework and is considered as the main driver for substitution of hazardous chemicals. It puts the burden of proof on the industry: industrial companies have to demonstrate that no safer alternatives are available and that the chemicals can be controlled. If non-negligible uncertainties remain, the applicant bears the risk of the rejection of its application. It is the best procedure to obtain information on how, where and for what the SVHC is used, and the best procedure to accelerate and scrutinise substitution efforts by companies.

Authorisation has contributed to the reduction of the emissions of SVHCs, improved transparency and communication with authorities; it is a driver for innovation and helps to create a market for alternatives. It has resulted in relocation or cessation of activities in only very few cases.[77]

Despite its important benefits, the authorisation process is not working well: almost all applications for authorisation were granted, even when alternatives were available. This has resulted in the continued use and exposure of people and the environment to substances of very high concern. Furthermore, alternative providers, have lost billions of euros due to authorisations being granted despite the existence of alternatives. Frontrunners who are actively substituting substances with problematic properties have been negatively affected by the current implementation of the authorisation process.

According to the report 'Need for Speed'[78] published by the EEB, the median time for a chemical to be phased out under the authorisation process (from SVHC intention to Commission decision for Applications for Authorisation) is nine years and three months.

The problems of the authorisation procedure is that it relies mainly on how the legal text has been interpreted and implemented.[79] This has led to work for public authorities when the application should have been rejected from the outset, prolonged discussions, delays in the adoption of the final decision and several objections from the European Parliament as well as court cases. The ruling of the Court of Justice C-389/19 P on one of these cases mandates fundamental changes in the approach followed.

The most recent REACH review concluded that the authorisation process needs to be implemented more efficiently and with quicker decision-making, the requirements needed to be simplified, and the process needed to be more workable and more predictable for applicants.

[77] Advancing REACH: Evaluation of five years of operation and the challenges ahead. (2021, March). Umweltbundesamt. Retrieved March 9, 2023, from www.umweltbundesamt.de/sites/default/files/medien/5750/publikationen/2021-03-03_texte_41-2021_advancing_reach_ap_5-4.pdf

[78] European Environmental Bureau. "Need for Speed: WHY IT TAKES THE EU A DECADE TO CONTROL HARMFUL CHEMICALS AND HOW TO SECURE MORE RAPID PROTECTIONS." (2022). Available at: https://eeb.org/wp-content/uploads/2022/07/Need-for-speed_EXECUTY-SUMMARY.pdf.

[79] Advancing REACH: Evaluation of five years of operation and the challenges ahead. (2021, March). Umweltbundesamt. Retrieved March 9, 2023, from www.umweltbundesamt.de/sites/default/files/medien/5750/publikationen/2021-03-03_texte_41-2021_advancing_reach_ap_5-4.pdf

Changes expected in the REACH reform

The Chemicals Strategy for Sustainability promised the following reforms to the REACH authorisation process:

- **Accelerating the substitution** of the most harmful chemicals by setting more ambitious criteria for the identification of substances of very high concern, and by accelerating the authorisation process for these substances.
- **Enhancing transparency** and stakeholder involvement by publishing more information on the substances under REACH evaluation, and by involving stakeholders more closely in the decision-making process.
- **Simplifying and streamlining** the authorisation procedure by introducing a more structured approach to the assessment of alternatives, by setting clearer deadlines for the evaluation of applications, and by improving the coordination between different authorities involved in the process.

Overall, the aim of these reforms is to ensure that authorisation is more effective, transparent, and efficient, and that it contributes to the transition towards a more sustainable and circular economy.

The introduction of the EUC could simplify and speed up the process both for applicants and authorities by limiting the applications for authorisation that need an in-depth assessment to those considered essential or where no alternatives exist. Non-essential uses should not be granted an authorisation for the continued use of an SVHC. Essential uses could be granted authorisation given that adequate risk management measures are in place.

The REACH revision is an opportunity to clarify the current provisions of the legal text, streamline and reinforce the capacity of authorisation to substitute SVHCs, reduce the burden on authorities and improve the protection of people and the environment. The extent of the benefits of the reform will depend on the final proposal by the Commission.

Overview of lost benefits due to a REACH delay

The proposed reforms of the authorisation process would enhance the phase-out of SVHCs, ensuring that those SVHCs posing risks are subject to appropriate risk management measures (authorisation granted with conditions) or substitution (no authorisation granted). If the reform is delayed, the related risk reduction would not occur, as the number and amounts of SVHCs in processes and products will not be reduced.

If the REACH revision is delayed, the authorisation process will not be implemented more effectively and efficiently, and decisions will remain uncoordinated and partly inconsistent.

Similar to what will happen with the application of GARM, the improvement of the authorisation procedure will reduce the amount of (consumer) products containing hazardous chemicals. This is an essential enabler of the circular economy, as material cycles will be clean(er) from the start. Worker exposure to SVHCs in the waste sector as well as the potential contamination of recycled materials or the need for resource-intensive decontamination processes would be prevented.

The promotion of substitution of SVHCs with safer alternatives by an improved authorisation would certainly drive innovation, in turn creating opportunities for businesses that specialise in developing and manufacturing safer chemicals, materials and products. In addition, the proposed reform would promote the development of a more level playing field, where all businesses must meet the same requirements for authorisation, thus potentially improving competitiveness in the market.

The report[80] 'Unlock the Market - Economic Incentives for Alternatives to Hazardous Chemicals' by ChemSec demonstrates the flaws in authorisation. It highlights the costs of a lost market and the lack of alternative providers, especially for sectors like paints. The report estimates that even a small percentage of wrongly granted authorisations can result in losses amounting to billions of euros. The delay on tackling and improving authorisation affects the frontrunners who are actively substituting substances with problematic properties.

The projected improved transparency and traceability through increased stakeholder involvement would help businesses and consumers have access to more information about the chemicals used in products. This would help promote more responsible sourcing and manufacturing practices and support the development of more circular supply chains.

4.6 Combination effects / mixture assessment factor (MAF)

Current situation

Humans and the environment are constantly exposed to thousands of different chemicals from various sources, including food and food packaging, air, water, cosmetics, everyday products, indoor air etc. Sound scientific evidence shows that the effects of several substances with similar target organs and/or modes of action add up.[81,82] Due to such combination effects, exposure to several chemicals may cause adverse effects, even if all substances in a mixture are present below their individual effect thresholds. While the composition of intentional mixtures, i.e. chemical products placed on the market such as paints or cleaning agents is known, the composition of unintentional mixtures, i.e. the co-occurrence of particular chemical substances in a particular environmental compartment or within human bodies can hardly be identified.

REACH chemical safety/risk assessment under REACH foresees that risks from individual substances (only) along their life cycle are evaluated. In the hazard assessment, exposure levels - the derived no effect level (DNEL) for human health and the predicted no effect concentration (PNEC) for the environment - are defined, below which no adverse effects are expected.

[80] ChemSec. 'Unlock the Market: Economic Incentives for Alternatives to Hazardous Chemicals' (2022). Available at: https://chemsec.org/app/uploads/2022/01/ChemSec_Unlock-the-market-Economic-incentives-for-alternatives-to-hazardous-chemicals.pdf.

[81] Cf. for example: European Commission (2020): COMMISSION STAFF WORKING DOCUMENT Progress report on the assessment and management of combined exposures to multiple chemicals (chemical mixtures) and associated risks. SWD(2020) 250 final. Available at: https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_mixtures.pdf; Kortenkamp et al. (2009): State of the Art Report on Mixture Toxicity. Final Report. Available at: https://ec.europa.eu/environment/chemicals/effects/pdf/report_mixture_toxicity.pdf, CHEM Trust (2022): Chemical Cocktails – The neglected threat of toxic mixtures and how to fix it. Available at: https://chemtrust.org/chemicalcocktails/

[82] https://chemtrust.org/chemicalcocktails/

The DNELs and PNECs are based on (eco-)toxicological data to which safety factors are applied that take account of several uncertainties, such as the interspecies variability for interpolation of data from animals to humans, or the reliability of the data. **There is no safety factor to take account of the cumulative exposures of humans and the environment to multiple substances from multiple sources**.[83].

The project HBM4EU[84] generated human biomonitoring data on a number of hazardous chemicals across the EU. An assessment of risks from cumulative exposures to five phthalates showed that 17% of the European teenagers are at risk due to exposure to a mixture of these five phthalates. The study specifies that 63% of these risks would have remained unnoticed if risks had been assessed for the individual substances, only.[85]

The results of an assessment of exposure to several PFAS also shows risk to a significant share of the people that participated in the human biomonitoring.[86] More examples of mixture risk assessments, including for the environment are provided in the Commission staff working document on mixtures. In conclusion, the current risk assessment approach clearly underestimates chemical risks because combined exposures are not considered.

Changes expected in the REACH reform

The Chemicals Strategy specifies: “As it is currently not realistic nor economically feasible to specifically assess and regulate an almost infinite number of possible combinations of chemicals, scientific consensus is emerging that the effect of chemical mixtures needs to be taken into account and integrated more generally into chemical risk assessments.”[87]

It is proposed that the EU introduces a Mixture Assessment Factor (MAF) into REACH and other relevant legislation. A MAF is an additional safety factor for use in the risk assessment of single chemicals that takes account of the fact that humans and the environment are co-exposed to an unknown number of substances and allows considering combination effects without performing a mixture-specific assessment.

It is expected that the MAF is integrated either into the REACH text specifying the requirements for the chemical safety assessment and/or Annex I, outlining the details of conducting a chemical safety assessment under REACH.[88] It is expected to be applicable to any safety/risk assessment performed under REACH, including for authorisation applications, restriction dossiers and substance evaluations, unless a generic risk assessment is performed.

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[83] SWD on mixtures

[84] www.hbm4eu.eu/

[85] Lange et al. (2022): Cumulative risk assessment of five phthalates in European children and adolescents. In *International Journal of Hygiene and Environmental Health* 246 (2022) 114052. Available at: www.sciencedirect.com/science/article/pii/S1438463922001353

[86] W. Bil et al. (2023): Approaches to mixture risk assessment of PFASs in the European population based on human hazard and biomonitoring data. In International Journal of Hygiene and Environmental Health 247 (2023) 114071. Available at: www.sciencedirect.com/science/article/pii/S1438463922001353

[87] Chemicals Strategy for Sustainability

[88] As the REACH proposal has not been published it is as yet unclear whether the MAF will be introduced with or without possibilities to deviate from using it. Reasons for deviation might be that a substance is found unlikely to significantly contribute to combination effects, or the availability of specific information that could replace the MAF. As an option to deviate from applying a MAF would not lead to qualitative changes in impact but would mainly reduce the number of substances for which impacts can be expected, this is not further considered in the analysis.

What is unclear is, among other things:

- What size the MAF would have, whether the same MAF would be applied for the environment and human health and whether it may be possible to deviate from using a MAF – in discussions, the size of the MAF ranged from 2 to 100
- If and how a MAF would also be applied to non-threshold substances
- If the MAF would be applicable to all or only some substances/hazardous properties and for all or only the higher tonnage bands etc.

Although how the concrete REACH proposal will be designed is yet unclear, the overall outcome would be an increase in Risk Characterisation Ratios (RCRs) for all assessed substances, as compared to an assessment without the MAF. For non-threshold substances, the MAF might contribute in another way, potentially increasing a regulatory urgency.

As of February 2023, ECHA's database lists 23,910 chemicals with active registrations, of which 4,187 are in the tonnage band of 1-10 t/a. The MAF would only be relevant for CSAs, if it were required for low volume substances (cf. Section 4.1.1). 6,834 substances are listed as having a CSA. Of these, substances classified as hazardous identified as SVHC would require a hazard and exposure assessment, with the MAF being applied.

In addition, newly registered substances would require application of the MAF. The share of substances for which this would result in RCRs exceeding 1 is unknown.

Overview of lost benefits due to a REACH delay

If the MAF is applied to the registrants' CSAs, RCRs will increase and, if REACH is properly implemented, more substances will be assessed as "not adequately controlled" in one or several of their uses (i.e. RCR > 1). For these uses identified as "not safe", registrants may:

- Refine the assessment either generating more hazard data (improve information basis) to refine the DNELs/PNECs or introducing stricter risk management measures, which would have to be implemented by the downstream users (à exposure reduction); or
- Stop identifying the use(s) as safe in the CSA and stop communicating them as identified uses in their safety datasheet, resulting in:
    - A substance not being applied in that particular use anymore; or
    - Downstream users making a downstream use CSR to assess the safety of the use (applying the MAF as well) resulting in the continued use, potentially with additional control measures (RCR < 1) or substitution of the substance in this use (RCR > 1).

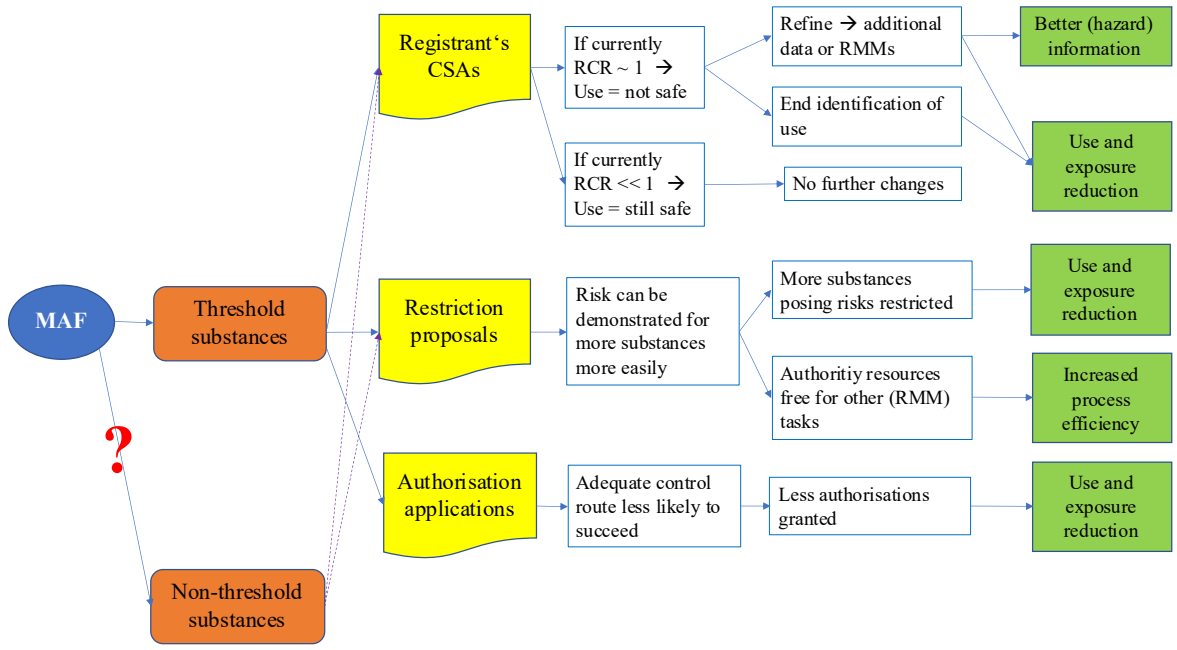
Member States and ECHA may already consider combined exposures to multiple substances in their risk assessments, e.g. in the substance evaluation process or in restriction dossiers.

However, as shown at the example of the phthalates restriction dossier[89] this approach is not standard and hence requires high efforts to be generally accepted.

If the MAF was implemented, combined effects from unintentional mixtures would have to be considered as a requirement.[90] Hence, the burdens to prove a risk from a substance in restriction dossiers (Art. 68.1) would decrease and the efforts for industry to demonstrate adequate control in authorisation applications would increase (if SVHCs have a threshold).

More substances could be restricted and less substances might be granted an authorisation via the 'adequate control route'. The impacts of the MAF on substance evaluation is considered low, as this procedure is mainly used to identify hazards and not risks.

Figure 5: Gains from implementing a MAF under REACH



OSH legislation (in particular the Chemical Agents Directive, CAD[91]), requires the employers to assess the risks from chemical agents at workplaces, which includes considering intentional and unintentional mixtures. Assuming the CAD is properly implemented, the level of worker protection is unlikely to be significantly changed by the introduction of a MAF. However, use and exposure reduction via recommended risk management measures from suppliers as well as (more) restrictions and less authorisations would occur.

[89] Denmark suggested a restriction for four phthalates based on considerations of combined effects and (non-public) human biomonitoring data. The restriction was rejected and re-submitted with newer data and a strengthened argumentation. The second restriction proposal was adopted, acknowledging the cumulative risks.

[90] Generic restrictions would not need a specific risk assessment and hence, no impacts are expected for restrictions under Art. 68.2.

[91] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work

Consumer and environmental exposures would be reduced by the MAF via the phase-out of uses which are not identified by registrants, restrictions and non-granted authorisations.

The reduction of use of hazardous chemicals in products would also support the circular economy (less wastes containing hazardous substances to separate, more and cleaner secondary materials).

Similar to the restriction and authorisation processes, the MAF would indirectly enhance the push for safe and sustainable chemicals, as in particular those substances with severe hazards and uses with high exposure potentials will be affected from the need to be phased out.

A delay of the REACH reform risks losing all these positive impacts on human health, the environment, the circular economy as well as competitiveness and innovation.

5 Other impacts of the REACH revision

In this chapter we look at the other impacts of a delay in the REACH reform.

5.1 Chemicals Strategy for Sustainability, Green Deal and Global Sustainable Development Goals

The European CSS[92] was developed with the aim to improve the safe and sustainable use of chemicals in the EU. The Strategy sets targets and goals for the entire lifecycle of chemicals. It aims to reduce the risks posed by hazardous chemicals, to promote innovation and development of safe use chemicals (in products), to improve transparency and information, to foster innovation and development of safer alternatives, and to encourage a transition towards a circular economy for chemicals. The CSS is built on the principles of the EU's chemicals regulation, REACH, and is a key part of the EU's efforts to achieve a more sustainable and healthy future for its citizens and the environment.

Since entry into force in 2007, REACH has not been revised, as legislators and stakeholders found it better to improve annexes, guidance and implementation practices. However, to support the goals of the CSS, the reform of both the legal text and its annexes are inevitable, with numerous studies demonstrating deficiencies.

It is clear that any delay in the publication of the REACH revision proposal means a (further) delay in achieving its own goals and also on the delivery of the Chemicals Strategy for Sustainability goals.

In addition, REACH also needs to be revised to increase its support for the implementation of the UN's Global Harmonised System for Classification[93] and the global Sustainable Development Goals (SDGs) related to chemicals. The global SDGs include that the negative impacts from chemicals should be minimised by 2030.

[92] Chemicals Strategy for Sustainability Towards a Toxic-Free Environment." (2020). Available at: https://environment.ec.europa.eu/strategy/chemicals-strategy_en.

[93] United Nations Economic Commission for Europe (UNECE). "About the GHS." (n.d.). Available at: https://unece.org/about-ghs.

In a global context, an improved REACH regulation can more efficiently and effectively support the implementation of this goal, by:

- accelerating the generation of hazard information to identify hazardous chemicals (information requirements)
- restricting the use of hazardous chemicals in (consumer) products (GARM) and thereby contributing to reduced exposures from EU-produced goods
- requiring producers importing into the EU to adopt European standards
- influencing global chemicals standards by means of setting examples of progressive, sustainability and precautionary oriented legislation

The delay of REACH also has an impact on the deliverables of the European Green Deal[94], of which the CSS is a key component. This should align chemicals policies with other green policies, in order to support the transformation of Europe into a global frontrunner in sustainability.

Alignment is sought e.g. with the Water Package, Eco-design Regulation, Industrial Emissions, CLP Regulation, Cosmetics Product Regulation, Toy Safety Directive, and Food Additives & Food Contaminants Legislation. Therefore, a delay of the REACH reform will also have an impact in the ability to revise and implement these other pieces of legislation.

5.2 Impacts of REACH information requirements on workers' health

The level of Occupational Safety and Health (OSH) is related to REACH in several ways:

- Employers have a legal obligation to assess and manage the risks associated with the use of hazardous substances in the workplace. They use information from suppliers communicated via safety data sheets and labels (generated in the registration phase/ CSA) to conduct their risk assessment at workplaces.
- Workers use REACH information in the SDS at their workplaces for safe storage, handling and disposal of chemicals.
- Restrictions may cover the use of chemicals in mixtures or articles at workplaces and contribute to exposure reduction if these are prohibited (substitution) or subject to conditions (concentration limits, measures at workplaces). The extension of the GARM to professional uses would significantly reduce exposure levels and in particular the risk of occupational cancers.
- Authorisations may lead to the phase-out of SVHCs in workplaces (substitution) or stricter risk management measures, both leading to exposure and risk reduction.

[94] "European Green Deal." (n.d.). Available at: https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en.

- The identification of SVHCs under REACH alarms employers and workers to be particularly cautious and push for substitution of these substances. This enhances the OSH requirements to assess substitution possibilities as part of the workplace risk assessment.
- The classification of (more) substances (for more endpoints) would lead to the inclusion of these substances in the workplace risk assessment (cf. above) and the provision of information in the safety data sheet (cf. above).
- Hazard information may trigger the development of OELs and/or increasing exposure controls at workplaces.

The delay in the revision of the REACH legislation has a significant impact on the health of workers, particularly with regards to exposure to CMR substances. According to Tony Musu, Senior Researcher for the European Trade Union Institute (ETUI) "*work-related cancers are the first cause of death at work with more than 100 000 deaths per year in the EU – These cancers are preventable, they are due to bad working conditions with carcinogens. Most of the time, workers don't know they are exposed."*

A delay in the REACH revision results in a delay in protection for workers, causing them to be exposed to harmful chemicals for a longer period, leading to huge treatment costs for the healthcare systems and production losses for companies due to sick-leaves of their workers.

For a better protection of workers under REACH a strict interpretation of “essential use” is crucial to prevent unnecessary workers’ exposure to hazardous chemicals.

5.3 Impacts on products and consumers health

The level of consumer protection depends on the REACH reform via several mechanisms:

- **Restrictions** covering mixtures and articles limit the potential exposure of consumers to hazardous substances. The GARM could address the most hazardous substances in an efficient and effective (fast) way.
- The **classification** of (more) substances, for more endpoints, would lead to (almost) automatic bans in mixtures according to REACH Annex XVII as well as under some product legislation, such as the Cosmetics Regulation or the Toy Safety Directive, resulting in reduced consumer exposure to hazardous substances.
- **New hazard information**, including on EDCs, would be used for risk assessments under other legislation, potentially leading to specific restrictions or other measures reducing consumer exposure, e.g. under the Food Contact Materials Legislation.
- **Authorisations** may lead to the phase-out of SVHCs in consumer products, also reducing consumer exposure; however, imported articles would not be affected, due to the current exemption in the legal text.
- The **identification of SVHCs** under REACH would enable consumers to obtain information on the SVHC content in articles (Art. 33). Furthermore, SVHCs are likely to

be excluded from eco-labelled products and product groups covered by the Eco-Design for Sustainable Products Regulation (ESPR).

- The implementation of the **MAF** would lead to identifying unsafe uses of chemicals in consumer products, resulting in their phase-out and related exposure reduction.

The number of consumer products containing hazardous chemicals is much higher than consumers are aware off.[95] For example, of the 500+ toys and children's products tested by the European Consumer Organisation's (BEUC) member Forbrugerrådet TÆNK, between 2015 and 2019, 21% contained one or more chemicals of concern, including many that are illegal.

Pelle Moos, Senior Advisor for Chemicals Policy and Product Safety at BEUC, states that "*Consumers are simultaneously exposed to chemicals from several sources including the products they use in their everyday lives. The REACH reform must include a default ban on chemicals of high concern – such as those that may cause cancer, birth defects or reproductive harm – in all consumer products. This is an essential step towards the promise of toxic-free consumer lives made in the EU Chemicals Strategy*".

The European Parliament already highlighted hazardous chemicals in products as a priority issue that must be tackled.[96] These chemicals can cause a range of health effects, from allergies to cancer, heart disease, infertility, and IQ loss. The delay in revising REACH means that consumers continue to be exposed to them until the regulation is revised, improved and implemented.

The delayed REACH reform also affects the effectiveness of enforcement as the lack of information on which products might contain what chemicals will remain, hampering increased compliance checks and related product safety in the market, including for online sales.

5.4 Impacts on environmental protection

REACH affects the level of environmental exposure through emission and exposure reductions through the mechanisms described for workers (Section 5.2) and consumers (Section 5.3). Therefore, also for the environment, the main impact of the REACH delay is a delay in exposure reduction to hazardous chemicals, which would be achieved via restrictions, authorisations, the phase out of uses due to a failure to demonstrate safe use (CSA) and the identification of SVHCs.

This impact is most significant for persistent chemicals (i.e. PBT, vPvB, PMT and vPvM substances), because once emitted they will not be degraded or destroyed. **Every additional year of emissions will inevitably increase the environmental chemical burden and add to existing exposures, accelerating the chemicals crisis and further pushing the planetary boundaries.** Ultimately, this will severely impair ecosystem functioning and contribute to a (faster) loss in biodiversity due to adverse effects on wildlife.

[95] BEUC, "Towards Toxic-free Consumer Lives: How EU Law Can Better Protect Consumers Against Exposure to Hazardous Chemicals," BEUC-X-2021-038, March 2021, accessed March 6, 2023, www.beuc.eu/sites/default/files/publications/beuc-x-2021-038_towards_toxic-free_consumer_lives.pdf.

[96] (pnt. 21): www.europarl.europa.eu/doceo/document/TA-9-2020-0201_EN.html

The implementation of several linked pieces of EU environmental legislation is facilitated by information from REACH on hazards and uses, for example:

- The **Water Framework Directive** aims at the protection and management of water resources. Some hazardous substances require monitoring and have environmental quality standards (EQSs). Hazard information contributes to adding more substances to the list, establishing EQSs and identifying emission sources from use data.
- The **Industrial Emissions Directive** sets limits on emissions of pollutants from industrial facilities, including requirements for emissions monitoring and reporting. The BAT reference documents and the permitting processes would benefit from better use information on chemicals.
- The **Air Quality Directive** sets air quality standards for pollutants that have significant effects on human health and the environment. REACH information on uses could support the identification of relevant emission sources.

5.5 Impacts on the circular economy

A circular economy should generate safe secondary materials, i.e. free from toxic chemicals and separate toxic chemicals from the material flows. The most efficient way to achieve this, is to prevent that hazardous chemicals are contained in products that become waste.

Therefore, the main loss from a delayed REACH reform is that the replacement of hazardous chemicals in products by safer alternatives will be delayed. The same mechanisms are relevant here as discussed above (cf. sections on workers, consumers and the environment).

If REACH is delayed, hazardous chemicals will continue to enter the waste stage either:

- preventing the reuse or recycling
- resulting in the downcycling of wastes to secondary materials of lower (chemical) quality that are applied in low-value applications; or
- contaminating secondary materials potentially putting humans and the environment at risk from (unknown) exposure to these substances

Depending on the product lifetime, they will become waste, possibly in 30 to 50 years (e.g. construction products). As information on the content of hazardous substances in products will not be generated if REACH, delayed recycling will also be disabled in the future, since the actors of the waste treatment chain will have no information on the product composition.

The impacts of these losses/ delays are of economic nature, as lower amounts of high-quality secondary materials are generated than could be with the REACH reform, resulting in low incentives for the recycling economy to invest and a failure to replace primary materials. They are also a failure to increase the level of protection, as contaminated secondary materials put humans and the environment at risk.

5.6 Impacts on competitiveness, innovation and the transition

Competitiveness and innovation are enhanced by the REACH reform mainly by:

- Providing a predictable and clear regulatory framework enabling sustainable investments into future-proof chemicals and technologies; a delay would support those companies unwilling to adapt
- Promoting the substitution of chemicals of concern by safe and sustainable chemicals, thereby frontrunning global developments in this regard, by restricting the use and increasing transparency of the use of hazardous chemicals
- Incentivising innovation for safe and sustainable replacements of hazardous chemicals, including by allowing co-operation across and along supply chains through enhanced transparency
- Safeguarding investments of frontrunner companies
- Decreasing dependence on external supply chains by enable the use of (cleaner) waste as a (cleaner) resource

Theresa Kjell, ChemSec's Senior Policy Advisor, emphasised that the delay of REACH is affecting frontrunner companies as they are already actively investing on substituting hazardous substances, which in some cases can have high economic costs. A recent ChemSec report[97] highlights that an authorisation process updated in line with the targets of the CSS will generate a huge incentive for companies that already promote the substitution of hazardous chemicals to ultimately phase them out from consumer products. The study shows that the loss for alternative providers with the current flawed system is in the range of billions of euros.

According to Theresa Kjell, **a strong REACH is crucial for European competitiveness and investment**. She stated that REACH, if updated to promote substitution and reduce the use of hazardous chemicals, would lower costs associated with educating workers, waste handling, and health costs for workers, ultimately improving the overall performance of the industry. Similarly, costs from sick leaves of workers could be saved if less hazardous substances are used or their use is better controlled.

The delay in the REACH legislation revision is also a concern for most investors. Companies that invest in hazardous chemicals, such as PFAS, can be heavily penalised by investors who are also pushing for more transparency from the chemicals industry. Therefore, it is crucial to prevent hazardous chemicals like PFAS from being allowed on the European market, for investment stability and leadership in the European market.

Also from the chemical industry perspective, Sylvie Lemoine, executive director of the European Chemical Industry Council (CEFIC), in interview for the EEB, agreed that the REACH revision is essential for the European chemicals industry predictability, investment and innovation. In her words:

[97] ChemSec). "Unlock the Market: Economic Incentives for Alternatives to Hazardous Chemicals." (2022). Available at: https://chemsec.org/app/uploads/2022/01/ChemSec_Unlock-the-market-Economic-incentives-for-alternatives-to-hazardous-chemicals.pdf.

"The new REACH should support our industry in the unprecedented double twin transition. It should ensure we can innovate and invest with confidence in the materials of tomorrow, help boost circularity, step up enforcement, streamline regulatory procedures, remove bottlenecks, give a thrust to alternatives to animal testing and create markets for safe and sustainable chemicals. We need a REACH that does all these things to move further along the Transition Pathway to 2050".

6 Conclusions

The REACH revision, as promised in the CSS, has the potential for significant positive impacts on human health and the environment, the functioning of the circular economy, and the competitiveness and innovation potential of the European industry.

The mechanisms through which these benefits are achieved are:

- **Simplified and accelerated restrictions** of the most hazardous chemicals in combination with a (strict) essential use concept and the consideration of the effects of mixtures of chemicals
- **An improved authorisation system** in combination with a (strict) essential use concept and the consideration of the effects of mixtures of chemicals
- **An improved information base** on hazards and on the uses of chemicals, via:
  - New information requirements for endocrine disruption, neurotoxicity and immunotoxicity
  - Increased information requirements for registration and the requirement for CSA/CSR for low volume chemicals
  - The inclusion of polymers in the registration scope
- **The ending of unsafe uses** based on safety/risk assessments considering mixture effects

The improved enforcement of all REACH provisions will increase their effectiveness. In particular, the improved ability to classify substances (and mixtures) and identify their hazards and uses will have further knock-on effects in downstream legislation, which also contributes to an improved level of protection.

As such, it is essential to ensure that the revision of this regulation is carried out efficiently and effectively. The scenario 1 timeline presented in the Chapter 1.2 of the report, which includes **the publication of the REACH revision proposal by June 2023, provides a clear roadmap** for achieving this goal.

Delaying the publication of the REACH revision proposal, as this report demonstrates, will have **serious consequences for workers, consumers and the environment**, who would continue to be exposed, unnecessarily, to potentially harmful chemicals.

Industries in Europe rely on predictability in regulations to strengthen their position as leaders in the global market, particularly at a time when investments are being made in the green transition. **Delaying the publication of the REACH revision would cause uncertainty, potentially leading to a loss of market share to competitors from countries such as China and the US.**

Furthermore, the REACH revision would contribute to the implementation of the EU's Sustainable Development Goals and climate and social targets. It would ensure that the use of chemicals in the EU is safe and sustainable, which in turn would benefit the environment and society as a whole. A delay in the REACH revision could put the achievement of these goals at risk, with far-reaching consequences for the EU and the world.

Therefore, **we strongly urge the European Commission to publish the REACH revision proposal in June 2023**, as outlined in scenario 1. **This timeline would allow for an efficient and effective revision of the regulation, ensuring the protection of workers and consumers' health, providing industries with predictability, and contributing to the achievement of the EU's Sustainable Development Goals and climate and social targets**.

One solution to make early publication easier could be to publish a proposal that contains the core legislative text, then to let the annexes be revised separately and decided by comitology.

This approach would ensure that the main REACH text is revised quickly and that the co-legislators will not have to decide on highly scientific topics which falls out of their area of expertise.

It is time to ensure the REACH proposal is brought out. The benefits of this reform far outweigh the costs, and numerous studies have highlighted the ineffectiveness of the current regulations.

Any further delay endangers human health and the environment and will penalise those companies trying to make a transition to safer and more sustainable chemicals. The clock is ticking.

The von der Leyen Commission’s five-year term will end in 2024 – significant progress can still be made in the remaining period, but for this **we need the REACH revision to be proposed by June 2023.**

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Protecting humans and wildlife
from harmful chemicals