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A young child with blonde hair, wearing a white sailor's cap and a blue and white horizontally striped t-shirt, is sitting inside a large, open cardboard box. The child is holding a vintage-style brass telescope to their eye and looking towards the right. The background is a plain, light-colored wall. The top of the image has a dark blue header with the EEB logo and text. A white rectangular box contains the title text.

From Risk to Resilience:

Navigating Towards a Toxic-Free Future



The EEB is Europe's largest network of environmental citizens' organisations. We bring together over 180 member organisations from 40 countries. We stand for sustainable development, environmental justice & participatory democracy.

The EEB is an International non-profit association /
Association internationale sans but lucratif (AISBL).
EC register for interest representatives:
Identification number 06798511314-27
BCE identification number: 0415.814.848
RPM Tribunal de l'entreprise francophone de Bruxelles

Published April 2024
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We extend our sincere gratitude to the individuals from Parliament, the Commission, member states, industry, and NGOs who generously shared their insights and expertise during the interviews for this report. Your contributions have been invaluable.

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We gratefully acknowledge financial assistance from the Norwegian Ministry of Climate and Environment and the European Commission

With the support of the LIFE Programme of the European Union



Views and opinions expressed are however those of the author(s) and do not commit the donors.

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Foreword

As European elections approach and the ability of officials to complete their work programme winds down, the European Environmental Bureau has taken a close look at the status of an inspirational plan by Ursula von der Leyen's European Commission to "significantly strengthen" protections against hazardous chemicals. The results show promising signs of progress, but there is still much left to be done. Unfortunately, the dramatic transformation we were promised seems unlikely to happen—at least for now.

Europe is recognised as being more capable than any other region at managing the widespread and increasing use of hazardous chemicals in its economy. In reality, however, regulatory loopholes and inaction have hindered officials from fully understanding the true nature of many substances they have approved, while neglecting to account for the genuine costs of inaction on our health and future well-being. Quick to approve their use and achingly slow to catch up with the dangers, policy makers remain loath to use financial and legal remedies. It often takes them more than a decade to control what they eventually prove are uncontrolled and serious harms being done to people and the environment. Then the European Green Deal came along and offered something dramatically better. Launched in 2020 to a warm welcome from health, environment and consumer groups, the Chemicals Strategy for Sustainability (CSS) recognised the "urgent need" to "significantly increase" legal protections and promised "considerably stepping up enforcement of EU rules."

The strategy promised to toughen up 40 or so regulations and transform the bloc into a global leader in the production of safer chemicals. Seriously risky chemicals still today being used in children's products, food packaging, clothing and other everyday products would be banned. Toxic PFAS 'forever chemicals', progressively and permanently polluting the blood of all Europeans, would be banned in all but 'essential uses'. The unethical practice of selling to less developed nations millions of tonnes each year of chemicals that we consider too dangerous and banned years ago would end. Europe would stop trying to 'empty the sea with a teaspoon' by regulating chemicals one by one and instead put an end to whole chemical families. Most notably, the EU's cornerstone REACH Regulation would finally be turned from the toothless it has been since its troubled birth over a decade ago into the global inspiration it was intended as. Four years later, where are we?

Tatiana Santos

Head of Chemicals Policy at the EEB

Executive Summary

Introduction

This report comprehensively evaluates how ambitious and how far advanced the Chemicals Strategy for Sustainability (CSS) is today. It takes in REACH, the CLP, the 'One Substance, One Assessment' package and initiatives like the Essential Use Concept (EUC) and Generic Approach to Risk Management (GARM). Adjacent plans on PFAS and Endocrine Disruptors, the Zero Pollution Action Plan and the Circular Economy Action Plan are also considered. Sectoral legislation with chemical control provisions, such as the Industrial Emissions Directive and the Ecodesign for Sustainable Products Regulation, are referenced to ensure this is a comprehensive assessment. Our report also offers a case study on the PFAS that illustrates a range of familiar problems that continue to hold back effective chemical protections, from the proliferation of chemical diversity outpacing regulatory oversight to the chilling lack of corporate integrity. Furthermore, the case study exposes significant gaps in enforcement and a concerning level of ignorance among downstream users of chemicals. **The failure to effectively control PFAS pollution not only poses direct health risks but also highlights broader difficulties in managing chemical risks in Europe.** Our report concludes with recommendations we hope will be taken up by the next Commission when it is appointed by the end of the year, as well as new and experienced parliamentarians and member states.

Key Findings

Four years since the bold CSS manifesto for change, just one out of 13 EU Chemical Strategy benchmarks have been fully met with the expected level of ambition. That one clear

success has been to strengthen the CLP, a decade-old regulation that plays a crucial role in identifying and labelling chemical threats. Weeks from being approved by Parliament and Council, the enhanced law paves the way for substantial bans of endocrine disruptors and persistent chemicals that have long outstayed their welcome.

Moderate or considerable levels of progress have also been made in most of the other reform areas, including measures to crack down on PFAS; to protect water; detox waste streams; shield us from mysterious but dangerous chemical cocktails; and to go beyond the normal one-by-one approach to regulating chemicals that experts told the EEB has been like "emptying the sea with a teaspoon".

The table below summarises our conclusions in each of the 13 main legislative focal areas analysed. Red stands for a low level of achievement, orange for moderate, yellow for considerable and green for a high level of ambition or implementation.

The single greatest failure has been a decision by the Ursula von der Leyen Commission to freeze sorely needed reforms of the EU's cornerstone REACH Regulation. This will remain largely ineffective for years to come, stalling progress for many of the other promised reforms. Another unmet promise was to stop the worst chemicals, those already banned in Europe, from being exported to world regions least able to deal with their impacts.

Overall, there has been a concerningly moderate to low level of fulfilment of the CSS, highlighting a lack of determination among policymakers to take essential steps to safeguard public health and the environment from hazardous chemicals.

POLICY AREA	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
CLP		
REACH		
SSbD		
Essential use concept		
GARM		
Cocktail Effects		
OSOA		
PFAS action plan		
Endocrine disruptors (EDs)		
Export ban		
IED and E-PRTR		
Water		
Circular economy		

The mixed bag of progress and failure outlined above means that problems that have long plagued EU chemical controls continue. These are:

Knowledge gaps: groping in the dark

There continues to be a generally poor public understanding of chemical risks, including the properties, uses and human or environmental exposure of most chemicals in use today. The

principle of 'no data, no market' is routinely bypassed due to a loophole allowing for lax chemical registration. This means critical hazard information is missing from top to bottom of supply chains and substances are being used without adequate oversight or safety measures. This general lack of adequate information also creates significant challenges for authorities to regulate chemicals promptly. Simply put, there's considerable uncertainty about whether the wide

variety of chemicals used in our economies may pose risks.

'No Data, No Problem'

Our report reveals significant flaws in REACH. The regulatory process is notably slow —often taking a decade or more, with chemicals presumed safe, granting them nearly automatic market access. Furthermore, REACH's reliance on voluntary compliance by companies has fostered a culture of widespread non-compliance. In other words, the lack of stringent enforcement mechanisms means consequences for violations are rare. Additionally, although the noble Precautionary Principle is embedded in REACH, it is often more myth than reality, as evidenced by our case study on PFAS chemicals.

Emptying the Sea with a Teaspoon

Controlling chemical substances one-by-one or in narrowly defined groups is the prevailing practice, which one expert described as akin to trying to empty the sea with a teaspoon. The solution lies in regulating broader families of substances based on common characteristics, an approach that the CSS pledged to adopt. However, the narrow focus of restrictions, lengthy decision-making processes, and lack of clarity persist in impeding progress, allowing the slow poisoning of our health and environment to continue.

Lack of timely action

Officials tasked with protecting the public and the environment often have a puzzling tendency to delay action, particularly within the European Commission. This is largely due to the absence of legally binding deadlines and a lack of a sense of public duty, and even where such deadlines exist, they are frequently ignored, often to the approval of industry lobbyists. This lack of urgency means that chemicals known to be hazardous and inadequately controlled, i.e. in dangerous use, continue to pose risks, with potentially serious consequences. This kind of inaction is a form of maladministration that could put lives at risk.

Neglected victims

European citizens are not properly empowered to protect their rights in the face of chemical hazards. They deserve the power to know about threats present in everyday products in their homes and workplaces, to demand preventive action and seek compensation for harms they

have suffered. The lack of mechanisms for citizen engagement and recourse weakens the regulatory framework's ability to address the health and environmental concerns of affected individuals and communities.

Recommendations

In response to these findings, the report offers a series of targeted recommendations to enhance chemical control policies and address identified shortcomings, ultimately aiming to strengthen the sustainability and safety of the European chemicals landscape.

1. Accelerating Regulation of Hazardous Chemicals

Use the available information to streamline the regulation of hazardous chemicals by adopting group-based approaches. Ban the most harmful chemicals in consumer, professional and non-essential industrial uses, with a focus on persistent chemicals and endocrine disruptors. Leverage recent revisions to the CLP Regulation to expedite hazard identification for these chemical groups.

2. Giving REACH Teeth: Ensuring Industry Liability and Enforcement

Enhance REACH with harmonised, robust, dissuasive sanctions and a revocation mechanism. Hold chemical companies accountable for harm caused by their chemicals. Enforce financial responsibility to cover monitoring, enforcement, compensation, and remediation costs. Incorporate the Polluter Pays Principle in the legal text.

3. Fulfilling Pending Chemicals Strategy for Sustainability Promises

Promptly implement pending actions outlined in the CSS, including banning the most harmful chemicals, adopting the essential use concept, implementing mixture assessment factors, regulating endocrine disruptors, executing the PFAS action plan and halting exports of banned chemicals.

4. Enhancing Authorities' Accountability

Strengthen accountability mechanisms for the European Commission and national competent authorities responsible for chemicals control.

Empower and oblige authorities to take decisive actions to address (emerging) chemical risks and ensure timely compliance with regulatory requirements.

5. Empowering Citizens and Establishing Compensation Mechanisms

Provide citizens with accessible information on chemical risks and enable public participation in decision-making processes. Establish access to justice and compensation mechanisms for victims of chemical pollution, ensuring avenues for redress and remediation for affected individuals and communities.

6. Mainstreaming Intrinsically Safe and Sustainable Chemicals, Materials and Products, and Promoting Substitution

Mainstream inherently safe and sustainable chemicals, materials and products across all sectors of industry and daily life. Implement policies and economic instruments that encourage the use of these alternatives while promoting substitution strategies. Establish an EU-wide substitution support centre to facilitate the transition to safer and more sustainable alternatives.

7. Bridging the Data Gap

Prioritise efforts to fill the remaining data gap in chemical and polymer information by ensuring that REACH generates comprehensive data on hazards, uses and exposure. Improve accessibility of this information to authorities and stakeholders across supply chains to enhance transparency and traceability of chemicals in materials, products and waste.

In conclusion, **while the CSS represents a commendable step towards sustainable chemical management, its implementation has encountered significant challenges as demonstrated by the PFAS pollution scandal.** By addressing these bottlenecks and adopting the recommendations outlined above, policymakers can realise the inspiring potential of the CSS, prevent further chemical catastrophes and ensure a safer and more sustainable environment for Europeans and the wider world.

Glossary

BAT	Best Available Technique
BPA	Bisphenol A
BREFs	Best Available Techniques Reference Documents
CEAP	Circular Economy Action Plan
CLP	Regulation on Classification, Labelling and Packaging of substances and mixtures
CMR	Carcinogenic, Mutagenic, and Reprotoxic
CSO	Civil Society Organization
CSS	Chemicals Strategy for Sustainability
DPP	Digital Product Passport
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Environment Agency
EDs	Endocrine Disruptors
EFSA	European Food Safety Authority
EGD	European Green Deal
EP	European Parliament
E-PRTR	European Pollutant Release and Transfer Register
EQS	Environmental Quality Standards
ESPR	Ecodesign for Sustainable Products Regulation
EUC	Essential Use Concept
EU	European Union
GARM	General Approach to Risk Management
IED	Industrial Emissions Directive
PFAS	Per- and Polyfluoroalkyl Substances
REACH	Regulation on the registration, evaluation, authorisation and restriction of chemicals
SEAC	Socio-Economic Analysis Committee
SOC	Substances of Concern
SSbD	Safe and Sustainable by Design
OSOA	One Substance One Assessment
PBT - vPvB	Persistent, bioaccumulative, toxic - Very persistent, very bioaccumulative
PMT- vPvM	Persistent, mobile, toxic - Very persistent, very mobile
POP	Persistent Organic Pollutants
PPWD	Packaging and Packaging Waste Directive
RAC	Committee for Risk Assessment
RSB	Regulatory Scrutiny Board
TWI	Tolerable Weekly Intake
UN GHS	United Nations' Globally Harmonised System
UWWTD	Urban Waste Water Treatment Directive
ZPAP	Zero Pollution Action Plan

Introduction

This report provides an overview of the objectives and commitments outlined in the EU Chemicals Strategy for Sustainability¹ (the Strategy or CSS), published by the European Commission (EC) in October 2020, along with other related strategies introduced as part of the European Green Deal² (EGD). It aims to evaluate the progress in implementing the Strategy by detailing the actions the Commission has proposed and assessing the policies and legislation put forward to achieve the objectives, as well as identifying any missed opportunities.

In particular, the report will analyse the revision of the Regulation on the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH)³, the Classification, Labelling and Packaging Regulation (CLP)⁴, the 'One Substance, One Assessment' package (OSOA)⁵, the Recommendation on an assessment framework for Safe and Sustainable by Design of chemicals and materials⁶, or the development of an 'Essential Use Concept' (EUC) and the Generic Approach to Risk Management (GARM, previously called GRA). Additionally, the assessment will consider other plans and strategies that are adjacent to or complement the CSS, such as the Commission's working document on poly- and perfluoroalkyl substances (PFAS)⁷, the accompanying document on Endocrine Disruptors⁸, the Zero Pollution Action Plan (ZPAP)⁹, the European Industrial Strategy¹⁰ and the Circular Economy Action Plan¹¹.

To ensure a thorough understanding, the report will also reference sectoral legislation that includes chemical control provisions, such as the Industrial Emissions Directive (IED)¹², the European Pollutant

¹ European Commission, Communication on the Chemicals Strategy for Sustainability, Towards a Toxic-Free Environment (COM/2020/667 final), 2020, European Commission. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN>

² European Commission, Communication on The European Green Deal (COM/2019/640 final), European Commission, 2019. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2019%3A640%3AFIN>

³ European Commission, Consolidated text on the Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), European Commission, 2023. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20231201>

⁴ European Commission, 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, European Commission, 2008. Available at: <https://eur-lex.europa.eu/eli/reg/2008/1272/oj/eng>

⁵ European Commission, 'One substance, one assessment' package, European Commission, 2023. Available here: https://ec.europa.eu/commission/presscorner/detail/en/ip_23_6413

⁶ European Commission, Recommendation establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials (C(2022) 8854 final), European Commission, 2022. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022H2510>

⁷ European Commission, Staff Working Document on Poly- and perfluoroalkyl substances (PFAS), (SWD(2020) 249 final), European Commission, 2022. Available at: <https://circabc.europa.eu/ui/group/8ee3c69a-bccb-4f22-89ca-277e35de7c63/library/e94fa1f8-864f-421e-af20-b2b68f3a6335/details?download=true>

⁸ European Commission, Staff Working Document on the Fitness Check on endocrine disruptors (SWD(2020) 225 final), European Commission, 2022. Available at: <https://circabc.europa.eu/ui/group/8ee3c69a-bccb-4f22-89ca-277e35de7c63/library/b5784473-6312-4ce1-884b-c60c983f924c/details?download=true>

⁹ European Commission, Communication on the Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil' (COM/2021/400 final), European Commission, 2021. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021DC0400&qid=1623311742827>

¹⁰ European Commission, Communication on A New Industrial Strategy for Europe (COM/2020/102 final), European Commission, 2020. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0102>

¹¹ European Commission, Communication A new Circular Economy Action Plan For a cleaner and more competitive Europe (COM/2020/98 final), European Commission, 2020. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1583933814386&uri=COM:2020:98:FIN>

¹² European Commission, Proposal for a Directive on industrial emissions (integrated pollution prevention and control) (COM/2022/156 final), European Commission, 2022. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0156&id=1710420279575>

Release and Transfer Register (E-PRTR)¹³, the Urban Waste Water¹⁴, the Packaging and Packaging Waste Directive¹⁵ and the Ecodesign for Sustainable Products Regulation (ESPR)¹⁶.

This comprehensive analysis of the Strategy and its implementation will support the identification of the main bottlenecks currently faced in chemicals control. A case study on the regulation of PFAS will illustrate how these identified obstacles hinder effective chemicals control.

The report will conclude with proposals and recommendations for a future work plan on chemicals. These suggestions aim to assist the European Institutions in advancing and achieving its objectives related to chemicals policy and the protection of both the environment and public health.



¹³ European Commission, Proposal for a Regulation on reporting of environmental data from industrial installations and establishing an Industrial Emissions Portal (COM/2022/157 final), European Commission, 2022. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0157>

¹⁴ European Commission, Proposal for a Directive concerning urban wastewater treatment (recast), (COM/2022/541 final), European Commission, 2022. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0541>

¹⁵ European Commission, Proposal for a Regulation on packaging and packaging waste (COM/2022/677 final), European Commission, 2022. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0677>

¹⁶ European Commission, Proposal for a Regulation establishing a framework for setting ecodesign requirements for sustainable products (COM/2022/142 final), European Commission, 2022. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2022%3A0142%3AFIN>

Methodology

This report aims to evaluate the fitness of the CSS in addressing chemical pollution. This evaluation involves assessing both the ambition and implementation level of the Strategy, while also identifying missed opportunities and main bottlenecks for current chemicals control.

To conduct this evaluation, we examined the Communication of the European Commission on the EU's Chemicals Strategy for Sustainability¹⁷ along with several of its annexes, such as the CSS accompanying documents of PFAS¹⁸ and Endocrine Disruptors¹⁹. We selected the most relevant actions of the CSS and assessed its implementation level.

Tracking the implementation of specific CSS actions and timelines involved utilising information available on the Commission's website²⁰, including its tracking table on the state of implementation of the CSS actions²¹. The action numbers referenced in this document correspond to the Commission's table.

After outlining the objectives and promised actions of the CSS, we analysed the level of implementation of each objective and action. This analysis entailed both quantitative and qualitative assessments on envisaged timelines and intended deliverables and outcomes.

Quantitative analysis involved comparing the expected outcomes set by the CSS with actual execution rate, primarily sourced from the Commission's website²². Qualitative analysis aimed to measure to what extent approved legislation or policy proposals have helped or hindered the effective implementation of the CSS objectives and identified missed opportunities. This analysis was supported by gathering views from experts and stakeholders, compiling existing reports regarding the CSS, and reviewing statements, assessments and consultation outcomes published by the EC. Additionally, we examined how CSS objectives have influenced chemicals control in related areas, such as industrial emissions, water, circular economy and pesticides, referencing parallel strategies and plans published under the EGD, such as the Zero Pollution Action Plan²³, the European Industrial Strategy²⁴ and the Circular Economy Action Plan²⁵.

We conducted interviews, discussion groups and distributed questionnaires to gather the insights from diverse stakeholders, including representatives of European Institutions (Commission and Parliament), EU member states, industry and civil society organisations. These stakeholder views are integrated throughout the report and detailed in Annex I.

¹⁷ European Commission, Communication on the Chemicals Strategy for Sustainability, Towards a Toxic-Free Environment (COM/2020/667 final), 2020, European Commission. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN>

¹⁸ European Commission, Staff Working Document on Poly- and perfluoroalkyl substances (PFAS), (SWD(2020) 249 final), European Commission, 2022. Available at: <https://circabc.europa.eu/ui/group/8ee3c69a-bccb-4f22-89ca-277e35de7c63/library/e94fa1f8-864f-421e-af20-b2b68f3a6335/details?download=true>

¹⁹ European Commission, Staff Working Document on the Fitness Check on endocrine disruptors (SWD(2020) 225 final), European Commission, 2022. Available at: <https://circabc.europa.eu/ui/group/8ee3c69a-bccb-4f22-89ca-277e35de7c63/library/b5784473-6312-4ce1-884b-c60c983f924c/details?download=true>

²⁰ European Commission, Implementation of the Chemicals Strategy, European Commission. Available at: https://environment.ec.europa.eu/strategy/chemicals-strategy/implementation_en

²¹ European Commission, STATE OF THE IMPLEMENTATION OF THE ACTIONS ANNOUNCED UNDER THE CHEMICALS STRATEGY.

Available at

https://environment.ec.europa.eu/system/files/2021-11/Table_implementation_CSS_actions.pdf

²² European Commission, Directorate-General for Environment website on Chemicals, Available at:

https://environment.ec.europa.eu/topics/chemicals_en

²³ European Commission, Communication on the Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil' (COM/2021/400 final), European Commission, 2021. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021DC0400&qid=1623311742827>

²⁴ European Commission, Communication on the A New Industrial Strategy for Europe (COM/2020/102 final), European Commission, 2020. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0102>

²⁵ European Commission, Communication A new Circular Economy Action Plan For a cleaner and more competitive Europe (COM/2020/98 final), European Commission, 2020. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1583933814386&uri=COM:2020:98:FIN>

To provide an overview of the assessment on the implementation of each topic, subsections begin with informative tables summarising the actions related to each topic and providing assessments on the implementation and ambition achieved. Annex II contains an overview of all tables included in the report.

These tables offer two evaluations: one regarding the extent to which actions have been implemented, and the other regarding the ambition to deliver those actions and achieve the intended objectives of the CSS.

On the column related to level of implementation, we evaluate the extent to which CSS objectives have been achieved, with reference to deliverables set by the Commission in the implementation table on its website²⁶. Evaluation criteria include:

- Low (Red): the action has not been launched;
- Moderate (Orange): minor progress has been achieved, but much remains to be done;
- Considerable (Yellow): significant progress has been made, but not to the extent expressed in the CSS;
- High (Green): action has been fully implemented.

The qualitative evaluation of ambition, on the last column, assesses whether actions taken and initiatives implemented (or not) have served to achieve the overarching objectives of the CSS and the EGD. Criteria include:

- Low (Red): measures are unsuitable to fulfil the intended actions and CSS objectives;
- Moderate (Orange): some progress has been made to partially reach the goals set by the CSS, but significant progress is still required;
- Considerable (Yellow): measures are delivered and fit for purpose, but do not completely reach the CSS goals;
- High (Green): actions put in place have been effective and satisfactory, contributing to achieving the CSS goals.

The chapter on the bottlenecks for chemicals control is a qualitative analysis based on the observations made in the previous sections, stakeholders views and previous EEB reports²⁷.

Finally, the last chapter offers recommendations and suggestions for effective chemicals control in Europe, drawn from observations made in previous chapters regarding CSS ambition, missed opportunities, implementation level and encountered bottlenecks, while also considering insights from stakeholders interviewed.

²⁶ European Commission, STATE OF THE IMPLEMENTATION OF THE ACTIONS ANNOUNCED UNDER THE CHEMICALS STRATEGY, European Commission. Available at: https://environment.ec.europa.eu/system/files/2021-11/Table_implementation_CSS_actions.pdf

²⁷ Dolores Romano and Tatiana Santos, A Roadmap to revitalize REACH. REACH authorisation process. A critical assessment, EEB, November 2015. Available at: <https://eeb.org/wp-content/uploads/2019/07/Report-Roadmap-to-Revitalise-REACH.pdf>

European Environmental Bureau (EEB), Restricted Success: EEB's appraisal of restriction under REACH, EEB, 28 June 2017. Available at: <https://eeb.org/library/restricted-success-eebs-appraisal-of-restriction-under-reach/>
Dr. Hélène Loonen, Dolores Romano, Tatiana Santos and Elise Vitali, CHEMICAL EVALUATION. Achievements, challenges and recommendations after a decade of REACH, EEB, April 2019. Available at: <https://eeb.org/wp-content/uploads/2019/07/Report-Substance-Evaluation-under-REACH.pdf>

[content/uploads/2019/07/Report-Substance-Evaluation-under-REACH.pdf](https://eeb.org/library/the-need-for-speed-why-it-takes-the-eu-a-decade-to-control-harmful-chemicals-and-how-to-secure-more-rapid-protections/)

Tatiana Santos, Vito Buonsante, Hélène Loonen and Geraldine Borja, The Need For Speed – Why it takes the EU a decade to control harmful chemicals and how to secure more rapid protections, EEB, July 2022. Available at:

<https://eeb.org/library/the-need-for-speed-why-it-takes-the-eu-a-decade-to-control-harmful-chemicals-and-how-to-secure-more-rapid-protections/>

Helene Duguay and Dolores Romano, A roadmap to nowhere? The EU's bold plan to quit the most harmful chemicals is a year old. We assess its effectiveness. EEB and Client Earth, 2023. Available at: <https://eeb.org/library/a-roadmap-to-nowhere-the-eus-bold-plan-to-quit-the-most-harmful-chemicals-is-a-year-old-we-assess-its-effectiveness/>

The CSS promises and level of implementation

On 15 October 2020, the European Commission adopted the EU Chemicals Strategy for Sustainability²⁸ (CSS), a critical component for the achievement of the zero-pollution ambition and a toxic-free environment goal outlined in the European Green Deal (EGD)²⁹. Acknowledging the urgent need to address the health and environmental challenges caused by harmful chemicals, the CSS aimed implement concrete actions to ensure chemicals are safe and sustainable by design and minimise their adverse impact on the planet and current and future generations.

The Strategy delineated four primary overarching objectives:

- Strengthen the EU legal framework to address environmental and health concerns;
- Simplify and consolidate the legal framework;
- Develop a comprehensive knowledge base on chemicals;
- Provide a model inspiring chemicals management globally.

To achieve these goals, the Strategy included some flagship initiatives³⁰, including phasing-out the most harmful substances from consumer products, minimising and substituting substances of concern in products, addressing the combined effects of chemicals; and ensuring that producers and consumers have access to information on chemical content and safe use. This latter initiative involves introducing information requirements within the context of the Sustainable Product Policy Initiative. Additionally, the CSS Communication was complemented by other plans and strategies that contribute to chemicals control. These include the Commission's working documents on PFAS and endocrine disruptors, the Zero Pollution Action Plan, the European Industrial Strategy and the Circular Economy Action Plan, all of which aim to revise or introduce policies and legislation to fulfil the CSS objectives.

In this chapter we will assess the ambition of the CSS and the level of implementation of key actions committed by the Strategy. The table provides an overview of the policies and pieces of legislation analysed in this report, along with their current implementation status:

²⁸ European Commission, Communication on the Chemicals Strategy for Sustainability, Towards a Toxic-Free Environment (COM/2020/667 final), European Commission, 2020. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN>

²⁹ European Commission, Communication on The European Green Deal (COM/2019/640 final), European Commission,

2019. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2019%3A640%3AFIN>

³⁰ European Commission, Press release "Green Deal: Commission adopts new Chemicals Strategy towards a toxic-free environment", European Commission, 14 October 2020. Available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1839

Overview table:

POLICY AREA	MAIN ACTIONS AND DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
CLP	Revision of regulation: Proposal published by EC in December 2022. Expected to be adopted soon by the Council and Parliament. New hazard classes: Delegated Act published by EC in December 2022, adopted by EP and Council after scrutiny in 2023.	Legal proposal published, awaiting final approval by EP and Council New hazard classes implemented in CLP regulation.	The proposal for revision of the CLP regulation met the CSS ambition. New hazard classes for EDs, PBT/vPvBs, and PMT/vPvMs are included in the CLP Regulation in line with CSS ambition.
REACH	Several studies and consultations were launched, and many different expert working groups were organised to advance proposals to reform REACH. An impact assessment was performed, and it received a positive opinion by the Regulatory Scrutiny Board.	Despite progress achieved, the Commission decided to stall the revision of REACH, no proposal has been published.	The draft options for the revision presented at CARACAL, e.g. on polymers registration, GARM, information requirements, authorisation and restriction didn't reflect the ambition of the Strategy.
SSbD	The EC has developed in December 2022 a framework defining the concept of 'safe and sustainable by design' and a set of criteria. However, the other key deliverable, the establishment of an EU-wide SSbD support network, remains undelivered.	One of the two main actions, the SSbD framework, has had significant progress.	The SSbD framework met the ambition of the CSS. Although the EC's recommendation for a testing period and a voluntary reporting mechanism has been very low in ambition. A revision of the framework has not been launched. The EU-wide SSbD support network was not developed.
ESSENTIAL USE CONCEPT	A supporting study was published in April 2023, but the promised actions were not delivered.	Not implemented.	The study was aligned with the ambition of the CSS, however it has not resulted in any policy outcome.
GARM	Proposals to broaden the GARM to prevent consumer products from containing CMRs, EDs, and PBTs. Additionally, CSS committed to evaluate extending this approach to include chemicals affecting immune, neurological or respiratory systems, as well as those toxic to specific organs. These actions are set to be implemented through legal proposals under REACH, the FCMs Regulation, the Cosmetics Regulation, and the Toy Safety Directive.	Main legislative proposal (REACH revision) not launched. Cosmetics Regulation revision not launched either. The other two initiatives (Toys and FCMs) launched but late and narrow scope.	Main legislative proposal (REACH revision) not launched. Cosmetics Regulation revision not launched either. The other two initiatives (Toys and FCMs) launched but late and narrow scope.

POLICY AREA	MAIN ACTIONS AND DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
COCKTAIL EFFECTS	Study presented and many discussions on MAF in different settings. MAF included in REACH Impact assessment. A proposal for revised EU Water Quality Standards was presented in October 2022.	The EC failed to present legislative proposals addressing mixture assessment for the Regulations on REACH, Food Contact Materials and Cosmetics. The combination effects of chemicals were addressed to some extent in proposals for revised EU water quality standards and in the Toys safety regulation.	While combination effects have been addressed to some extent in the revision of the EU Water Quality Standards and Toys Safety Regulation, much more work needs to be done to truly account for the combination effects of daily exposure to multiple chemicals of various sources.
OSOA	The EC legislative proposals for OSOA were published in December 2023.	Legal proposals published. The proposals address CSS actions on OSOA, except the ECHA Basic regulation.	While ambition of CSS is reflected in many proposals, ambition is not met, for example regarding early warning and action system.
PFAS ACTION PLAN	Several actions are proposed to address the presence and impact of PFAS across various legislative frameworks. These include proposals to restrict PFAS under REACH, review annexes of environmental quality and groundwater directives, introduce legal requirements on PFAS presence in products, revise industrial emissions legislation, address PFAS emissions in waste legislation including sewage sludge revision, and advocate for PFAS concerns within international conventions like the Stockholm and Basel Conventions.	Only the REACH restriction proposal and the proposal for revising Environmental Quality Standards Directive and the Groundwater Directive were launched. The other proposals were not announced or only partially.	Although the REACH restriction proposal met the level of ambition of the CSS, the proposal for revising the Environmental Quality Standards Directive and the Groundwater Directive launched were not sufficient to address the impact of the wide PFAS group. The other proposals were not announced or only partially.
ENDOCRINE DISRUPTORS (EDs)	The CLP has been amended to introduce endocrine disruptors as a new hazard class. The Restrictions Roadmap, published in April 2022, included restrictions of several groups of EDs.	Important action, such as the inclusion of EDs under CLP and the publication of the Restriction Roadmap, have been achieved. However, key CSS actions to be able to identify and finally regulate EDC have not been implemented.	Although some of the actions have partially contributed to achieving the goals set by the CSS, there is still significant progress to be made regarding the information requirements and regulatory control of EDs.

POLICY AREA	MAIN ACTIONS AND DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
EXPORT BAN	EC committed to present a legislative proposal to stop exports of banned chemicals.	A study was commissioned and a public consultation was launched, but a legislative proposal has not been presented.	As no proposal has been presented, EC didn't meet the CSS ambition.
IED and E-PRTR	The IED and E-PRTR revisions, as per the latest political agreement of March 2024, have included the foreseen provisions.	The texts have been revised and are expected to be adopted imminently. However, while some provisions partially address emissions and reporting of PFAS, not including the full list of PFAS is a missed opportunity.	Although some of the actions might have contributed partially to reaching the goals set by the CSS, there is still considerable progress to be made. Their effectiveness for chemicals control remains uncertain.
WATER	Reinforcement of provisions on combination effect, revision of EQS Standards and of the Groundwater Directive to add PFAS.	The adoption of the revised WFD is ongoing and a Council opinion expected very soon.	The proposal improves the situation but does not fully address the effects of chemical cocktails.
CIRCULAR ECONOMY	Measures focused on increasing transparency on substances of concern and restriction of chemicals of concern.	Although the Ecodesign Directive is close to be formally adopted, it did not fully tackle the actions of CSS.	The inclusion of a wide definition of Substances of Concern and transparency requirements meets the CSS ambition. However, the references to restrict chemicals introduced by the EP, although welcomed, does not match the CSS commitment.

The table summarises this report's findings regarding the implementation of the CSS action plan by EU institutions, focusing on the fulfilment of commitments and the level of ambition in achieving the CSS goals. Of the 13 selected actions, only one, the revision of the CLP Regulation, has been fully delivered while maintaining the CSS's level of ambition. Two actions, the revision of REACH and the ban on exports, have not been delivered at all. The majority of actions have been either partially or barely implemented. These findings indicate a disappointingly low level of fulfilment of the CSS

promises, reflecting a lack of ambition among policymakers to undertake the necessary actions to protect public health and the environment from harmful chemicals in Europe.

Of the 13 selected actions, only one, the revision of the CLP Regulation, has been fully delivered while maintaining the CSS's level of ambition

Ambition of the CSS

The perception among stakeholders is that the CSS was an ambitious strategy to tackle poorly regulated chemicals, as exemplified by the revised CLP, and acknowledged the need to ban certain groups of chemicals.

Civil society organisations (CSOs) expressed a very positive view of the CSS, citing important accomplishments such as the inclusion of new hazard classes (EDs, PBTs/vPvBs, PMTs/vPvMs³¹) in CLP and commitments to global harmonisation through the GHS; the publication of the Restrictions Roadmap acknowledging the need to ban groups of chemicals; the 'Safe and Sustainable by Design' (SSbD) framework; and the 'One Substance, One Assessment' (OSOA) package.

However, they noted several missing policy areas, such as:

- Addressing risks posed by the increasing volume and number of chemicals on the market, surpassing planetary boundaries;
- Harmonising enforcement, including a general lack of effective sanctions, despite massive non-compliance rates;
- Applying mixture assessment factors for pesticides;
- Increasing transparency and traceability (e.g. for substitution).

Policymakers and competent authorities considered the CSS as ambitious, addressing most of the gaps identified in fitness checks and evaluations of the different EU chemicals policies, and including major needed changes to the main body of chemicals legislation. They appreciated its comprehensive and horizontal approach.

Many policymakers believed that the CSS agenda generally supports the EU chemicals industry and supports its competitiveness by driving innovation towards clean and safe materials and products. However, other policymakers observed that the CSS did not fully enhance the

competitiveness and strategic autonomy of EU industry.

Policymakers noted challenges in achieving a coherent and comprehensive implementation and suggested better synergies with issues interconnected to chemicals policy, such as human rights (e.g. health, especially of women, a healthy environment and access to water), climate, energy use and a circular economy. They also identified a missed opportunities for better alignment with product policies and other laws, such as the new Ecodesign Regulation and IED.

Industry representatives described the CSS as ambitious, progressive and inclusive. Because of its holistic approach, the CSS represents a step forward in streamlining the complex EU environmental policy landscape and enhancing risk management efficiency. Moreover, they believed that the CSS had the potential to foster international alignment. Industry stakeholders appreciated the CSS approach to minimising exposure to hazardous substances in consumer products, particularly through initiatives like defining the essential use concept and adopting a generic approach to risk management. They expected that these measures would speed up protection compared to traditional substance-by-substance regulatory actions.

Industry stakeholders also commended the CSS for promoting the needed innovation towards safe and sustainable chemicals and for proposing critical actions against the most problematic groups of substances, such as PFAS and endocrine disruptors. They noted that the CSS encouraged industry to phase-out toxic substances from supply chains and identify safer substitutes. Additionally, industry stakeholders appreciated the CSS's holistic approach to chemicals management, competitiveness and innovation, emphasising the importance of circularity and sustainability in product development.

³¹ The new hazard classes being introduced are:
Category 1 and 2 endocrine disruption for human health
Category 1 and 2 endocrine disruption for the environment

PBT (persistent, bioaccumulative, toxic) / vPvB (very persistent, very bioaccumulative)
PMT (persistent, mobile, toxic) / vPvM (very persistent, very mobile)

However, industry stakeholders identified several areas for improvement. They highlighted the need for better data sharing to reduce compliance costs, especially for SMEs, and enhance transparency in supply chains, particularly regarding chemical ingredients for downstream users, i.e. enhanced data requirements in safety data sheets. For downstream users this is critical for finding and substituting hazardous chemicals in consumer products or tracking substances of concern under the upcoming ESPR.

Additionally, they criticised the lack of enforcement of existing rules and suggested a more efficient use of data along supply chains (e.g. in safety data sheets) to improve risk management measures, something also needed for compliance with other legislation, such as occupational health and safety laws. Industry stakeholders also mention that the CSS did not look sufficiently into optimising existing resources of authorities to reduce unnecessary administrative procedures and called for better integration of chemicals, waste and products initiatives and concepts.

Finally, they mentioned the lack of planning in the CSS to ensure sufficient support for SMEs to implement different CSS initiatives.

EEB's views

The EEB considers the CSS an ambitious strategy that aimed to address longstanding shortcomings of EU chemicals policies, including the need to improve the information on hazards, exposure and uses of chemicals; the introduction of a chemicals management hierarchy and of new concepts to improve and speed up the regulation of chemicals (e.g. essential use concept, MAF); or its commitment to ban the most harmful chemicals in consumer and professional uses.

However, as noted by other stakeholders, the CSS fell short in addressing the escalating risks posed by the increasing production, use and emissions of chemicals, which have now surpassed safe planetary boundaries. It also did not thoroughly address the issues of non-compliance and enforcement of existing regulations. Additionally, there were missed opportunities to build synergies with and align the CSS with other sectoral legislation, such as those related to biodiversity, agriculture, circular economy, industrial emissions, climate and waste. Furthermore, the CSS overlooked the opportunity to establish incentives (legal, technical, economical) for substitution and the promotion of alternative providers.

Regulation on Classification, Labelling and Packaging of substances and mixtures (CLP)

CSS objectives and actions

ACTION	INDICATIVE TIMMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#27 Proposal to amend the CLP Regulation to introduce new hazard classes on endocrine disruptors, PBTs/vPvBs and persistent and mobile substances, and apply them across all legislation.	2022	CLP legal proposal.	Proposal published in 2022 and implemented since 2023.	New hazard classes introduced in CLP for endocrine disruptors, PBTs/vPvBs and persistent and mobile (PMTs/vPvMs) substances.
#51 Proposal to amend CLP Regulation to give the Commission the mandate to initiate harmonised classification.	2022	CLP legal proposal.	Proposal published in 2022, currently awaiting formal approval by the co-legislators.	Revised CLP regulation includes mandate for the Commission to initiate harmonised classification.
#81 Proposal at the UN GHS level to introduce, adapt or clarify criteria/hazard classes in line with the CLP Regulation.	2022	CLP legal proposal - New hazard classes in GHS.	Proposal published in 2022 and introduction proposed to UN GHS subcommittee in 2022.	CLP legal proposal was published and meets CSS ambition; But much remains to be done regarding implementation in GHS and final level of ambition unclear.

The CSS sets forth the European Union's ambitious vision for achieving a toxic-free environment. At the heart of this strategy is the goal to establish a robust legal framework that more effectively addresses environmental and health concerns related to chemical usage. A central aspect of this approach involves the prohibition of the most harmful chemicals in

consumer products, except where their use is deemed essential. The first step towards a ban is the hazard identification of chemicals through the CLP regulation. However, the CSS noted that the CLP regulation did not properly address the identification of substances of very high concern due to endocrine disrupting properties or due to high persistence.

Endocrine disruptors (EDs) are associated with a plethora of adverse effects in people and other organisms, including infertility, thyroid disorders, diabetes, obesity, developmental effects and learning disabilities. Persistent chemicals raise significant concerns due to their potential for causing widespread and irreversible environmental pollution, attributable to their persistence combined with either high bioaccumulation (PBT/vPvB) or high mobility (PMT/vPvM) in the environment. Such chemicals, exemplified by Per- and Polyfluoroalkyl Substances (PFAS), pose a global threat to public health through the contamination of food and drinking water and the environment.

To address these issues and strengthen the effectiveness of the CLP regulation, the Commission proposed several actions within the CSS, including:

- Revising the CLP Regulation to empower the Commission to initiate harmonised classification and labelling [Action 51];
- Broadening the scope of the CLP regulation to incorporate new hazard classes for endocrine disruptors and persistent chemicals, recognising their potential for causing long-term and widespread effects [Action 27].

Furthermore, the CSS outlines the Commission's aspiration to lead globally in promoting high standards for the management of chemicals. This ambition included promoting the introduction of these new hazard classes at the international level, specifically through the following action in the CSS:

- Proposing the introduction of new hazard classes at the United Nations Globally Harmonised System (UN GHS) for the classification and labelling of chemicals [Action 81]

These actions underscore the EU's commitment to not only improving chemical safety within its borders but also elevating global standards for the management and regulation of hazardous chemicals.

Assessment of Implementation

Implementation level

- Revision of the CLP Regulation through Ordinary Legislative Act [including Action 51]

The Commission published a proposal to revise the CLP Regulation on 19 December 2022, for adoption through Ordinary Legislative Procedure, which involved co-decision by the European Parliament and Council. The compromise text on the revision of CLP was agreed in the interinstitutional negotiations between representatives of the European Parliament and Council on 5 December 2023. The agreed text was approved by the Council's permanent representatives on 22 December 2023. The final approval by the co-legislators and publication is expected in the first half of 2024.

- Introduction of new hazard classes by Delegated Act [Action 27]

On the same day as the CLP revision proposal, 19 December 2022, the Commission also published a proposal for the new hazard classes to be incorporated into the CLP Regulation. This proposal was enacted through a Delegated Act, following scrutiny by the European Parliament and the Council. The delegated regulation entered into force on 20 April 2023. It established a transitional period during which manufacturers, importers, downstream users and distributors have the option to voluntarily apply the new hazard classifications. Mandatory classification of substances according to these new hazard categories will start on 1 May 2025, for substances newly introduced to the market, and on 1 November 2026, for those already on the market before 1 May 2025.

- Introduction of the new hazard classes in the UN GHS [Action 81]

In 2022, the Commission took the initiative to propose the introduction of the new CLP hazard classes within the framework of the United Nations Globally Harmonised System (UN GHS). The Commission is leading an informal working group under the UN GHS subcommittee, which

also considers the establishment of criteria for potential additional new hazard categories, including immunotoxicity, neurotoxicity and terrestrial toxicity.

Stakeholders' views

Stakeholders have expressed a range of views on the revision of the CLP Regulation and the broader CSS. While **there is general agreement that the revision of the CLP Regulation is a success**, especially the addition of new hazard classes, various concerns and recommendations have also been highlighted.

Positive Feedback:

Inclusion of New Hazard Classes: The addition of specific hazard classes for PMT/vPvM, PBT/vPvB, and endocrine disrupting substances has been well-received, marking progress in identifying and managing chemical risks more effectively.

Impact on Environmental Regulations: The new hazard classifications under CLP are expected to influence other environmental regulations positively, such as the classification of waste, by identifying hazardous components more clearly.

Gender-Related Issues: The European Parliament's mandate to consider gender-related issues in chemical hazard assessment has been viewed positively, acknowledging the nuanced impacts chemicals can have on different genders.

UN GHS Discussions: Initiating discussions at the UN GHS level to introduce new hazard classes, as revised in the CLP, is seen as a successful move towards global harmonisation of chemical safety standards.

Concerns and Recommendations:

- **Classification Limits for EDs:** the generic concentration limits set for classifying mixtures as hazardous are not appropriate for endocrine disruptors, particularly given that EDs are non-threshold substances that can have adverse effects at very low concentrations.

- **Harmonised Classification Process - Delays:** The process for harmonised classification remains lengthy, even with the new provision foreseeing that the Commission shall adopt new harmonised classification, preferably before the end of the calendar year, following the publication of the European Chemicals Agency's (ECHA) opinion by its Risk Assessment Committee (RAC). This is a positive step, but leaves room for longer delays to adoption. The intention of the Commission to favour the CLH process instead of the SVHC identification process will lead to more delays in the identification of the most harmful substances.
- The **revision of information requirements** under REACH should take account of the CLP criteria, while the integration of New Approach Methodologies (NAMs) should not compromise the level of information available.
- **PMT/vPvM Classification and REACH:** It is positive that PMT/vPvM substances have been included as a separate hazard class in CLP. However, the delay in revising REACH to include them as a distinct SVHC category, as promised in the CSS, is seen as a missed opportunity for effective regulatory action of these substances of very high concern, such as PFAS.

In summary, stakeholders recognise the strides made by the revised CLP Regulation and the CSS towards a safer and more sustainable environment. However, they also emphasise the need for continuous improvement in implementation processes, information requirements and the integration of these new classifications into broader environmental and health regulations to ensure comprehensive protection against chemical risks. Discussions within this working group are expected to extend over the coming years, reflecting ongoing international efforts to enhance chemical safety and harmonisation.

The CSS commitments regarding the CLP Regulation have been largely delivered.

Mandate for Harmonised Classification and Labelling: The inclusion of a mandate for the Commission to initiate harmonised classification and labelling (action 51) is a positive step that facilitates a more proactive approach in controlling harmful chemicals.

Introduction of New Hazard Classes: The introduction of the new hazard classes in CLP (action 27) for endocrine disruptors, PBT, vPvB, PMT, and vPvM substances, is a significant advancement as it allows coherent and legally binding hazard identification of these hazardous chemicals across legislation. This move is also expected to improve communication about these hazards to workers and consumers, trigger further regulatory control measures under other pieces of legislation and increase incentives to companies to use safer chemicals. It can ultimately contribute to better protection of human health and the environment from the threats of these harmful chemicals.

Group Assessments for Classification: the proposals to strengthen the classification and labelling of hazardous chemicals, including the use of group assessments for harmonised classification and labelling is welcomed to streamline and potentially expedite the classification process.

Introduction of new hazard classes in UN-GHS: The Commission's efforts to introduce the new hazard classes in the United Nations Globally Harmonised System (UN GHS) for Classification and Labelling demonstrates the Commission's ambition to become a global leader in increasing chemical safety and harmonisation.

Concerns and Missed Opportunities:

Weakening of the European Parliament's Proposals: Some of the European Parliament's proposals, such as the inclusion of gender equality considerations, prioritisation of PMT/vPvM substances for harmonised classification and labelling, setting strong and clear deadlines for the Commission action

following RAC opinions, and improving the classification and labelling inventory, were either diluted or omitted in the compromise text. This represents a missed opportunity to speed up regulatory action and enhance protection for human health and the environment.

High Generic Concentration Limits: The concern over high generic concentration limits for triggering the classification of mixtures and substances containing more than one constituent highlights a potential loophole where mixtures containing individual hazardous chemicals (such as carcinogens and endocrine disruptors) in small amounts may not be classified as hazardous, undermining protection efforts.

Classification exemption for plant extracts: The derogation from certain classification rules for plant extracts, such as essential oils, containing hazardous ingredients (such as carcinogens, mutagens, endocrine disruptors, reprotoxic chemicals) undermines the hazard identification, labelling and communication of the presence of such highly toxic constituents in these substances of natural origin to workers and consumers, thereby potentially undermining the protection.

Evidence Requirement for EDs Identification: The high level of evidence required for identifying EDs is a bottleneck, possibly slowing down the hazard identification process and delaying protective actions. The stalled revision of information requirements under REACH contributes to this bottleneck.

Process of introduction of new hazard classes at UN GHS Level:

While we welcome the effort to introduce new hazard classes at the global level through the UN GHS, there is concern that these discussions could lead to criteria for EDs and persistent chemicals that are less protective than those currently in the CLP regulation. Any dilution of criteria at the UN GHS level would need to be mirrored in the CLP regulation, potentially weakening protections. To counter potential backsliding in protection levels, the EEB stresses the importance of active involvement by EU stakeholders in the UN GHS discussions. This is to ensure that the high protection standards set by the CLP regulation are not compromised.

REACH

REACH

ACTION	INDICATIVE TIMMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#9 Ensure that authorisations and derogations from restrictions for recycled materials under REACH are exceptional and justified.	As of 2020.	N/A	Not launched.	Not launched.
#20 Roadmap to prioritise carcinogenic, mutagenic and reprotoxic substances (CMRs), endocrine disruptors, persistent, bioaccumulative and toxic (PBT and very persistent and very bioaccumulative (vPvB) substances, immunotoxicants, neurotoxicants, substances toxic to specific organs and respiratory sensitisers for (group) restrictions under REACH.	2021	Staff working document.	Fully implemented.	The published roadmap does not match the ambition of the CSS, regarding the scope or timelines.
#21 Proposals to extend the generic approach to risk management to ensure that consumer products do not contain chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative and toxic; assess the modalities and timing to extend the same approach to further chemicals including those affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ.	2022	REACH legal proposal.	Not launched.	Not launched.

ACTION	INDICATIVE TIMMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#22 Proposal to amend REACH Article 68(2) to include professional users.	2022	REACH legal proposal.	Not launched.	Not launched.
#23 Introduce mandatory legal requirements under the General Product Safety Directive and restrictions in REACH to enhance the safety of children from hazardous chemicals in childcare articles and other products for children (other than toys).	2022	REACH legal proposal.	The EC will present a draft proposal to the REACH Committee for discussion during 2024.	The reduced number of chemicals that will be addressed with the proposal does not match the ambition of the CSS.
#28 Update information requirements to allow the identification of endocrine disruptors in relevant legislation particularly under REACH, legislation on cosmetic products, food contact materials, plant protection products and biocidal products.	2022	REACH legal proposal.	Legal proposal not published. Study report presented and options discussed in workshops and (ad hoc) CARACAL meetings.	Options proposed by Commission will improve situation, but do not fully account for combined effects of chemicals, therefore did not match CSS ambition. Furthermore, final level of ambition is unknown.
#30 Assess how best and introduce (a) mixture assessment factor(s) in Annex I of REACH.	2022	REACH legal proposal.	Legal proposal not published. Study report presented and options discussed in workshops and (ad hoc) CARACAL meetings.	Options proposed by Commission will improve situation, but do not fully account for combined effects of chemicals, therefore did not match CSS ambition. Furthermore, final level of ambition is unknown.
#33 Proposal to amend REACH Article 57 to add endocrine disruptors, persistent, mobile and toxic (PMT), and very persistent and very mobile (vPvM) substances to the list of substances of very high concern.	2022	REACH legal proposal.	Not launched.	Not launched.

ACTION	INDICATIVE TIMMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#38 Proposal to restrict PFAS under REACH for all non-essential uses including in consumer products.	2022-2024	REACH restriction.	Significant progress. Five member states have presented a wide scope restriction proposal under REACH.	It matches the CSS ambition as it addresses all uses proposing time limited derogations for uses for which no alternatives are available.
#49 Proposal to revise the REACH Authorisation and Restriction processes.	2022	REACH legal proposal.	Not launched.	Not launched. The options presented by COM at CARACAL do not meet the CSS ambition.
#63 Amend REACH to ensure compliance checks on all registrations of substances under REACH and to allow for the revocation of registration numbers.	2022	REACH legal proposal.	Proposal not published. Options discussed at (ad hoc) CARACAL meetings.	The options presented by EC at CARACAL partly matched CSS ambition. Final level of ambition unknown.
#72 Proposals to revise requirements for registration in REACH to ensure: the identification of substances with critical hazard properties, including effects on the nervous and immune systems, the move towards grouping approaches, the registration of a sub-set of polymers, information on the overall environmental footprint of chemicals, the obligation of chemical safety reports for substances between 1-10 tonnes.	2022	REACH legal proposal.	Legal proposal not published. Proposals discussed by CARACAL Subgroups.	Final level of ambition unknown.

Together with the CLP, the revision of REACH was one of the main objectives of the CSS. The Strategy included a wide range of measures to strengthen and develop REACH, including reforming the Authorisation and Restriction procedures, strengthening consumer protection from hazardous chemicals and extending information requirements.

The implementation of many of the above measures required REACH to be revised. However, such a revision has not been put forward and this has negatively affected the implementation of most actions. It is uncertain if, when and with what level of ambition the REACH revision will be implemented in future (in 2025 at the earliest).

Registration and Evaluation

CSS objectives and actions

The CSS set forth several objectives and corresponding actions to tackle challenges related to non-compliance of registration dossiers and the data gaps in legal information requirements for Registration under REACH.

The Commission has acknowledged the problem of high level of non-compliance of the registration dossiers³². One of the key commitments of the CSS was to simplify, consolidate and fully implement EU rules on chemicals. This included implementing a zero-tolerance stance on non-compliance to facilitate timely regulation of harmful chemicals. The Commission pledged to introduce the polluter-pays principle as well as to reinforce the no data, no market principle set out in the REACH Regulation. This included ensuring compliance of all registration dossiers and revoking registration numbers in cases of non-compliance:

- Amend REACH to ensure compliance checks on all substance registrations under REACH and enable the revocation of registration numbers [Action 63]

Another objective of the CSS was to establish a comprehensive knowledge base on chemicals. The Commission proposed expanding information requirements for registration dossiers under REACH. This expansion aimed to enable the effective identification of all carcinogens irrespective of the volume, and other substances with critical hazard properties, including effects on the nervous and immune systems. Additionally, it aimed to enable safety assessment of chemicals with low production volumes, the registration of certain polymers of concern, and the assessment of how to introduce information requirements on the overall environmental footprint of chemicals. The requirement of more hazard information within registration dossiers was expected to result in

faster hazard classification of a broad range of chemicals:

- Proposals to revise registration requirements in REACH to ensure identification of substances with critical hazard properties, including effects on the nervous and immune systems, the move towards grouping approaches, registration of a subset of polymers, inclusion of information on the overall environmental footprint of chemicals, and the obligation of chemical safety reports for substances produced in quantities between 1-10 tonnes [Action 72].

Assessment of implementation

Implementation level

Ensure compliance checks on all substance registrations under REACH and allow for the revocation of registration numbers [Action 63]

The Commission convened Ad hoc CARACAL meetings in 2022 to discuss proposals for revising the Registration and Evaluation processes under the REACH revision. Discussions included the introduction of an expiration date for registration dossiers, extending the completeness check at registration and revocation of market access in case of non-compliance.

However, the Commission has confirmed that the proposal for revising the REACH Regulation will not be published during the current mandate, leaving uncertainty about whether and when the new Commission will continue the revision.

Update information requirements under REACH [Action 72]

Several reports have been prepared presenting various options for revising the information requirements under REACH. The Commission

³² European Commission, Communication on the Commission General Report on the operation of REACH and review of certain elements Conclusions and Actions Conclusions and

Actions (COM/2018/0116 final), European Commission, 2018. Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2018:0116:FIN>

organised CARACAL subgroup meetings and presented the results at CARACAL³³ to discuss the proposals for the different measures under Action 72. Options for the REACH revision discussed were included in the Impact Assessment submitted to the Regulatory Scrutiny Board (RSB) in 2022.

While the revision of the REACH Annexes could be done independently from the overall REACH reform through the comitology procedure, the Commission has confirmed that the proposal for the revision of the REACH Annexes will not be presented under the mandate of the current Commission.

Stakeholder's views

Almost all stakeholders expressed regret over the postponement of the REACH revision, as numerous actions and objectives of the Strategy were intended to be implemented through this legislation. Moreover, there is concern among many stakeholders that the potential failure to proceed with the revision could adversely impact the entire chemicals legislation framework. For instance, the extension of information requirements might not occur, resulting in a lack of data for identifying substances under the new hazard classes in CLP. Additionally, stakeholders are uncertain about whether and when the Commission will propose changes to the REACH annexes via Comitology.

Stakeholders emphasised that the revision of information requirements should align with the CLP criteria and include New Approach Methodologies (NAMs). They added that amendments to information requirements should not only aim to identify all carcinogenic and ED substances, but this goal should extend to all other most harmful substances as well.

Furthermore, some stakeholders regret the significant investment of time and resources in

discussions and studies preparing for REACH 2.0 (e.g., Mixture Assessment Factor) and that political choices and geopolitics are delaying the possibility to have a more efficient and effective REACH.

EEB's views

The high level of non-compliant registration dossiers is a major factor contributing to the delayed implementation of REACH³⁴. **This generalised non-compliance not only burdens the Evaluation process and strains public resources at the European Chemicals Agency (ECHA), but also leads to delays in identifying and managing the hazards posed by harmful chemicals.** While new registrations are granted market access within three weeks under the current REACH rules, it often takes over a decade to identify and control these harmful chemicals³⁵. Much of this time is largely consumed by collecting the necessary data for hazard identification (SVHC identification or hazard classification).

The Commission's decision to stall the revision of REACH exacerbates these delays in hazard identification and risk management, as provisions for registration and evaluation will not be strengthened in the near future. This situation leaves both people and the environment exposed to potentially toxic chemicals for years, and fails to provide incentives for companies to provide updates or additional information, or to search for safer and more sustainable alternatives.

The stalled update of the information requirements is another area that prevents swift regulation of chemicals of high concern.

³³ European Commission, DG DIGIT, CIRCABC Website on CARACAL Sub-Groups. Available at: https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/fbde80c-6952-4561-a8c8-c44af05ad66c?p=1&n=10&sort=modified_DESC

³⁴ Dr. Hélène Loonen, Dolores Romano, Tatiana Santos and Elise Vitali, CHEMICAL EVALUATION. Achievements, challenges and recommendations after a decade of REACH, EEB, April 2019. Available at: [https://eeb.org/wp-](https://eeb.org/wp-content/uploads/2019/07/Report-Substance-Evaluation-under-REACH.pdf)

[content/uploads/2019/07/Report-Substance-Evaluation-under-REACH.pdf](https://eeb.org/wp-content/uploads/2019/07/Report-Substance-Evaluation-under-REACH.pdf)

³⁵ Tatiana Santos, Vito Buonsante, Hélène Loonen and Geraldine Borja, The Need For Speed – Why it takes the EU a decade to control harmful chemicals and how to secure more rapid protections, EEB, July 2022. Available at: <https://eeb.org/library/the-need-for-speed-why-it-takes-the-eu-a-decade-to-control-harmful-chemicals-and-how-to-secure-more-rapid-protections/>

Restriction and Authorisation

CSS objectives and actions

The CSS aimed to strengthen the legal framework to address the pressing environmental and health concerns posed by hazardous chemicals. This involved revising the REACH Authorisation and Restriction chapters and, concurrently, improving the protection against the most harmful chemicals by prioritising group restrictions within the current system.

Among the actions affecting the Restriction and Authorisation processes in REACH, the CSS outlined various ambitious actions:

- Establishing a roadmap to prioritise certain groups of substances for restrictions under REACH [Action 20];
- Proposing restrictions on hazardous chemicals in childcare articles and other products for children (other than toys) [Action 23];
- Proposing amendments to REACH Article 57 to add endocrine disruptors, persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances to the list of substances of very high concern [Action 33];
- Proposing restrictions on PFAS for all non-essential uses, including in consumer products [Action 38];

Proposing a revision of REACH Authorisation and Restriction processes [Action 49].

Assessment of Implementation

Implementation level

The Commission carried out several consultations and workshops on the revision of the REACH Authorisation and Restriction processes (action 49), presenting regular updates during CARACAL meetings, where member states and stakeholders could discuss the proposed revision options. However, discussions on these chapters remain ongoing. Although several options were included in the Impact Assessment, the Commission initiated a new study to assess the possibility of introducing derogations to restrictions based on voluntary substitution planning commitments. Nevertheless, as mentioned above, uncertainty persists regarding whether the new Commission will reinitiate the revision process.

In 2022, the Commission published a Restrictions Roadmap³⁶ (action 20) prioritising (groups of) substances of high concern for restrictions under REACH. The roadmap includes chemicals proposed both by the Commission and member states, to be restricted while the REACH is revised. An updated version of the Restrictions Roadmap was presented at CARACAL in March 2024³⁷.

Several proposals to restrict PFAS (action 38) were included in the Restrictions Roadmap. A proposal by Germany to restrict PFHxA³⁸ gained support from the REACH Committee in February 2024, hence adoption is expected soon. Additionally, a Commission proposal to ban PFAS used in firefighting foams³⁹ (FFF) awaits a draft decision by the Commission, while a wide scope proposal by five national authorities⁴⁰ is

³⁶ European Commission, Staff Working Document on the Restrictions Roadmap under the Chemicals Strategy for Sustainability (SWD(2022) 128 final), European Commission, 2022. Available at: <https://ec.europa.eu/docsroom/documents/49734/attachment/1/translations/en/renditions/native>

³⁷ European Commission, DG DIGIT, CIRCABC Website on CARACAL Sub-Groups. Available at: https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/fbde80c-6952-4561-a8c8-c44af05ad66c?p=1&n=10&sort=modified_DESC

³⁸ ECHA, Registry of restriction intentions until outcome, undecafluorohexanoic acid (PFHxA), its salts and related substances, ECHA. Available at: <https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18323a25d>

³⁹ ECHA, Registry of restriction intentions until outcome, Per- and polyfluoroalkyl substances (PFAS), ECHA. Available at: <https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1856e8ce6>

⁴⁰ The Netherlands, Germany, Sweden, Denmark and Norway

under assessment by ECHA's Risk Assessment Committee, and Socio-Economic Analysis Committee (SEAC)⁴¹.

Moreover, the Restrictions Roadmap includes a proposal to restrict carcinogens, mutagens and reprotoxic chemicals in childcare articles under REACH, following the fast-track procedure established in its Article 68.2. The Commission has announced its intention to present a draft decision for voting at the REACH Committee in 2024.

Stakeholder's views

The postponement of the REACH revision is widely regarded as a significant missed opportunity by most stakeholders. As one stakeholder points out ***“the postponement of the REACH revision and the risk that the revision will not take place at all may affect the entire [body of] chemicals legislation in an undesirable way”***. Stakeholders are concerned about the Commission's apparent intention to “downplay the importance of the Authorisation system and in future to regulate substances mainly through the Restriction system”.

While stakeholders generally welcomed the publication of the Restrictions Roadmap, some express disappointment that concrete actions to implement the roadmap have been lacking, with deadlines being missed without clear objectives being achieved. For example, one stakeholder notes “the proposal by the Commission to restrict PFHxA and related substances was not in line with the ambition set by the CSS, especially in view of the change of scope to a targeted instead of a broad restriction. Furthermore, there has been significant delay on the Commission proposal to restrict PFAS in firefighting foams, for

which no formal timeline has been presented as of yet”.

EEB's views

Several improvements in the REACH legal text are needed to speed up the regulation of harmful chemicals under REACH Authorisation and Restriction processes. For instance, implementing the Essential Use Concept, improving the information on uses and alternatives, establishing incentives for substitution (such as fees for downstream users), or obliging the provision of information to authorities, would require changes in the current legal provisions. However, an adequate implementation of the REACH legal text, particularly in Authorisation, such as refusing authorisation when alternatives are available, rejecting upstream applications, etc, as well as prioritising group restrictions, can enhance the protection of people and the environment against harmful chemicals in the meantime^{42,43}.

While the publication of the Restrictions Roadmap has provided clarity on authorities' plans to regulate the most harmful chemicals, its ambition is low compared to the problem we face, and it allows, and even contributes to, slow and weak regulation. A higher commitment by the Commission, ECHA and member states is needed to adequately protect people and the environment⁴⁴.

⁴¹ ECHA, Submitted restrictions under consideration, Per- and polyfluoroalkyl substances (PFAS), ECHA. Available at: <https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term>

⁴² Dolores Romano and Tatiana Santos, A Roadmap to revitalize REACH, EEB, 2017. Available at: <https://eeb.org/library/a-roadmap-to-revitalise-reach/>

⁴³ Dolores Romano, Tatiana Santos, Greg Howard, Vito Buonsante, Tony Musu, Ninja Reineke, Pieter De Pous, Elisabeth

Ruffinengo. Restricted Success: EEB's appraisal of restriction under REACH, EEB, 2017. <https://eeb.org/library/restricted-success-eebs-appraisal-of-restriction-under-reach/>

⁴⁴ Helene Duguy and Dolores Romano, A roadmap to nowhere? The EU's bold plan to quit the most harmful chemicals is a year old. We assess its effectiveness. EEB and Client Earth, 2023. Available at: <https://eeb.org/library/a-roadmap-to-nowhere-the-eus-bold-plan-to-quit-the-most-harmful-chemicals-is-a-year-old-we-assess-its-effectiveness/>

Safe and Sustainable by Design

CSS objectives and actions

ACTION	INDICATIVE TIMMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#2 Develop EU safe and sustainable-by-design criteria for chemicals.	2022	Staff working document.	Criteria published.	Unclear progress and applicability.
#3 Establish an EU-wide safe and sustainable-by-design support network.	2023	Coordination and support.	Not launched.	Not launched and missed opportunity to boost substitution.

Safe and Sustainable by Design⁴⁵ (SSbD) is a fundamental component of the CSS aimed at preventing future chemical problems by promoting and incentivising innovation and the utilisation of chemicals and materials developed on principles of safety and sustainability. The CSS recognises that "the transition to chemicals that are safe and sustainable by design is not only a societal urgency but also a significant economic opportunity."

In addition to fostering the development of chemicals and materials without hazardous properties, the SSbD framework encompasses various environmental and sustainability aspects, including climate impact, energy usage, biodiversity and natural resource preservation. Alongside the directly related actions outlined above, twelve timed measures in the CSS are associated with SSbD, nearly equalling those concerning strengthened chemicals legislation. These measures include:

- Developing EU safe and sustainable-by-design criteria for chemicals [Action 2];
- Establishing an EU-wide safe and sustainable-by-design support network

to bolster activities in this realm [Action 3];

Assessment of Implementation

Implementation level

The Commission has made significant progress in defining SSbD and developing a framework, including criteria for assessing the safety and sustainability of chemicals, materials and products [Action 2]. Collaborative efforts between the Commission's Joint Research Centre (JRC) and DG Research and Innovation (RTD) have led to the publication of various documents, including a survey of existing sustainability frameworks and a Recommendation establishing a European assessment framework for SSbD chemicals and materials⁴⁶ that lays the foundation for the development of a common EU framework for SSbD. Additionally, the Commission organised three workshops, a special seminar in the European Parliament, as well as a technical report detailing the stepwise assessment of SSbD has been released, along with case studies examining the applicability of SSbD criteria to selected chemicals and products. These case studies, developed by the JRC, in

⁴⁵ The CSS Communication defines safe and sustainable-by-design as "a pre-market approach to chemicals that focuses on providing a function (or service), while avoiding volumes and chemical properties that may be harmful to human health or the environment, in particular groups of chemicals likely to be (eco) toxic, persistent, bio-accumulative or mobile. Overall sustainability should be ensured by minimising the environmental footprint of chemicals in particular on climate

change, resource use, ecosystems and biodiversity from a lifecycle perspective."

⁴⁶ European Commission, Recommendation (EU) 2022/2510 of 8 December 2022 establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials (C/2022/8854), European Commission, 2022. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022H2510>

collaboration with a number of chemical manufacturing companies, include surfactants (enzymes) and phthalates (in plasticised PVC). In addition, the case studies serve to deduce which methods can be used at which level for testing safety and sustainability and which further methodological developments are required. The work will also serve to examine whether the present concept needs to be adapted and what form this might take.

While the establishment of an EU-wide safe and sustainable-by-design support network [Action 3] has not been reported, the Commission's Strategic Research and Innovation Agenda (SRIP) incorporates SSbD aspects. Moreover, the EU Partnership for the Assessment of Risks from Chemicals (PARC) project includes a specific task dedicated to SSbD, focusing on developing a toolbox for SSbD implementation, testing via case studies, knowledge dissemination and an education platform.

Stakeholder's views

Stakeholders generally praised the CSS for its focus on promoting innovation in safe and sustainable chemicals. The introduction of the Safe and Sustainable by Design (SSbD) concept and roadmap was well-received, with stakeholders acknowledging its potential to facilitate non-toxic material cycles and enhance protection against harmful chemicals and introducing criteria for essential uses.

While stakeholders appreciated the initiation of the SSbD framework and discussions, some expressed concerns about its operationalisation and implementation. They emphasised the need to integrate social and economic dimensions into the SSbD framework and ensure it does not merely become another risk assessment tool. Additionally, stakeholders raised concerns about the slow progress in providing access to safe and sustainable alternatives for downstream users and called for increased funding for innovation and research throughout the value chain. Specifically, they highlighted the importance of understanding risks associated with legacy chemicals in recycled products and the necessity

for faster innovation in safe and sustainable substitutes.

EEB's views

The Commission Recommendation “establishing a European assessment framework for ‘safe and sustainable by design’ chemicals and materials”⁴⁷ offers a valuable framework with the potential to position the EU as a global leader in safe and sustainable innovation, thereby enhancing industry competitiveness.

The classification of substances into three groups: most harmful substances (Group A), substances of concern (Group B) and other hazardous substances (Group C), provides clarity while the cut-off criteria for the most harmful substances is crucial for ensuring inherently safe and sustainable innovation in the EU.

However, there are uncertainties regarding the inclusion of substances without corresponding harmonised classifications and properties not yet considered in the CLP Regulation, such as effects on non-aquatic organisms, longevity of substances, PBT, vPvB, PMT, vPvM or chronic water pollution.

It remains unclear how the consideration of such approaches is to be promoted. Although there are a few reporting obligations in the area of regulations on sustainable financing etc, that at least take up aspects and certain funding structures, further optimisation of the framework conditions are probably needed in order to anchor SSbD broadly in the economy.

While the integration of SSbD in the design and evaluation phases is commendable, challenges arise from insufficient data availability for assessing both new and existing substances. This particularly concerns lifecycle assessments, toxicity aspects and also more extensive sustainability aspects such as climate change, resources, eutrophication, land and water use, as well as impacts on the atmosphere are addressed. The lack of concrete links between

⁴⁷ ⁴⁷ European Commission, Recommendation (EU) 2022/2510 of 8 December 2022 establishing a European assessment framework for ‘safe and sustainable by design’ chemicals and

materials (C/2022/8854), European Commission, 2022. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022H2510>

SSbD and existing legislation on chemicals, products and waste further complicates its future implementation.

Furthermore, there is a risk, promoted by industry players, of deviating from the original idea of SSbD, moving towards a more risk-based assessment, which may undermine its purpose.

The SSbD network has not advanced. Also, the limited focus on supporting chemical manufacturers rather than promoting EU-wide substitution by downstream users raises concerns.

Industry engagement is essential to fully harness the potential of SSbD and drive safe and green innovation in the EU.

Generic Approach to Risk Management, GARM

CSS objectives and actions

ACTION	INDICATIVE TIMMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#21 Proposals to extend the generic approach to risk management to ensure that consumer products do not contain chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative and toxic; assess the modalities and timing to extend the same approach to further chemicals including those affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ.	2022	REACH legal proposal.	Not launched.	Not launched.
	2023	Food contact materials regulation legal proposal.	GARM proposal published on bisphenols. Could have been implemented with a wider scope.	One chemical category included, and proposal published with one year delay.
	2022	Cosmetic products regulation legal proposal.	Not launched.	Not launched.
	2022	Toy Safety Directive legal proposal.	Extension of GARM proposed.	Proposal delayed by two years and not ambitious enough.

The Strategy aims to create a toxic-free environment and prevent the harmful effects of substances of concern. It focuses on applying a general approach to risk management, which involves banning certain highly hazardous substances from consumer products and articles, unless their use is deemed essential, and no acceptable alternatives exist. This approach, known as the Generic Approach to Risk Management (GARM) alongside the Essential Use Concept, is crucial for various CSS activities, including the REACH revision and other EU legislation related to cosmetics or toys. The goal is to minimise human and environmental exposure to harmful substances by strictly

regulating their presence in everyday and professional products.

According to the CSS, significant efforts within EU chemicals legislation have focused on reducing citizen exposure to carcinogenic substances, facilitated in part by a preventive approach across legislation and the implementation of GARM. In the EU legislative framework, GARM acts as an automatic trigger for predefined risk management measures, such as packaging requirements, restrictions or bans, based on a chemical's hazardous properties and generic considerations of exposure, particularly in products intended for children or with widespread use⁴⁸.

⁴⁸ European Commission, Staff working document on the Fitness check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries (SWD/2019/199 final/2),

European Commission, 2019. Available at: [https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1566802607995&uri=CELEX:52019SC0199R\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1566802607995&uri=CELEX:52019SC0199R(01))

However, the CSS recognises that the majority of chemicals in the EU are presently regulated on a case-by-case basis and there is ample evidence supporting the use of GARM as the default option for the most harmful chemicals. The Commission has committed to gradually extending this approach. Initially, it plans to broaden the generic risk management approach to ensure consumer and professional products are free from chemicals causing cancers, gene mutations, reproductive or endocrine disruptions, or exhibiting persistence and bioaccumulation. Subsequently, a comprehensive impact assessment will be conducted to define the modalities and timing for expanding this generic approach to include other chemicals, such as those affecting immune, neurological or respiratory systems, as well as those toxic to specific organs.

Assessment of Implementation

Implementation level

GARM is currently applied to carcinogenic, mutagenic and reprotoxic (CMR) substances under REACH, the Toy Safety Directive and the Cosmetics Regulation, and to certain hazardous substances in the Biocidal Products and Plant Protection Products Regulations. The plan also includes expanding its application to other hazard categories under various legislative proposals, such as REACH, Food Contact Materials Regulation, Cosmetic Products Regulation and the Toy Safety Directive.

REACH: GARM was included in the public consultation on the REACH revision, workshops related to EC consultancy studies, a targeted consultation on Authorisation and Restriction processes, interviews with selected stakeholders

and discussions at several CARACAL meetings. An online workshop in March 2022⁴⁹ focused on extending GARM under REACH, aiming to leverage positive experiences from the REACH Authorisation and Restriction processes and improve their effectiveness. The workshop explored the use of harmful substances potentially subject to GARM, analysing REACH registration data and the impact of potential restrictions. However, progress on GARM's application in REACH has stalled due to the Commission's decision to pause its revision.

Food Contact Materials: In February 2024, the Commission released a draft proposal⁵⁰ to ban bisphenol A (BPA) in plastic food contact materials and others, including varnishes, coatings, printing inks and adhesives, planning to adopt this in the first quarter of 2024.

Toys Directive: The revision of the Toys Directive⁵¹ was launched in July 2023 by the Commission, which proposed extending the current CMR ban to endocrine disruptors, chemicals affecting the respiratory system, chemicals that are toxic to specific organs and are persistent, bioaccumulative, and toxic. The European Parliament, in March 2024, supported this proposal and introduced group restrictions on PFAS and bisphenols⁵².

Cosmetics Regulation: Although the Commission was expected to adopt a legislative proposal by the end of 2022⁵³, no proposal had been launched by the time this report was published.

Packaging and Packaging Waste Regulation (PPWR): While the Commission did not propose GARM application, the European Parliament and Council reached a provisional agreement in March 2024 on the PPWR to ban PFAS in food

⁴⁹ European Commission, Workshop on the extended generic risk management approach under REACH, European Commission. Available at: https://single-market-economy.ec.europa.eu/events/workshop-extended-generic-risk-management-approach-under-reach-2022-03-21_en

⁵⁰ European Commission, Food safety – restrictions on bisphenol A (BPA) and other bisphenols in food contact materials, European Commission. Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13832-Food-safety-restrictions-on-bisphenol-A-BPA-and-other-bisphenols-in-food-contact-materials_en

⁵¹ European Commission, Proposal for a Regulation on the safety of toys and repealing Directive 2009/48/EC (COM/2023/462 final), European Commission, 2023. Available

at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2023%3A462%3AFIN>

⁵² European Parliament, Press release “Parliament backs tighter EU rules for toy safety”, European Parliament, 13 March 2024. Available at: <https://www.europarl.europa.eu/news/en/press-room/20240308IPR19012/parliament-backs-tighter-eu-rules-for-toy-safety>

⁵³ European Commission, EU chemicals strategy for sustainability – Cosmetic Products Regulation (revision), European Commission. Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13197-EU-chemicals-strategy-for-sustainability-Cosmetic-Products-Regulation-revision-_en

contact packaging, pending formal approval before enforcement.

Stakeholder's views

Positive Aspects:

- Stakeholders appreciated the CSS's focus on minimising consumer exposure to hazardous substances in consumer products, highlighting the introduction of the essential use concept and the generic approach to risk management.
- The CSS is credited with highlighting critical issues for the green transition, especially the GARM.

Concerns and Criticisms:

- Concerns were raised about delays in defining the essential use concept and GARM due to the postponed REACH revision.
- Many stakeholders were eager for the improvements a revised REACH could offer, especially in enhancing aspects like risk management effectiveness.
- A consensus among stakeholders suggests that the CSS has fallen short in fully implementing GARM, which is crucial for sector-specific legislation such as Cosmetics, leading to apprehension about it potentially culminating in non-mandatory guidelines with vague impacts on chemical policy.

Overall view: There is a strong call among stakeholders to progress with the GARM, seen as a vital instrument for addressing concerns with chemical mixtures, polymers, substances of low and medium tonnage and to prevent regrettable substitution.

EEB's views

The CSS aimed to address the critical issue of hazardous chemicals, such as carcinogens and

endocrine disruptors (EDs), in everyday products to protect vulnerable groups and fulfil a Zero-Pollution vision. However, the urgent and ambitious application of the GARM is crucial to meet these objectives.

During the opening remarks at the press conference on the Chemicals Strategy for Sustainability in October 2020, Executive Vice-President Timmermans stated, "[a]s a rule, the use of the most harmful substances will be prohibited in consumer products." However, an impact assessment on the REACH revision in July 2023 revealed⁵⁴ that the Commission's scenarios fell significantly short of CSS aspirations. **Even in the most optimistic scenario, only half of products containing the most dangerous chemicals would be addressed, and in the worst case, merely 1%.** This discrepancy exists despite the societal healthcare savings from prevented impacts being ten times the costs of industry substitution. Achieving a GARM with high ambition appears challenging due to the contentious nature of the issue. This could result in a REACH revision proposal that inadequately extends GARM.

Furthermore, there is concern that the essential use concept might be diluted, leading to broad and lenient exemptions from GARM restrictions for whole product categories or industries. The failure to revise REACH amplifies the need to question the application of GARM and EUC across various product laws.

Despite these challenges, the Commission proposed an ambitious group ban under food contact materials law, which is an important step forward, although limited to one chemical group. It has also made strides in applying GARM to toys, although the co-legislators further enhanced this proposal, indicating that the Commission's efforts did not match the CSS's ambition level. Similarly, the revision of the Packaging and Packaging Waste Regulation (PPWR) saw the potential inclusion of a PFAS ban, thanks to a Parliamentary intervention. Yet, the anticipated reform of the Cosmetics Regulation has not been initiated by the Commission.

⁵⁴ European Environmental Bureau (EEB), Largest ever public screening finds "alarmingly high" chemical exposure, EEB, 11

July 2023. Available at: <https://eeb.org/european-citizens-alarmingly-high-chemical-exposure/>

Essential Use Concept (EUC)

CSS objectives and actions

ACTION	INDICATIVE TIMMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#26 Define criteria for essential uses, taking into account the definition of the Montreal Protocol.	2022	Will be relevant for several pieces of legislation - PFAS restriction prepared by five member states; REACH revision proposal, Ecodesign, Green claims, etc.	Not launched.	Proposal blocked at political level for two years, although a comprehensive and relevant supporting study was published.

A CSS goal is to ban the so-called "most harmful chemicals" in consumer and professional products, except where their use is deemed essential for societal needs. This objective involves establishing criteria for essential uses, ensuring these chemicals are only allowed when they are necessary for health, safety or critical societal functions, and when there are no suitable environmental or health alternatives. This effort is supported by the introduction of a Generic Approach to Risk Management (GARM) in conjunction with the Essential Use Concept (EUC).

These initiatives are interconnected and span various CSS activities with the aim of integrating the EUC across EU legislation, including but not limited to the REACH revision, cosmetics and toys legislation, impacting both broad and specific risk assessments. The approach to defining essential uses is inspired by the Montreal Protocol⁵⁵, albeit with a focus on a

wider array of chemicals beyond those impacting the ozone layer.

Assessment of Implementation

Implementation level

The implementation of the EUC action involved various consultation forums, including the REACH revision public consultation, workshops within the EC consultancy studies, targeted consultations on Authorisation and Restriction processes, stakeholder interviews and CARACAL meetings from December 2021 to Spring 2022⁵⁶. In April 2023, a comprehensive supporting study was published⁵⁷.

Despite the initial timeline aiming to present the essential use criteria by the end of 2022 and incorporate them into the proposed REACH regulation revision, the EUC proposal has not yet been launched.

⁵⁵ UN Environment Programme, Ozone Secretariat. Handbook for the Montreal Protocol on Substances that Deplete the Ozone Layer, UNEP, 2020. Available at: <https://ozone.unep.org/sites/default/files/Handbooks/MP-Handbook-2020-English.pdf>

⁵⁶ Wood E&IS GmbH, Ramboll, European Commission, Supporting the Commission in developing an essential use concept – Workshop report, Wood E&IS GmbH, April 2022. Available at:

<https://environment.ec.europa.eu/system/files/2022-05/Essential%20Use%20Workshop%20Report%20final.pdf>

⁵⁷ Kastalie Bougas, Kristina Flexman, et al., SUPPORTING THE COMMISSION IN DEVELOPING AN ESSENTIAL USE CONCEPT – Final Report, European Commission, March 2023. Available at: <https://op.europa.eu/en/publication-detail/-/publication/69d5ea0d-d359-11ed-a05c-01aa75ed71a1/language-en/format-PDF/source-283635189>

Stakeholder's views

Most stakeholders acknowledge that the CSS has effectively brought critical issues for the green transition to the forefront of the legislative programme, including the essential use concept. They agree that the CSS appropriately addresses the reduction of consumer exposure to hazardous substances by introducing concepts like the EUC and the GARM. However, many express concerns about the delayed implementation of the essential use concept, particularly due to delays in the REACH revision.

EEB's views

The principle is clear: consumer products should be free from the most harmful chemicals, with no exceptions deemed essential for society. However, if the GARM ensures the automatic removal of these chemicals, rare exceptions may be allowed under strict conditions, such as short transition periods. The concept of essential use must prioritise alternatives; where alternatives exist, no use of the most harmful chemicals can be deemed essential. This approach ensures hazardous chemicals are phased-out, benefiting companies offering safer alternatives.

A comprehensive study published in April 2023 aimed to further define EUC criteria for phasing-out harmful chemicals. As foreseen by the CSS, it proposed sub-options for integrating EUC within REACH reform and explored implementation across various EU legislations, including the Restriction of Hazardous Substances Directive, food contact materials legislation, the Cosmetic Products Regulation, the Taxonomy Regulation and the End-of-life Vehicles Directive.

However, concerns arise regarding the Essential Use Concept and its potential for counterproductive effects if poorly designed. Discussions on EUC have primarily focused on REACH rather than broader legislation, leading to a shift in priorities. There's a risk that EUC could lead to broad exemptions from GARM restrictions for entire product groups or industries. A workable opt-out mechanism is needed, not solely reliant on EUC.

Despite initial plans for its presentation by the end of 2022, the EUC proposal has been blocked at a political level for two years and has been downgraded from a Communication to mere guidance.

Cocktail Effects

CSS objectives and actions

ACTION	INDICATIVE TIMMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#30 Assess how best and introduce (a) mixture assessment factor(s) in Annex I of REACH.	2022	REACH legal proposal.	Legislative proposal not published. Commission launched study report and organised several workshops and (ad hoc) CARACAL meetings.	Options proposed by Commission could improve situation but did not fully account for combined effects of chemicals, therefore did not match CSS ambition. Furthermore, final level of ambition is unknown.
#31 Introduce or reinforce provisions to take account of the combination effects of chemicals in water, food contact materials, food additives, toys, detergents, cosmetics.	2022	Revision of the Priority Substances List in the Water Framework Directive, and of the Annexes to the EQSD and GWD Part of revision of the Food Contact Materials regulation Part of revision of the Food additives Commission Regulation Part of revision of the Toy Safety Directive Part of the revision of the Cosmetic Products Regulation.	Proposals published for Water Framework Directives and Toys Safety Regulation Not published for Food Contact Materials, Food additives, Regulation and Cosmetic Products Regulation.	Combination effects considered to some extent in revisions of Water Framework Directive and Toys Safety regulation. Level of ambition unknown. Legal proposals not published for revision of Food Contact Materials and Cosmetic Products regulations.

The Green Deal acknowledged the need to address the combined effects of pollutants, recognising that people and other living organisms are exposed daily to a wide array of chemicals from diverse sources. To tackle this, the Commission proposed addressing this cocktail effect of chemical mixtures in an integrated and more general way in risk assessments, a key action under the CSS:

- Account for the cocktail effects of chemicals when assessing risks from chemicals by assessing how best to introduce (a) mixture assessment factor(s) in Annex I of REACH [Action 30].

Furthermore, the CSS acknowledged that revising REACH alone would not be enough; efforts across various pieces of legislation were needed to fully account for combination effects,

due to the exposure to multiple chemicals from various sources:

- Introduce or reinforce provisions to take account of the combination effects of chemicals in water, food contact materials, food additives, toys, detergents, cosmetics [action 31].

Assessment of implementation

Implementation level

Mixture assessment factor in REACH [Action 30]

Despite several workshops organised by both member states and the Commission on the mixture assessment factor concept over the past years, the Commission has not published the intended legal proposal. With the revision of REACH not expected to be published under the current Commission's mandate, it is unclear if or when the proposal will be published. The introduction of the mixture assessment factor could potentially occur through a comitology procedure, that is, without the need to wait for REACH to be revised.

Implementation in other legislation [Action 31]

The Commission issued a proposal for revised EU Water Quality Standards in October 2022, amending the Water Framework Directive, the Groundwater Directive and the Environmental Quality Standards Directive. The Commission also published a proposal for the revision of the Toys Safety Regulation in July 2023, addressing cocktail effects to some extent. Legal proposals have not been published for the Food Contact Materials Regulation, Food Additives Regulation or Cosmetic Products Regulation.

Stakeholder's views

This subject was not mentioned in detail by stakeholders.

EEB's views

Exposure to numerous harmful chemicals from different sources daily is a well-known issue, with monitoring studies revealing the simultaneous presence of dozens to hundreds of these chemicals in both human and environmental samples⁵⁸. Despite this recognition⁵⁹, the current EU framework for chemicals legislation, including REACH, falls short in adequately addressing the combined exposure and effects of these chemicals. On the contrary, chemical safety assessments typically focus on single substances, neglecting the cumulative impact of exposure to multiple chemicals. This oversight leads to an underestimation of the risks associated of chemical exposure in both the REACH regulation and sectoral legislation.

The Commission's failure to publish proposals for implementing Mixture Assessment Factors in chemical safety assessments under REACH, the Food Contact Materials, Food Additives, and Cosmetics regulations perpetuates the underestimation of risks associated with the combined toxicity of exposure to multiple chemicals from various origins. Consequently, **citizens and the environment continue to be exposed to unhealthy levels of chemical cocktails, highlighting the urgent need for action.**

Some steps have been taken to address combination effects in other pieces of legislation. For instance, the Toys Safety Regulation proposal includes a provision to take account of any known additional hazards from combined exposure to different chemicals present in the toy. The European Parliament has adopted a further amendment to consider combined effects of chemicals in this revision. It remains to be seen how combination effects will be addressed after the inter-institutional negotiations.

The Commission issued a proposal for revised EU Water Quality Standards in October 2022, amending the Water Framework Directive, the Groundwater Directive and the Environmental

⁵⁸ CHEM Trust, CHEMICAL COCKTAILS The neglected threat of toxic mixtures and how to fix it, CHEM Trust, March 2022. Available at: [Chemical-cocktails CHEM Trust-report March-2022.pdf](#)

⁵⁹ Council of the European Union, COMBINATION EFFECTS OF CHEMICALS - Council conclusions, Council of the European Union, 23 December 2009. Available at: [Combination effects of chemicals, Council conclusions, 2009](#)

Quality Standards Directive. While most new pollutants were added as individual substances, the proposal did to some extent address combination effects of chemicals in natural waters. For example, the proposed directive includes measures such as introducing thresholds for groups of pollutants, such as PFAS and pesticides, in surface and groundwater. While these thresholds are a step forward, they do not fully protect against potent pesticides. Additionally, the directive mandates the use of effect-based methods to monitor estrogenic hormones. However, there is much room for improvement, particularly in adopting a more ambitious group approach (group threshold) for substances with a similar mode of action, such as certain insecticides, herbicides and antibiotics.

Overall, it can be concluded that the combination effects due to exposure to many chemicals from different sources in daily life are not accounted for in the proposals.

One Substance, One Assessment - OSOA

CSS objectives and actions

ACTION	INDICATIVE TIMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#46 Establishment of a 'One substance, one assessment' process to coordinate the hazard/risk assessment on chemicals across multiple pieces of chemical legislation, through the use of a single Public Authorities Coordination Tool, an expert group and a Commission coordination mechanism.	As of 2021.	Extend PACT's mandate to addressing for other legislation. Establish Expert group of MS, Commission Services and Agencies and internal coordination mechanism.	Legal proposal published. Expert group established.	CSS Ambition met.
#47 Horizontal proposal for reallocation of EU technical and scientific work on chemicals to the EU agencies, including work of the SCCS and SCHEER.	2022	Legal proposal.	Legal proposal published.	Process is ongoing and final level of ambition unknown.
# 48 Proposal for a founding regulation for the European Chemicals Agency.	2023	Legal proposal (new Regulation).	Legal proposal published.	Level of ambition unknown.
#50 Data will be made available in appropriate formats and tools – i.e. IUCLID and IPCHEM - to ensure interoperability.	As of 2022	Mapping of the relevant data sets to be made available in appropriate formats is ongoing. Initiate process that will progressively make the data available in appropriate formats.	Legal proposal published.	Process is ongoing and final level of ambition unknown.

CSS objectives and actions

ACTION	INDICATIVE TIMMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#53 Establishment of an open platform on chemicals.	2023	Data on chemicals held by COM and Agencies available through the platform.	Legal proposal published.	Comprehensive proposal covering data under 70 pieces of legislation; however, the implementation is yet to be seen.
#54 Establishment of an EU repository of human and environmental health-based limit values.	2022	EU repository of human and environmental health-based limit values.	Legal proposal published.	Proposal meets CSS ambition.
#55 Establish tools and practices to ensure that relevant academic data is easily and readily accessible for safety assessments and is suitable for regulatory purposes.	As of 2022.	A guidance setting on minimum requirements for consideration of academic data in regulatory assessments and a search guide to help assessors to fulfil requirements to consider all available data in regulatory assessment.	Proposal partly published.	Proposal does not ensure that relevant academic data is easily and readily accessible.

CSS objectives and actions

ACTION	INDICATIVE TIMMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#56 Proposals to allow EU and national authorities to commission testing and monitoring of substances as part of the regulatory framework.	2023	Legal proposal (together with 57).	Legal proposal published.	Proposal allows ECHA to commission testing. National authorities are not mentioned.
#57 Horizontal proposal to remove legislative obstacles for re-use of data, to streamline the data flow across legislation and to extend the open data and transparency principles from the EU food safety sector to other pieces of chemical legislation.	2023	Legal proposal (together with 56).	Legal proposal published.	Proposals improve current situation; however final implementation is unknown. Proposals do not provide full transparency and access to data.
#76 Establish an EU Chemical Early Warning and Action System.	2023	Discussion in the framework of the one substance, one assessment.	Legal proposal published.	Action step is not developed in proposal.
#77 Development of an indicator framework on chemicals.	2024	Develop set of indicators.	Dashboard with set of 25 key indicators published.	Needs more indicators to monitor use of substances of very high concern, like those polluting drinking water.

The 'One Substance, One Assessment' (OSOA) initiative aims to simplify, streamline and better coordinate the processes for evaluating hazards and risks of chemicals. The purpose is to improve consistency and quality of assessments across different legislative frameworks. This approach intends to optimise the use of data, expertise and resources, thereby reducing burdens on stakeholders and increasing their confidence in the scientific underpinning of these assessments. Moreover, OSOA seeks to expedite the decision-making process, making it more predictable.

To achieve this, the Commission proposed a coordination mechanism that involves setting up a new expert group comprising representatives from member states and EU agencies. This group's mission is to facilitate discussions and harmonise safety assessments across various legislative contexts. Additionally, the approach includes the development of a unified, openly accessible data portal on chemicals and an early warning and action system for emerging chemical risks.

Assessment of Implementation

Implementation level

The Commission's introduction of three legislative proposals in December 2023 marks a significant step forward in the CSS under the OSOA framework. These proposals are being scrutinised by the European Parliament and the Council. However, interinstitutional negotiations are not expected to start until the second half of 2025. Furthermore, given the setbacks in environmental policy ambitions in the current political climate, the final outcome of the legislative process remains to be seen.

Key components of the December 2023 legislative package include:

- **Extension of PACT for legislation beyond REACH and CLP** [Action 46]: This aims to broaden the Public Activities Coordination Tool (PACT) to include legislation outside the scope of REACH and CLP, enhancing transparency and coordination in regulatory processes;
- **Re-allocating tasks among EU agencies** [Action 47]: This proposes a restructuring of responsibilities among EU agencies to foster efficiency and effectiveness in chemical assessments;
- **Ensuring interoperability across data sets** [Action 50]: Focuses on standardising data formats and tools (such as IUCLID and IPCHEM) to facilitate data sharing and interoperability;
- **Establishing an open data platform on chemicals** [Action 53]: Aims to create a centralised platform for accessing chemical data, promoting transparency and accessibility;
- **Creating an EU repository of human and environmental health-based limit values** [Action 54]: This involves compiling a comprehensive database of limit values for human and environmental health;
- **Granting ECHA the mandate to commission testing and monitoring** [Action 56]: This would allow ECHA to

directly commission chemical testing and monitoring activities;

- **Streamlining data flows across legislation** [Action 57]: Aims to eliminate barriers to data reuse and facilitate smoother data exchange across different legal frameworks;
- **Establishing an early warning and action system** [Action 76]: Proposes the creation of a mechanism to promptly identify and act on emerging chemical threats.

To guide the implementation of OSOA, an expert group with representatives from the EU Commission, Agencies and member states was established in 2021. However, its role has been primarily in an advisory capacity in the development of OSOA, rather than coordinating the work on chemical assessments directly [part of Action 46].

Stakeholder's views

Most stakeholders mentioned the OSOA package as a positive aspect of the CSS. It was regarded as a significant advancement in streamlining the evaluation and risk assessment process.

EEB's views

The goal of the OSOA proposals is to overcome inefficiencies, inconsistencies and slow procedures within the current system by streamlining the hazard and risk assessment of chemicals across the body of EU legislation. Additionally, it seeks to enhance access to information through a common open data platform on chemicals and establish an early warning and action system for emerging chemical risks. If properly implemented, these proposals have the potential to significantly improve the protection of human and environmental health.

However, the proposal for a data regulation lacks precision with respect to the coverage of certain highly relevant data items (e.g. on enforcement, information on alternatives and substances in articles). **The early warning and action system for emerging chemical risks lacks a process for action by authorities following the identification and reporting of early warnings.** Other areas where the Commission should have shown more

ambition includes increasing transparency and access to data, promoting the uptake of academic data and ensuring that the most protective opinion prevails in case of divergent opinions between agencies. Furthermore, it is crucial for the Commission to allocate sufficient resources to ensure the proper implementation of these proposals. The Commission failed to publish the basic regulation for ECHA addressing the organisational and financial aspects of the new and existing tasks assigned to ECHA. Rather, the legislative proposals aimed at re-attribution of tasks add workload to the REACH Committees, thereby copying to other legislation REACH structures that have proven dysfunctional and will add to the bottlenecks of committee work.

Action plan on PFAS⁶⁰

CSS objectives and actions

ACTION	INDICATIVE TIMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#8 Introduce legal requirements on the presence of [...] PFAS [...] through the initiative on sustainable products.	2022	Legal proposal on maximum levels for certain PFAS substances in food.	Not proposed.	Not proposed.
#38 Proposal to restrict PFAS under REACH for all non-essential uses including in consumer products.	2022-2024	REACH restriction.	Proposal launched by five MS and opinion making process ongoing.	Launched proposal maintained a high level of ambition as foreseen in the CSS.
#39 Review of the annexes of the Environmental Quality Standards Directive and of the Groundwater Directive to add PFAS where possible as a group.	2022	Legal proposal for the revision of the Priority Substances List in the Water Framework Directive, and of the Annexes to the EQSD and GWD.	EQS and Groundwater directives have been reviewed to include 24 PFAS.	The ambition of the CSS has not been fully reached as the whole group of PFAS has not been included.
#41 Proposal to revise the legislation on industrial emissions and the European Pollutant Release and Transfer Register to address emissions and reporting of PFAS from industrial plants.	2022	Legal proposal for the revision of the Industrial Emissions Directive.	The proposals by the EC for the IED and the E-PRTR only included a very limited number of PFAS.	The revisions address emissions and reporting of PFAS but does not meet the CSS ambition as it doesn't cover all PFAS.

⁶⁰ European Commission, Staff Working Document on Poly- and perfluoroalkyl substances (PFAS), (SWD(2020) 249 final), European Commission, 2022. Available at: <https://circabc.europa.eu/ui/group/8ee3c69a-bccb-4f22-89ca-277e35de7c63/library/e94fa1f8-864f-421e-af20-b2b68f3a6335/details?download=true>

CSS objectives and actions

ACTION	INDICATIVE TIMMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#42 Proposal to address the emissions of PFAS from the waste stage including through the revision of the legislation on sewage sludge.	2023	Legal proposal for the revision of the Sewage Sludge Directive.	There is no ongoing revision of the sewage sludge policy.	An evaluation was finalised in 2023, but no revision has been announced.
#43 Proposals under the Stockholm Convention and the Basel Convention to address PFAS concerns at a global scale.	2023-2024	Discussion for inclusion of PFHxS in the Stockholm Convention.	PFHxS has been included under the Stockholm Convention. Proposals under Basel Convention are still pending.	CSS ambition has been partially met as PFHxS is included under the Stockholm Convention, however, proposals under Basel Convention are still pending.

The CSS recognised that PFAS, as a group, required special attention due to “the large number of cases of contamination of soil and water - including drinking water - in the EU and globally, the number of people affected with a full spectrum of illnesses and the related societal and economic costs”. To tackle this issue, the CSS had several objectives:

- Banning all PFAS as a group in fire-fighting foams and other non-essential uses, allowing their use only when deemed essential for society;
- Implementing a group-based approach to address PFAS concerns across various relevant pieces of legislation, including those on water, sustainable products, food, industrial emissions and waste;
- Engaging with international organisations and third countries to address PFAS concerns on a global scale through bilateral policy dialogues with third countries and participation in relevant international fora;
- Establishing an EU-wide approach and providing financial support through research and innovation programmes to identify and

develop innovative methodologies for remediating PFAS contamination in the environment and in products;

- Providing research and innovation funding for safe innovations to substitute PFAS under Horizon Europe.

The actions to achieve these goals were published as a Staff Working Document⁶¹ and included:

- **REACH restriction:** Proposal to restrict PFAS under REACH for all non-essential uses including in consumer products [action 38];
- **Water legislation:** Review of the annexes of the Environmental Quality Standards Directive and of the Groundwater Directive to add PFAS where possible as a group [action 39];
- **Horizontal Products legislation:** Introduce legal requirements on the presence of [...] PFAS [...] through the initiative on sustainable products [Action 8];

⁶¹ COMMISSION STAFF WORKING DOCUMENT Poly- and perfluoroalkyl substances (PFAS) Accompanying the document 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.
<https://op.europa.eu/en/publication-detail/-/publication/2614f1f2-0f02-11eb-bc07-01aa75ed71a1/language-en>

- **Industrial Emissions:** Proposal to revise the legislation on industrial emissions and the European Pollutant Release and Transfer Register to address emissions and reporting of PFAS from industrial plants [action 41];
- **Waste legislation:** Proposal to address the emissions of PFAS from the waste stage, including through the revision of legislation on sewage sludge [action 42];
- **International conventions:** Proposals under the Stockholm Convention and the Basel Convention to address PFAS concerns at a global scale [action 43].

Assessment of Implementation

Implementation level

REACH restrictions [action 38]

Since the publication of the CSS, three proposals for restricting PFAS under REACH have been presented. Germany prepared a proposal to ban PFHxA⁶² that has recently garnered support from the REACH Committee. ECHA, at the behest of the EC, has put forward a proposal to prohibit PFAS in firefighting foams⁶³, which is currently awaiting approval by the REACH Committee. Five member states have jointly proposed a comprehensive restriction on all PFAS⁶⁴ a proposal currently under assessment by ECHA's risk assessment and socio-economic analysis committees (RAC and SEAC).

Water legislation [action 39]

In response to the need for updated risk assessments, the European Food Safety Authority (EFSA) published a new risk assessment of PFAS in 2020, resulting in a revised tolerable weekly intake (TWI) for a group of four PFAS substances.

Building on this assessment, the EC proposed updates to the Water Framework Directive (WFD) and its associated directives, including Environmental Quality Standards Directive and the Groundwater Directive. These updates include adding 24 PFAS to the list of priority

substances in both surface water and groundwater laws, with a threshold of 4,4 ng/L expressed as PFOA equivalents.

As of the publication of this report, the Commission proposal has been supported by the European Parliament, while the Council is still discussing its position.

Additionally, PFAS were incorporated as a new parameter in the European Drinking Water Directive (EU) 2020/2184, offering member states two alternatives: "total PFAS" (covering perfluorinated and polyfluorinated alkyl substances) and the "sum of PFAS" (encompassing carboxylic and sulfonic acids with chain lengths from C4 to C13), each with corresponding concentration thresholds.

Horizontal Products legislation [Action 8]

The Sustainable Products Initiative (SPI) offered a potential avenue for addressing the phase-out of PFAS and other hazardous substances in articles and recycled materials. However, The Commission chose not to explicitly address PFAS in the framework of the SPI or the resulting proposal for an Ecodesign Regulation (ESPR). Instead, the draft ESPR regulation primarily focuses on basic transparency requirements for substances of concern, with specific regulatory requirements regarding such substances only addressed in delegated acts targeting individual product groups. Currently, there are no horizontal requirements on PFAS applicable across all product groups, with information requirements being explicitly regulated through the product passport introduced by the ESPR.

Additionally, no requirements on PFAS have been introduced in the General Product Safety Directive.

Industrial emissions [action 41]

The Commission published a proposal for the revision of the Industrial Emissions Directive and the E-PRTR, including emissions and reporting requirements only for PFHxA, PFOS and PFOA (see more details in IED section below).

⁶² ECHA, RoI Restriction of PFHxA and its salts.
<https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18323a25d>

⁶³ ECHA, RoI Restriction of PFAS in FFF
<https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1856e8ce6>

⁶⁴ ECHA, RoI Restriction of PFAS
<https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b>

Waste legislation [action 42]

The Commission proposed revising the Packaging and Packaging Waste Regulation (PPWR). Although it didn't initially include bans on PFAS, a ban on PFAS in food contact packaging was agreed upon during negotiations with the EP and the Council.

Regarding the proposal to address the emissions of PFAS from the waste stage, including through revision of legislation on sewage sludge, an evaluation was finalised in 2023 as part of the revision of the Urban Waste Water Treatment Directive, but no revision has been announced.

International Conventions [action 43]

The parties to the Stockholm Convention decided to include PFHxS, its salts and related compounds in the treaty in 2022. The Commission added this group of PFAS to the POPs Regulation in 2023.⁶⁵

Additionally, long-chain perfluorinated carboxylic acids (C9-21 PFCAs) are being considered for inclusion in the Stockholm Convention.

Stakeholders' views

Stakeholders welcomed the efforts to present the PFAS group restriction and to identify steps to promote safe and sustainable chemicals, especially concerning problematic substances like PFAS. The CSS played a crucial role in shedding light on the PFAS issue, initiating research programs and devising plans to tackle poorly regulated chemicals, exemplified by the publication of the PFAS action plan outlining significant actions to address PFAS problems.

While important progress has been made with proposals to restrict all PFAS put forward by some member states, the so-called universal PFAS (uPFAS) restriction, much work remains. Stakeholders generally agreed that a universal PFAS restriction would greatly improve the situation, though some advocated for a step-by-

step approach, targeting specific uses initially. Concerns were also raised about the potential burden of documentation associated with the PFAS restriction, particularly for SMEs.

In addition to the uPFAS restriction, stakeholders emphasised the need to control PFAS pollution at its source and address historic contamination, remediation and the implementation of the precautionary principle. Concerns were raised about the delay in implementing the PFAS action plan's commitment to funding research and innovation for safe PFAS substitutes under Horizon Europe.

Positive responses were received for actions on PFAS under the Industrial Emissions Directive (IED), the Water Framework Directive (WFD) and the prohibition of PFAS in the Packaging and Packaging Waste Directive (PPWR). However, many sources of contamination remain unaddressed.

Overall, stakeholders acknowledged that while some measures have been taken and others are planned in the short term to advance the addressing of PFAS pollution, the situation remains deeply concerning, especially due to the delay in the revision of REACH. Many shared deep concerns about PFAS pollution scandals arising in Europe and fear that the Commission's commitment to tackle the PFAS issue will be insufficient.

EEB's views

The EEB welcomes the three **REACH restriction proposals** that have been presented, namely PFHxA, PFAS in FFF and universal-PFAS. While the ban on PFHxA in consumer articles is a very positive step, concerns arise over the decision by the EC to reduce the original scope proposed by Germany, which covered industrial applications and fire-fighting foams, potentially diminishing the overall effectiveness of the restriction, and may set a worrying precedent. Similarly, **the general restriction of PFAS proposed by five member states is promising, due to its wide scope and time-limited derogations.** However,

⁶⁵ European Commission, Commission Delegated Regulation (EU) 2023/1608 of 30 May 2023 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorohexane sulfonic

acid (PFHxS), its salts and PFHxS-related compounds (C/2023/3387), European Commission, May 2023. Available at: https://eur-lex.europa.eu/eli/reg_del/2023/1608/oj

excluding pesticide and biocide active substances, which are not covered in other regulations, raises concerns about potential significant gaps.

The EEB is particularly concerned about prolonged delays by the EC in presenting restriction decision proposals to the REACH Committee, surpassing legal deadlines, as seen with PFHxA and PFAS in FFF draft decisions. Such delays undermine the effectiveness of these policy initiatives. We urge the EC to expedite its decision-making process, given the urgency of addressing PFAS contamination and its associated risks.

Furthermore, while the inclusion of 24 PFAS in the updated lists of surface and groundwater pollutants under the **Water Framework Directive** is acknowledged, it is clearly insufficient, given the estimated 10,000+ substances within the PFAS group. A more comprehensive approach, such as establishing a limit value for "total PFAS", is required.

Additionally, integrating findings and data from marine environments, as mandated by the **Marine Strategy Framework Directive**, is essential given the interconnectedness of surface water and marine ecosystems. This integration will ensure a more holistic assessment of PFAS contamination and its impacts on aquatic environments.

The absence of specific regulatory measures within the **Ecodesign Regulation (ESPR)** to enforce a comprehensive ban on PFAS in everyday products represents a notable missed opportunity, particularly as it was promised within the CSS. As stakeholders, we eagerly await further developments to determine if the European Commission will propose a ban on PFAS in specific product categories.

Similarly, the omission of the full list of PFAS in the revision of emissions and reporting requirements of the **Industrial Emissions Directive (IED)** and the European Pollutant Release and Transfer Register (E-PRTR) represents another missed opportunity.

Endocrine disruptors

CSS objectives and actions

ACTION	INDICATIVE TIMMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#20 Roadmap to prioritise [...] endocrine disruptors [...] for (group) restrictions under REACH.	2021	REACH Legal proposal.	The roadmap has been published.	The published roadmap does not match the ambition of the CSS, regarding the scope or timelines. All ED restriction proposals are delayed, including the restriction of bisphenols and phthalates.
#21 Proposals to extend the generic approach to risk management to ensure that consumer products do not contain [...] EDs [...].	2022	REACH Legal proposal.	Not launched. Drafts with options for the reform of REACH restriction process including Art 68.2 were presented by the EC for discussion at CARACAL.	The drafts with options presented by the EC to CARACAL didn't match the ambition of the CSS to ban EDs in consumer products and for professional uses.
	2023	Food contact materials regulation legal proposal.	The legal proposal for the revision of the FCM regulation is not published, however. However, a legal restriction proposal to ban BPA and other bisphenols with harmonised classification has been presented.	The proposal addresses only bisphenols, therefore its level of ambition is far from the CSS commitment to ban ED in FCM.
	2022	Cosmetic Products Regulation legal proposal.	Legal proposal not published.	Final level of ambition unknown.
	2022	Toy Safety Directive legal proposal.	The EC presented a legal proposal.	The proposal includes banning EDs in toys.

CSS objectives and actions

ACTION	INDICATIVE TIMMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
<p>#27</p> <p>Proposal to amend the CLP Regulation to introduce new hazard classes on endocrine disruptors, [...] and apply them across all legislation.</p>	2022	CLP legal proposal.	Fully implemented. The EC presented a proposal that was agreed.	The inclusion of EDs under CLP matches the CSS ambition.
<p>#28</p> <p>Update information requirements to allow the identification of endocrine disruptors in relevant legislation, particularly under REACH, legislation on cosmetic products, food contact materials, plant protection products and biocidal products.</p>	2022	<p>REACH legal proposal. Delegate Regulation amending Annex II and III to the Biocidal Products Regulation. Amendment of Communications 2013/C 95/01 and 2013/C 95/02 accompanying the Regulation on data requirements for active substances and Plant Protection Products. Part of the revision of the Food Contact Materials Regulation.</p>	<p>REACH: Although an expert subgroup of CARACAL advanced discussions on the topic, no legal proposal has been presented.</p> <p>Legal proposals not published for Food Contact Materials and Cosmetics regulations.</p>	<p>Options proposed by the Commission will improve the situation but did not allow for proper identification of EDs and therefore did not match the CSS ambition. Final level of ambition unknown.</p>

CSS objectives and actions

ACTION	INDICATIVE TIMMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#29 Accelerate the development and uptake of methods to generate information on endocrine disruptors through screening and testing of substances.	As of 2021.	Joint Research Centre validation study, related to the revision of information requirements under REACH and CLP Revision to include ED hazard criteria.	JRC published a validation study in 2023, including in vitro studies on thyroid activity, awaiting implementation at OECD for uptake.	Methods for thyroid activity have been validated but further work is needed on other endpoints.
#33 Proposal to amend REACH Article 57 to add endocrine disruptors, [...] to the list of substances of very high concern.	2022	REACH legal proposal.	Not launched.	No proposal presented. Final level of ambition unknown.

In the Strategy, the Commission acknowledged that the exposure of humans and the environment to endocrine-disrupting chemicals required specific attention. It explained that EDs are increasingly linked to diseases acting via the hormonal system, representing a serious risk to human health and wildlife as well as creating an economic cost for society. The Strategy also mentioned that although some pieces of legislation were able to identify EDs, the EU regulatory system is overall fragmented, limited and needs to be consolidated and simplified.

The Commission conducted a Fitness Check on EU regulatory measures that address the risks from exposure to endocrine disruptors⁶⁶, which was published as an annex to the CSS. The fitness check identifies several areas for improvement, including the limitations of current data requirements to identify EDs; the inconsistent use of generic and specific risk approaches; and the need for a horizontal approach to systematically assess and manage

the risks from aggregate exposure to the same EDs across different sectors and combined exposures to different EDs. It also notes provisions and regulatory processes for identifying and managing endocrine disruptors within various frameworks, including REACH, CLP, Biocidal Products, POPs, Toys, Food legislation, Cosmetic Products or Water.

The CSS commitments regarding endocrine disruptors include:

- Establishing legally binding hazard identification criteria for endocrine disruptors under CLP and applying it across all related legislation (action 27);
- Ensuring that endocrine disruptors are banned from consumer products as soon as they are identified, with exceptions only when their use is proven essential for society (actions 20 and 21);
- Strengthening workers protection by categorising endocrine disruptors as

⁶⁶ European Commission. Staff Working Document on the Fitness Check on endocrine disruptors. EC, October 2020. Available at : <https://circabc.europa.eu/ui/group/8ee3c69a->

[bccb-4f22-89ca-277e35de7c63/library/c4ff1905-5724-4c59-9dc6-3d33640a71f2/details?download=true](https://circabc.europa.eu/ui/group/8ee3c69a-bccb-4f22-89ca-277e35de7c63/library/c4ff1905-5724-4c59-9dc6-3d33640a71f2/details?download=true)

substances of very high concern under REACH (Action 33);

- Ensuring that sufficient and appropriate information is made available to authorities to facilitate the identification of endocrine disruptors by reviewing and strengthening information requirements across legislation (action 28);
- accelerating the development and adoption of methods for generating information on endocrine disruptors through screening and testing of substances (action 29).

Assessment of Implementation

Implementation level

The Commission has successfully included endocrine disruptors as a new hazard category for human health and the environment under the CLP (action 27), as described under the CLP chapter above.

The proposal to ban endocrine disruptors from consumer products by extending the generic approach to risk management under REACH, the Food Contact Materials (FCM) Regulation, the Cosmetic Products Regulation and the Toy Safety Directive (action 21) has so far only been advanced for toys⁶⁷. The FCM proposal only covers BPA and other bisphenols with ED classification⁶⁸.

Furthermore, the Commission and member states have developed plans to ban several endocrine disruptors in consumer products, as outlined in the Restrictions Roadmap. This includes bisphenols, flame retardants, phthalates and others. However, all these proposals are delayed, with many lacking timelines (action 20).

A CARACAL subgroup on EDs has been established by the Commission, which has convened meetings to explore options for updating information requirements. Despite

these discussions, no proposals have yet been advanced to update the REACH annexes.

In terms of research, the Commission has funded the EURION cluster, with eight research projects aimed at developing new testing and screening methods for identifying endocrine disrupting chemicals. The results of these projects are scheduled to be presented at a final conference in June in Brussels⁶⁹ (action 29).

Progress on other actions remains on hold pending the introduction of new information requirements under the REACH revision (action 27).

Additionally, the proposed revision of the Water Framework Directive includes provisions to address the cocktail effects of certain endocrine disruptors found in the aquatic environment via so-called effect-based monitoring.

Stakeholder's views

Overall, stakeholders regret the unfulfilled commitments on endocrine disruption. They specifically note the lack of progress in implementing expected changes to identify EDs within the revision of REACH, the Biocides Regulation, the FCM Regulation and the Cosmetics Regulation.

Despite these shortcomings, stakeholders welcome the inclusion of a ban on EDs in the Toys Safety Directive, the inclusion of hazard classes for EDs under the CLP Regulation and the proposal for banning BPA and other bisphenols in FCM. However, some stakeholders have raised concerns regarding the suitability of the adopted generic concentration limits set for triggering classification of mixtures, particularly for non-threshold substances and those having adverse effects at very low concentrations. These concerns highlight a critical area where the current regulatory framework may not

⁶⁷ European Commission. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the safety of toys and repealing Directive 2009/48/EC.

[https://www.europarl.europa.eu/RegData/docs_autres_institutions/commission_europeenne/com/2023/0462/COM_COM\(2023\)0462_EN.pdf](https://www.europarl.europa.eu/RegData/docs_autres_institutions/commission_europeenne/com/2023/0462/COM_COM(2023)0462_EN.pdf)

⁶⁸ European Commission. Food safety – restrictions on bisphenol A (BPA) and other bisphenols in food contact

materials https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13832-Food-safety-restrictions-on-bisphenol-A-BPA-and-other-bisphenols-in-food-contact-materials_en

⁶⁹ EURION - European Cluster to improve identification of endocrine disruptors, event webpage available here: <https://eurion-cluster.eu/event/eurion-cluster-final-event/>

adequately protect against the unique risks posed by endocrine disruptors.

EEB's views

The CSS has not delivered its promise to protect both people and the environment from the serious risks posed by endocrine disruptors. Although the inclusion of endocrine disruption for human health and wildlife as hazard classes under CLP marks notable progress, critical gaps remain. Key information requirements essential for identifying endocrine disruptors have yet to be integrated into REACH. Additionally, necessary provisions for the regulation of EDs have not been fully implemented in legislation concerning cosmetic products, food contact materials, plant protection products and biocidal products. These omissions continue to delay much-needed regulatory actions to address these chemicals.

Although the inclusion of endocrine disruption for human health and wildlife as hazard classes under CLP marks notable progresss [...] Key information requirements essential for identifying endocrine disruptors have yet to be integrated into REACH.

Export ban

CSS objectives and actions

ACTION	INDICATIVE TIMMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#84 Ensure that hazardous chemicals banned in the European Union are not produced for export including by amending relevant legislation if and as needed.	2023	Legal proposal.	A study was commissioned, and a public consultation was launched, but a legislative proposal has not been presented.	As no proposal has been presented, EC didn't meet the CSS ambition.

One of the primary objectives of the CSS was to serve as a role model for the sound management of chemicals globally. As part of this endeavour, the EC committed to “lead by example, and, in line with international commitments, ensure that hazardous chemicals banned in the European Union are not produced for export, including by amending relevant legislation if and as needed.”

Despite this commitment, chemicals that are banned or not authorised in the EU are still allowed to being manufactured for export. This practice means that chemicals known and proven to pose risks to human health and the environment in Europe, such as highly hazardous pesticides, are being exported to regions lacking the capacity to understand and mitigate their dangers, primarily in the Global South⁷⁰. **Halting the export of banned chemicals would not only align with the EU's international obligations under the Basel Convention but also with its international human rights obligations.**

To address this issue, the Commission initiated a public consultation⁷¹ and commissioned a study to assess the impacts of implementing an export ban, alongside exploring potential legislative avenues to enact such measures. Concurrently, the EC launched an impact assessment of the Prior Informed Consent (PIC) Regulation, with the intent to inform the development of a legal proposal. Additionally, ECHA published a report on the operation of PIC, offering recommendations for improvement⁷².

Unfortunately, progress on these initiatives stalled in 2023, together with the revision of REACH, and no legal proposal has been presented to date.

EEB's views

The CSS has failed to fulfil its commitment to safeguard people and the environment from the grave risks associated with hazardous chemicals banned within the EU. Considering the significant impacts caused by these chemicals, particularly in regions like the Global South, we call on the EC to take decisive action and introduce a legislative proposal without further delay.

⁷⁰ Pesticide Action Network Europe, Joint Statement: NGOs and Trade Unions demand the end of EU's export of banned pesticides and other hazardous chemicals, Pesticide Action Network Europe, 1 December 2022. Available at: <https://www.pan-europe.info/resources/letters/2022/12/joint-statement-ngos-and-trade-unions-demand-end-eu%E2%80%99s-export-banned>

⁷¹ European Commission, Public consultation webpage, Hazardous chemicals – prohibiting production for export of chemicals banned in the European Union, European Commission. Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13750-Hazardous-chemicals-prohibiting-production-for-export-of-chemicals-banned-in-the-European-Union_en

⁷² ECHA, Report on the operation of the Prior Informed Consent (PIC) Regulation 2023, ECHA, October 2023. Available at: https://echa.europa.eu/documents/10162/18272234/report_pic_art_22_2023_en.pdf/4175e2cc-be0a-ffc4-8406-598abc3212a8

Other related areas

As outlined by the Commission, the Strategy was meant to contribute to Europe's zero pollution ambition and complement other strategies, including the European Industrial Strategy, the Circular Economy Action Plan and other European Green Deal initiatives. This synergy was intended to collectively address overarching objectives related to industrial emissions, water management and contamination, and the circular economy, among other priorities.

- Industrial Emissions Directive⁷³ and the E-PRTR⁷⁴

CSS objectives and actions

ACTION	INDICATIVE TIMMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#7 Make amendments to EU legislation on industrial emissions to promote the use of safer chemicals by EU industry.	2022	Industrial Emissions Directive legal proposal.	The IED and the E-PRTR revisions are close to be adopted in trilogue.	The IED includes new provisions to promote safer chemicals, but its effectiveness is unclear and will largely depend on the BREF process and its implementation.
#41 Proposal to revise the legislation on industrial emissions and the European Pollutant Release and Transfer Register to address emissions and reporting of PFAS from industrial plants.	2022	Industrial Emissions Directive legal proposal.	The proposals by the EC for the IED and the E-PRTR only included a very limited number of PFAS.	While the inclusion of the whole PFAS list was proposed by the Parliament, only already highly regulated substances where included (PFOS and PFOA).

The CSS was expected to contribute to the zero-pollution ambition through the Zero Pollution Action Plan⁷⁵ and complement the European Industrial Strategy⁷⁶. In pursuit of this goal, the

Commission integrated several actions into the Industrial Emissions Directive (IED) to promote safe and sustainable-by-design chemicals. Action 7, specifically related to chemicals, called

⁷³ European Commission, Proposal for a Directive on industrial emissions (integrated pollution prevention and control) (COM/2022/156 final), European Commission, 2022. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0156&%3Bqid=1710420279575>

⁷⁴ European Commission, Proposal for a Regulation on reporting of environmental data from industrial installations and establishing an Industrial Emissions Portal (COM/2022/157 final), European Commission, 2022. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0157>

⁷⁵ European Commission, Communication on the Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil' (COM/2021/400 final), European Commission, 2021. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021DC0400&qid=1623311742827>

⁷⁶ European Commission, Communication on A New Industrial Strategy for Europe (COM/2020/102 final), European Commission, 2020. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0102>

for the revision of the IED to encourage industry in the EU to use safer chemicals by requiring on-site risk assessments and by restricting the use of substances of very high concern. To this end, the action plan of the Strategy included the establishment of key performance indicators (KPIs) to measure the industrial transition toward the production of safe and sustainable chemicals.

As part of an overarching strategy to address the use and contamination of PFAS, action 41, focused on utilising a group approach to restrict PFAS under the IED and the European Pollutant Release and Transfer Register (EPRTTR). This initiative aimed to regulate emissions and reporting of PFAS from industrial plants.

Assessment of Implementation

Implementation level

The implementation of the revised IED includes significant steps towards integrating measures related to chemicals [Action 7]. It aligns with the goals of the CSS and acknowledges the need to ensure a climate-neutral, clean and circular economy by 2050; optimise resource management and energy efficiency; and minimise pollution.

Article 13 of the revised IED formalises the involvement of ECHA in the preparation of Best Available Techniques (BAT) Reference Documents (BREFs), enhancing synergies between ECHA's work on chemicals and on the elaboration of BREFs. ECHA should also assist IED installation operators with guidance in conducting site-level risk assessment; identifying relevant substances for each sector covered by BREFs, ensuring the use of correct terminology, validating chemicals-related BATs and facilitating access to ECHA's database.

The revised IED also introduces provisions, such as article 14a, requiring the creation of a chemicals inventory, risk assessment of hazardous substances, and an analysis of substitution possibilities within the

Environmental Management System (EMS) of industrial installations.

Furthermore, the IED revision proposal incorporated new reporting requirements for perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) in the European Pollutant Release and Transfer Register. While the Impact Assessment⁷⁷ for the revision offered an opportunity to expand PFAS reporting beyond PFOA and PFOS, this was not included in the Commission's final text.

A provisional agreement on the revised IED was reached in November 2023, with subsequent endorsement by the ENVI Committee and formal adoption by Parliament in March 2024. The final text is expected to be adopted.

Stakeholder's views

Stakeholders generally expressed positive views regarding the revision of the IED, particularly the establishment of an inventory of hazardous substances. They appreciated the synergies created between the IED and REACH, which encourages substitution and allows REACH outputs to inform IED BREF processes. Stakeholders recognised the potential for REACH data to raise awareness and improve management of hazardous substances at industrial sites. However, some stakeholders suggested that further synergies between REACH and the IED could have been explored to enable more effective regulation of hazardous substances at site level.

Stakeholders welcomed the inclusion of PFAS in the IED. However, they expressed regret that the full list of PFAS was not included in the final text, viewing it as a missed opportunity that should be addressed in future revisions.

EEB's views

In our view, the provisions concerning the control and substitution of hazardous chemicals have indeed been strengthened, particularly with the requirement for substitution analysis for

⁷⁷ European Commission, Staff Working Document impact assessment report Accompanying the documents Proposal for a DIRECTIVE on industrial emissions (integrated pollution prevention and control) and Regulation on reporting of environmental data from industrial installations and

establishing an Industrial Emissions Portal, (SWD(2022) 111 final), European Commission, 2022. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022SC0111&%3Bqid=1710420235405>

hazardous substances used and produced, as outlined in article 14a. The obligation on permit writers to consider the hazardousness of pollutants in permitting, as well as the protection of water catchment areas, represent positive steps forward. Additionally, we welcome the enhanced maintenance and surveillance measures, along with the formalisation of ECHA's role in the BREF process.

However, we note that the objective of promoting the use of safer chemicals has not been sufficiently achieved, as the actual restrictions will depend on the outcomes of the BREFs currently under review. Concrete performance indicators were lacking in the Strategy to give meaning to the concept of safe and sustainable chemicals, specially within the BREF context. This gap could be addressed through upcoming benchmarks and BREF guidance.

In terms of synergies between chemicals legislation with the IED and EPRTR, we have also identified shortcomings in data integration for better screening of chemical uses (e.g. sector of use, exposure scenarios to feed into the pollution control legislation, etc). Integrating data generated via the IED and substitution analysis on all hazardous substances into REACH would have provided significant added value. However, the main approach for collecting BREF data, namely the questionnaire, may not be appropriate for this type of information. Thus, we recommend adapting the ECHA database to better accommodate BREF-related data needs.⁷⁸ Regarding the objective of tackling PFAS under the IED and E-PRTR, the Commission's proposal is very weak as only PFOS and PFOA will be included in Annex II. Although the European Parliament introduced the full list of PFAS in its trialogue position, it was not included in the final proposal. **Including the full list of PFAS in the**

legal text would have mandated monitoring requirements for all major industrial activities emitting to water, air and soil, and would have automatically obliged permit writers to set emission limits for the entire PFAS group.

Currently, only PFOS and PFOA will be included in Annex II of polluting substances of relevance to water and air, by 2026, following a revision instigated by the EC. This annex significantly influences permitting and emission limit values for polluting substances under the IED (Art. 14.1.a) and E-PRTR reporting obligations. However, since PFOS and PFOA are highly regulated substances already⁷⁹, we believe there will be very little added value to their inclusion in Annex II.⁸⁰ Therefore, we consider that action 41 has not been achieved to its full extent.

⁷⁸ European Environmental Bureau (EEB), Proposals for an EU BREF Process fit for the 2050 goals of climate neutrality, zero pollution and circular economy, EEB 23 February 2024. Available at: https://eipie.eu/wp-content/uploads/2024/03/EEB-proposals-for-the-BREF-process-reform_23Feb2024-1.pdf

⁷⁹ UN Environmental Programme, STOCKHOLM CONVENTION ON PERSISTENT ORGANIC POLLUTANTS (POPS), revised version, UNEP, 2019. Available at:

<file:///C:/Users/olatz.finez/Downloads/UNEP-POPS-COP-CONVTEXT-2021.English.pdf>

⁸⁰ EEB, Revised Industrial Emissions Directive and Regulation Establishing the Industrial Emissions Portal: outcomes and opportunities, EEB, April 2024. Available at: <https://eeb.org/library/revised-industrial-emissions-directive-and-regulation-establishing-the-industrial-emissions-portal-outcomes-and-opportunities/>

- Water

CSS objectives and actions

ACTION	INDICATIVE TIMMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#31 Introduce or reinforce provisions to take account of the combination effects of chemicals in water, [...].	2022	Legal proposal on the revision of the Priority Substances List in the Water Framework Directive, and of the annexes to the EQSD and GWD (among others).	The adoption of the revised WFD is ongoing and a Council opinion expected very soon.	The proposal improves the situation but does not fully address the effects of chemical cocktails.
#39 Review of the annexes of the Environmental Quality Standards Directive and of the Groundwater Directive to add PFAS where possible as a group.	2022	Legal proposal on the revision of the Priority Substances List in the Water Framework Directive, and of the Annexes to the EQSD and GWD.	The adoption of the revised WFD is ongoing and includes the list of 24 PFAS.	The proposal has acknowledged the issue but has failed in including the full list of PFAS.

As mentioned in the Cocktail effects section, the CSS recognised the importance of considering the effects of chemical mixtures and integrating them into chemical risk assessments more comprehensively. As part of this recognition, provisions were intended to be introduced or reinforced to account for the combination effects of chemicals in other relevant legislation, including water-related legislation.

In alignment with this approach, the CSS acknowledged the need for special attention to PFAS due to numerous cases of contamination of soil and water, including drinking water, both within the EU and globally. Thus, the Commission aimed to address PFAS using a group approach

under relevant legislation to water, among other areas. Specifically, the revision of the Groundwater Directive was highlighted to address chemical pollution regarding PFAS.

Assessment of Implementation

Implementation level

The Commission presented its proposal for revised EU Water Quality Standards (EQS) in October 2022, encompassing amendments to the Water Framework Directive, the Groundwater Directive and the Environmental Quality Standards Directive⁸¹. Notably, a group of 24 PFAS was added to the list of priority substances,

⁸¹ European Commission, Proposal for a Directive amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration

and Directive 2008/105/EC on environmental quality standards in the field of water policy (COM(2022) 540 final), European Commission, 2022. Available at:

highlighting their significance as critical pollutants for surface water. This implies that member states are mandated to monitor the presence of these substances in surface water and ensure that their associated environmental quality standards are not surpassed. However, it is important to note that most of the new pollutants were added as individual substances.

At the time of publication of this report, the Commission's proposed thresholds for PFAS in surface and groundwater have been adopted by the European Parliament, while the Council is still deliberating its position.

Stakeholder's views

This subject was not mentioned in detail by stakeholders.

EEB's views

As mentioned in the Cocktail effects chapter above, **while the proposal included some positive steps to address the combination effects of chemicals in natural waters, such as the establishment of a threshold for a group of 24 PFAS, we believe it falls short in fully addressing the complexities of chemical cocktails.**⁸² By primarily adding pollutants as individual substances, there's a risk of the lists becoming outdated quickly, while many substances of concern for aquatic life remain unlisted as priority substances. To effectively tackle this issue, we advocate for mixture assessments, including broad chemical screening at water body level, to identify hotspots and implement targeted measures to abate pollution at source.

We regret the Commission's decision not to go further with a group approach, particularly in establishing group thresholds for substances with similar modes of action, such as neonicotinoids, pyrethroid insecticides, photosynthesis-inhibiting herbicides, estrogenic hormones and macrolide antibiotics, to adequately account for their combined effects.

https://environment.ec.europa.eu/document/download/6e618dec-c528-4ba8-8900-1e020eefe393_en?filename=Proposal%20for%20a%20Directive%20amending%20the%20Water%20Framework%20Directive%2C%20the%20Groundwater%20Directive%20and%20the%20Environmental%20Quality%20Standards%20Directive.pdf

We believe that the effectiveness of the Commission proposal hinges on the outcome of the Council position and subsequent trilogue negotiations.

⁸² EEB, Surfrider Foundation Europe, HCWH Europe et al., Joint NGO analysis of the European Commission's proposal for revised list of priority substances for surface and groundwater, EEB, 2022. Available at: <https://eeb.org/wp-content/uploads/2022/12/Joint-NGO-analysis-lists-substances.pdf>

- Circular Economy

CSS objectives and actions

ACTION	INDICATIVE TIMMING	DELIVERABLES	LEVEL OF IMPLEMENTATION	LEVEL OF AMBITION
#7 Introduce legal requirements on the presence of substances of concern in products, including PFAS, through the initiative on sustainable products.	2022	Part of upcoming Sustainable Products initiative (revision of the Ecodesign Directive).	Although the Ecodesign Directive is close to being formally adopted, it did not fully tackle the aim and promised actions of CSS, including on PFAS.	There have been positive steps taken for SoC, transparency and traceability, but the actions have fallen short of achieving truly toxic free products and banning PFAS in specific product categories.

The CSS underscores the importance of promoting and mainstreaming the sound management of chemicals throughout their lifecycle as essential elements for sustainable development, aligning with the transition to a toxic-free and circular economy. Policy coherence for development is also highlighted as crucial in this endeavour.

Specifically, the Circular Economy Action Plan (CEAP) is referenced in the CSS, emphasising the importance of tackling chemical pollution both upstream and downstream. Upstream actions focus on ensuring that products are safe and sustainable-by-design, while downstream efforts aim to enhance the safety and trustworthiness of recycled materials and products.

The CEAP outlines various legislative proposals to establish sustainability principles and regulate certain aspects, particularly addressing the presence of hazardous chemicals in products. It seeks to foster circularity within a toxic-free environment, aligning with the CSS, and encourage the transition to 'safe-by-design chemicals' through progressive substitution of hazardous substances. It also acknowledges the compromised safety of secondary raw materials, where hazardous or even banned chemicals persist in recycled feedstock. Another key measure mentioned in the CEAP is the improvement of classification and management

of hazardous waste to maintain clean recycling streams, including through further alignment with the classification of chemical substances and mixtures where necessary. Lastly, the CEAP also addresses challenges related to the presence of hazardous chemicals in specific sectors, such as textiles, primarily through Ecodesign and the Sustainable Products Framework. It also entails a commitment to co-operate with industry to progressively develop harmonised systems to track and manage information on chemicals in products.

The main legislative tool proposed to achieve these objectives is the Ecodesign for Sustainable Products Regulation (ESPR).

Furthermore, the Packaging and Packaging Waste Regulation (PPWR) and the Green Claims Directive are also relevant for advancing the CSS goals. The PPWR, for instance, can contribute to non-toxic material cycles and minimising the presence of substances of concern in products, including packaging. Meanwhile, initiatives under the Sustainable Product Policy Initiative aim to ensure the availability of information on substances of concern throughout the lifecycle of materials and products, aligning with the objectives outlined in the CSS.

Assessment of Implementation

Implementation level

Ecodesign for Sustainable Products Regulation (ESPR):

The Commission's proposal for the ESPR, announced in March 2022, includes provisions related to chemicals, such as minimum requirements for different products groups and the introduction of a Digital Product Passport (DPP) to trace substances of concern along supply chains. The proposal also includes market surveillance measures for online marketplaces.

In Parliament, the Committee on the Environment, Public Health and Food Safety (ENVI) voted on a draft report in June 2023, introducing new provisions for the Commission's working plan of product groups, for which it would establish Ecodesign requirements for 2024-2027, and a public online platform allowing consumers to compare information included in the product passports.

The Council adopted its general approach in May 2023, and a provisional agreement was reached in December 2023, pending formal approval.

Packaging and Packaging Waste Regulation (PPWR):

The Commission published a proposal for the revision of Packaging and Packaging Waste Directive in November 2022, which would apply to all packaging and packaging waste.

ENVI adopted its report in October 2023, which includes a prohibition on food contact packaging containing PFAS. Both Parliament and Council adopted their negotiating positions, and provisional agreement was reached in March 2024, pending a plenary vote. Despite the provisional agreement maintaining the ban on PFAS in food contact packaging, the ban on Bisphenol A was removed.

Green Claims Directive (GCD):

The Commission's proposal for a directive on substantiation and communication of explicit environmental claims, the Green Claims Directive, was introduced in March 2023. It aims

to ensure that environmental claims made by companies on their products are reliable, comparable, and verifiable throughout the EU for consumers. The Directive requires companies to substantiate any voluntary green claims they make in business-to-consumer commercial practices, by complying with a number of assessment requirements, such as considering a product's lifecycle.

Although the Commission's proposal did not explicitly address hazardous substances, the responsible committees in Parliament (IMCO and ENVI) have recognised the importance of investigating this issue. As part of the proposal, the Commission would be required to provide a report on the use of explicit environmental claims on products or product groups containing certain hazardous substances or mixtures within one year.

Currently, the proposal is under consideration by the co-legislators. In Parliament, the file has been jointly allocated to IMCO⁸³ and ENVI committees, and their joint report was adopted by the Parliament in March 2024. Discussions on the proposal have also taken place in the Council, specifically within the Working Party on the Environment and the Working Party on Consumer Protection and Information.

Stakeholder's views

This subject was not mentioned in detail by stakeholders.

EEB's views

Ecodesign for Sustainable Products Regulation (ESPR):

The provisional agreement on the ESPR primarily focuses on restricting chemicals based on their potential to hamper recycling, increase costs, have adverse environmental impacts, or demand excessive energy or resources. This is at odds with the CSS commitment towards toxic-free products. The Commission's promised action on PFAS was not delivered either. However, there are some positive aspects to the agreement, such as the potential to restrict chemicals based on their impact on human health or the environment.

⁸³ European Parliament's Committee on Internal Market and Consumer Protection

Additionally, the introduction of a definition of substances of concern, particularly the inclusion of Persistent Organic Pollutants (POPs) regulated under the Stockholm Convention in the definition, is a positive development. This definition, coupled with the subsequent **requirement for businesses to disclose the presence of substances of concern in products, marks a significant advancement in improving transparency and traceability of harmful chemicals in everyday products.** It contributes to the goal of non-toxic material cycles. Particularly, as POPs are frequently found in consumer products made from recycled plastic materials, this measure is crucial for maintaining consumer trust and promoting recyclability.

Packaging and Packaging Waste Regulation (PPWR):

The Packaging and Packaging Waste Regulation revision proposed by the EC falls short of the CSS call for non-toxic material cycles and minimising the presence of substances of concern in products, including packaging and food packaging. The EC proposal was too vague on substances of concern and failed to incentivise the elimination of harmful chemicals in packaging. Also, the proposal prohibits to

regulation of substances in packaging for reasons related to chemical safety as part of the recyclability requirements.

However, the Parliament, in its plenary position, adopted bans for PFAS and BPA in food packaging. This stance has become a key negotiating priority for Parliament during the ongoing trilogues. Despite initial opposition from EC and the Council, it seems possible that the final text will include a mechanism to restrict PFAS in food packaging, although this restriction might be subject to revision once the uPFAS restriction under REACH takes place.

Green Claims Directive (GCD):

The introduction by Parliament to require a report on the use of explicit environmental claims on products or product groups containing certain hazardous substances or mixtures is very welcome. If the report finds that the combined use of hazardous substances and green claims is misleading in certain cases, the Commission could adopt delegated acts to introduce restrictions or prohibitions on the use of explicit environmental claims for this product or product group.



Identification of the main bottlenecks for current chemicals control

Through a comprehensive analysis of the European Chemicals Strategy for Sustainability and its implementation, this chapter aims to identify the main bottlenecks currently impeding effective chemicals control in Europe. A case study on the regulation, or lack thereof, of PFAS illustrates how these identified obstacles hinder the regulation of hazardous chemicals.

Case Study: The Uncontrolled Spread of PFAS Pollution

Per- and polyfluoroalkyl substances (PFAS) have been widely used since the 1940s, leading to pervasive contamination across Europe⁸⁴. The persistent, mobility or bioaccumulative nature of these chemicals means they are massively found in the environment, including drinking water and food, and bodies of all EU citizens, including vulnerable groups like children and infants, posing significant health risks that not only affect current generations but also future ones. How did we end-up in this critical situation?

Key Factors Contributing to PFAS Pollution:

Chemical Proliferation: The capacity of organic chemistry to generate tens of thousands of PFAS compounds has outpaced regulatory capacities, leading to a lack of comprehensive knowledge about the origin and full extent of PFAS contamination.

Lack of Corporate Responsibility: The uncontrolled proliferation of PFAS pollution can be attributed to the lack of corporate responsibility in managing and disclosing the associated risks of these chemicals. Despite early indications of PFAS' potential to persist indefinitely in the environment, bioaccumulate in human bodies and contaminate drinking water supplies, industries continued to expand their use of these chemicals in everyday products and industrial uses. Motivated by economic benefits and functional advantages, corporations overlooked the environmental and health risks posed by PFAS.

Corporations were often aware of PFAS' persistence and potential hazards but failed to adequately inform the public or regulators. This lack of transparency impeded early regulatory interventions that could have restricted the scope of contamination. The delay in acknowledging these risks significantly contributed to the uncontrolled spread of PFAS across various environments and populations.

Widespread Use: The versatility of PFAS led to their inclusion in an extensive array of consumer products and industrial processes, further exacerbating human and environmental exposure. Products ranging from stain-resistant fabrics to kitchenware and from food wrappers to cosmetic products contained PFAS, often without labelling or disclosure of potential health impacts. This pervasive presence made it nearly impossible for consumers to avoid PFAS exposure and complicated efforts to trace the sources of pollution.

⁸⁴ Stéphane Horel, Revealed: The massive contamination of Europe by PFAS 'forever chemicals', Le Monde, 23 February 2023. Available at: https://www.lemonde.fr/en/les-decodeurs/article/2023/02/23/revealed-the-massive-contamination-of-europe-by-pfas-forever-chemicals_6016906_8.html

Regulatory Failures:

REACH Regulation Shortcomings: Since its inception in 2007, there has been significant progress in regulating PFAS, notably through the restriction of C9-14 PFCAs and PFHxA, the identification of SVHCs like GenX and PFHxS, and the harmonized classification and labelling of several PFAS such as PFDA and APFO under the CLP. However, failures in implementing the REACH regulation, such as inadequate registration non-compliance with reporting requirements by companies, and challenges in assessing the risks of this extensive group of chemicals, have led to continued use and spread of PFAS pollution without sufficient oversight. The slowness and ineffectiveness of REACH exacerbate these issues. For instance, it took EU officials a total of 11 years to ban PFOA, a chemical group that the industry had already decided to voluntarily phase out 20 years before, 22 years after powerful US government health warnings, and 40 years after scientists began raising the alarm⁸⁵. Shortly after this restriction, a much more stringent ban was implemented globally under the Stockholm Convention⁸⁶, leading to the withdrawal of the initial restriction and wasting significant time and public resources.

Supply Chain Communication Failure: Ineffective communication between chemical manufacturers upstream and product manufacturers or consumers downstream has resulted in a lack of awareness about the dangers of PFAS and their advised uses (or uses advised against).

Underestimated Risks and Costs of Inaction and Lack of Precautionary Measures: The dangers and costs associated with these chemicals were significantly underestimated by the authorities for decades. In addition, the insufficient application of the Precautionary Principle has enabled the extensive use and environmental release of PFAS without fully understanding or managing their risks.

Challenges in Regulation:

Substance-by-Substance Approach: Regulatory efforts have typically focused on one substance at a time, which has been ineffective, given the vast number of PFAS compounds. This approach led to significant delays in restricting individual groups of substances like PFOS and PFOA and has been likened to "emptying the sea with a teaspoon."

Inadequate Legal Frameworks: The legal structures in place have not only failed to keep up with the scale and complexity of PFAS production but also lacked the enforcement mechanisms to compel compliance by industry.

Industry Compliance and Liability Issues: The regulatory framework has over-relied on industry cooperation, which has not been forthcoming. The industry has often failed to provide critical hazards and exposure information, engaged in regrettable substitutions and avoided liabilities for health and environmental damages.

Implications and Future Risks:

The ongoing challenges in regulating PFAS exemplify systemic issues within European chemical management frameworks. These include inadequate data collection, weak enforcement of existing laws, and a regulatory pace that lags far behind the rate of chemical innovation and dissemination. The failure to effectively control PFAS pollution not only poses direct health risks but also illustrates broader difficulties in managing chemical risks in Europe, underscoring the urgent need for comprehensive reform in chemical policy and regulation. Moreover, it's crucial to acknowledge that PFAS pollution can persist for decades,

⁸⁵ Tatiana Santos, Vito Buonsante, Hélène Loonen, Geraldine Borja. THE NEED FOR SPEED. WHY IT TAKES THE EU A DECADE TO CONTROL HARMFUL CHEMICALS AND HOW TO SECURE MORE RAPID PROTECTIONS. EEB, July 2022. Available at: https://eeb.org/wp-content/uploads/2022/07/Need-for-speed_Online_Final.pdf

⁸⁶ Zanda Romata, Marie Escorneboueu. PFOAs Inclusion in the POP Regulation: Interactions Between the REACH and POP Regulations and Conflicting Provisions. Steptoe, September 2020. Available at: <https://www.steptoelaw.com/en/news-publications/pfoas-inclusion-in-the-pop-regulation-interactions-between-the-reach-and-pop-regulations-and-conflicting-provisions.html>

centuries, and sometimes indefinitely, further emphasising the gravity of the situation and the long-term implications of inadequate regulation and control measures.

Conclusion:

The case of PFAS pollution in Europe highlights a critical situation where regulatory, knowledge and enforcement gaps have allowed a hazardous chemical group to become widely distributed and entrenched in the environment and in human populations. This case study underscores the necessity for a robust, responsive and precautionary regulatory approach to chemical management that can adapt to the challenges posed by modern chemical use and protect public health and the environment effectively.

The substance by substance approach led to significant delays in restricting individual groups of substances like PFOS and PFOA and has been likened to "emptying the sea with a teaspoon."

The CSS details several bottlenecks within the current regulatory framework to address the risks posed by hazardous chemicals. These include deficiencies in the knowledge base on chemicals and weaknesses in the legal framework. Stakeholder perspectives, along with additional insights from the EEB, provide further clarity on the main bottlenecks that have led us to the extraordinary contamination and growing health crisis resulting from chemical pollution.

Stakeholder's views

Registration and Supply Chain Communication: Major failures

Stakeholders highlight significant shortcomings in registration requirements, compliance and communication along supply chains. The principle of 'no data, no market', intended to hold industries accountable for demonstrating the safety and compliance of their chemicals, has faltered. Use of hazardous chemicals go unreported, with substances used and incorporated into a wide array of consumer products without limitations or legal consequences, while industrial emissions remain largely uncontrolled. Registration has also failed because many chemicals are under a threshold to require information disclosure.

In addition, ineffective communication between upstream and downstream users hampers the dissemination of crucial information regarding chemical hazards and recommended uses. Upstream users, responsible for registering chemicals, have little information on downstream uses as the communication along supply chains is not working. This deficiency is considered disastrous, in any direction. In addition, downstream users may not receive important safety information and 'uses advised against' information.

Officials express regret over REACH's failure to generate sufficient information, notably on substance uses and exposure scenarios, for preparing restriction proposals, necessitating the initiation of calls for evidence and consultations with stakeholders to gather the missing information. Industry stakeholders, particularly downstream users, highlight the lack of consideration for exposure information from manufacturers which they consider key to identifying and prioritising uses to be risk-managed.

REACH Lacking Teeth and Industry Lacking Liability

Stakeholders mention the naivety of REACH and its lack of teeth, as it relies heavily on industry cooperation. For instance, it permits firms to avoid providing important safety information to authorities and fails to stop regrettable substitution. They consider that industry has not lived up to their responsibilities. A respondent wondered if the US system might be better. In that system, chemicals are not banned, but have stronger instruments to determine causalities of the damage, hence industry is more often liable for the damages they are responsible for.

Challenges of the Substance-by-Substance Approach and Prolonged Regulatory Processes

The substance-by-substance approach to regulating PFAS is considered a main bottleneck in effectively managing the risks of these chemicals. This method, which addresses only a limited number of substances, groups or uses at a time, has been criticised for its inefficiency. For example, the Commission launched the first PFAS restriction 15 years ago, addressing only PFOS. Subsequent efforts to extend the restriction to PFOA received strong opposition, delaying its ban for another decade. Recent restrictions, such as those on PFHxA in certain consumer products and PFAS in firefighting foams, are also viewed as examples of narrow scope PFAS restrictions. One stakeholder noted “this approach is like emptying the sea with a teaspoon”.

Moreover, although the universal PFAS restriction is generally seen as a potential breakthrough, stakeholders hope that it will not be watered down and already regret that it does not formally apply the essential use concept.

One official concludes: “after the process, we will determine the best way to prepare restrictions.” This statement underscores the ongoing debate and uncertainty over the most effective regulatory strategies for PFAS and similar substances.

EEB's views

Over recent years, the EEB and other NGOs⁸⁷ have published several reports evaluating the effectiveness of REACH. These evaluations cover specific areas such as the Authorisation⁸⁸, Restriction⁸⁹ and Evaluation⁹⁰ processes as well as a comprehensive assessment of the time needed to regulating chemicals⁹¹.

These assessments have pinpointed several critical bottlenecks in the control of chemical risks:

The ‘no data, no problem’ approach

A significant bottleneck in the current regulatory framework under REACH is the 'no data, no problem' debacle. The intended 'no data, no market' rule mandates that chemicals must not be granted market access until authorities are given all available and relevant data on their hazards and uses. In reality, there is no quality check of data before chemicals are assigned, within as little as three weeks, a registration number: the licence for placing them on the market. Those chemicals are presumed safe by downstream users, despite incomplete or flawed hazard and exposure data submitted during the REACH registration process.

This approach undermines the fundamental principle of REACH, shifting the substantial burden of proof from manufacturers and importers, who are supposed to demonstrate the safety of their substances in all uses, to regulators, who are left with the task of proving whether a chemical is unsafe, using dossier or substance evaluation which may take over seven years. A further five to nine years are needed to ban a chemical under REACH's Restriction process or curb a chemical under the Authorisation process respectively.⁹²

The lack of consequences for companies submitting inadequate hazard and exposure data under REACH, coupled with REACH's lack of clarity regarding ECHA's mandate to withdraw non-compliant registrations,

⁸⁷ Client Earth, REACH-ing further - what do we want to see in the EU's reformed chemicals law?, Client Earth, 2023. Available at : <https://www.clientearth.org/latest/news/reach-ing-further-what-do-we-want-to-see-in-the-eu-s-reformed-chemicals-law/>

⁸⁸ Dolores Romano and Tatiana Santos, A Roadmap to revitalize REACH. REACH authorisation process. A critical assessment, EEB, November 2015. Available at: <https://eeb.org/wp-content/uploads/2019/07/Report-Roadmap-to-Revitalise-REACH.pdf>

⁸⁹ European Environmental Bureau (EEB), Restricted Success: EEB's appraisal of restriction under REACH, EEB, 28 June 2017. Available at: <https://eeb.org/library/restricted-success-eebs-appraisal-of-restriction-under-reach/>

⁹⁰ Dr. Hélène Loonen, Dolores Romano, Tatiana Santos and Elise Vitali, CHEMICAL EVALUATION. Achievements, challenges and recommendations after a decade of REACH, EEB, April 2019. Available at: <https://eeb.org/wp-content/uploads/2019/07/Report-Substance-Evaluation-under-REACH.pdf>

⁹¹ Tatiana Santos, Vito Buonsante, Hélène Loonen and Geraldine Borja, The Need For Speed – Why it takes the EU a decade to control harmful chemicals and how to secure more rapid protections, EEB, July 2022. Available at: <https://eeb.org/library/the-need-for-speed-why-it-takes-the-eu-a-decade-to-control-harmful-chemicals-and-how-to-secure-more-rapid-protections/>

⁹² Tatiana Santos, Vito Buonsante, Hélène Loonen and Geraldine Borja, The Need For Speed – Why it takes the EU a decade to control harmful chemicals and how to secure more rapid protections, EEB, July 2022. Available at: <https://eeb.org/library/the-need-for-speed-why-it-takes-the-eu-a-decade-to-control-harmful-chemicals-and-how-to-secure-more-rapid-protections/>

exacerbates the circulation of potentially hazardous chemicals. This situation not only burdens regulatory bodies responsible for safeguarding public and environmental health, but also compromises their effectiveness.

Lack of legally binding deadlines

The absence of mandatory timelines for various stages of chemical regulation significantly hampers effective risk management. This includes:

ECHA Compliance Checks: ECHA's current mandate requires the Agency to check only 20% of dossiers per tonnage band. "Zero tolerance" against non-compliance requires full scrutiny. In addition, ECHA lacks binding deadlines to complete compliance checks on registration dossiers, which is crucial for ensuring that chemical data submitted by companies is accurate and adequate. It can take more than five years, or in worst case scenarios, over ten years to collect the data from industry requested under compliance checks.

Member State Evaluation: There are no fixed deadlines for member states to complete the evaluation of chemical risks, leading to potential delays in identifying hazards. Substance Evaluation typically takes seven to nine years to conclude from the initial raising of concern, if further data generation is needed.

Commission Decision-Making: The European Commission has the legal obligation to draft decisions within three months, but no deadline to adopt final decisions. It is alarming that it spends an average of two years, and sometime over a decade, to decide on regulatory actions for known harmful chemicals.

Industry Lack of Responsibility and Liability: Systematic Evasion and Lack of Consequences

As detailed in our 'Need for Speed' report, a pervasive challenge in effective chemical regulation is the routine manipulation of the system by the chemical industry. An alarming 83% of hazard data submitted by firms was found unreliable upon inspection in 2023⁹³, suggesting a deliberate strategy to underreport risks to avoid regulation. Such systematic misrepresentation could be classified as gross negligence, but the pattern of behaviour over the last 17 years indicates a strategic choice, knowing that detection levels of non-compliances are low and dissuasive sanctions are only rarely employed, and knowing that acknowledgment of hazards sends a bad signal to the market and could trigger unwanted regulatory interventions. This issue is exacerbated by a culture of litigation within the industry, where companies frequently engage in vexatious legal challenges against decisions made by the European Chemicals Agency and the European Commission. These challenges often concern Crucial hazard data, such as carcinogenicity, that should underpin market access, indicating a deep-seated resistance to regulatory oversight. Moreover, industry benefits of the fact that, once chemicals are registered and may be placed on the market, formulators and producers continue to incorporate these into a wide array of consumer products, often for decades, without significant legal or economic repercussions, even if later banned due to proven hazards. Notable examples include:

Bisphenol A (BPA): discovered in 1891 and now one of the most prevalent chemicals worldwide, BPA is routinely found in consumer products such as toys, reusable water bottles, and food and beverage can linings. It is detected in nearly all Europeans, with human exposure levels frequently surpassing the new, drastically reduced 'tolerable' limit, by 20,000 times, set by the European Food Safety Authority (EFSA)⁹⁴.

Perfluorooctanoic Acid (PFOA): Extensively used in a myriad of products across all EU member states since its mass production began in the 1940s by 3M, with EU restrictions only implemented in 2020. PFOA remains detectable in virtually all living organisms today.

Compliance with Authorisation and Restriction are at likewise concerningly low levels.

⁹³ ECHA, Progress in evaluation in 2023. Available at: <https://echa.europa.eu/dossier-evaluation-progress-2023>

⁹⁴ EFSA. Re-evaluation of the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs. EFSA, April 2023. Available at : <https://www.efsa.europa.eu/sites/default/files/2023-04/efsa-6857-bpa-pls.pdf>

Despite clear evidence of harm, there remains a striking lack of legal or financial consequences for the producers and users of these chemicals. A poignant example is PFAS, where numerous pollution incidents have contaminated drinking water and food, affecting millions. Yet, in Europe, those responsible for such environmental damage face minimal accountability. This glaring oversight highlights the critical need for regulatory frameworks that not only prevent such incidents but also hold polluters responsible for their actions.

Lack of Accountability by national authorities and the Commission

The issue of irresponsibility and lack of liability among chemical companies is further compounded by a concerning lack of accountability within the competent authorities themselves. As acknowledged by ECHA and EEA, “Authorities now have much better knowledge about the hazardous properties of chemicals that are used across the EU, resulting in many actions to minimise and control the risks of several groups of substances”⁹⁵. There are instances where substance evaluations or assessments of regulatory needs clearly signal the need for regulatory action, such as classification or restriction, yet neither national authorities nor the Commission are obliged to act. This absence of compulsory action allows for a systemic inertia within regulatory practices. Moreover, the Commission fails to meet its own legal deadlines for decision-making on regulatory actions, without being held accountable. This failure goes largely unchallenged, leading to a situation where non-compliance with procedural timelines has become the norm. **This lack of accountability perpetuates a regulatory landscape where urgent and necessary actions are delayed, undermines the effectiveness of chemical safety regulations and puts public health and the environment at risk.**

European Commission inaction.

A major bottleneck in the effective regulation of chemicals arises from the Commission’s evident tendency towards inaction. Delays spanning several years in decision-making processes for chemical regulation highlight a troubling pattern of maladministration within the Commission. This systemic delay is triggered by the undue assessment and consideration of the costs of inaction regarding chemical pollution and the lack of application of the Precautionary Principle. Industry stakeholders have an unreasonable level of influence on the Commission’s decision-making processes, often resulting in a state of regulatory paralysis. This undue influence has been particularly evident in the prolonged delay of the REACH revision, showcasing a systemic failure to prioritise long-term public health and environmental protection over short-term industry economic interests.⁹⁶

Consequently, regulatory actions essential for controlling hazardous chemicals are stalled, perpetuating risks to human health and the environment across Europe.

Lack of empowerment of European citizens to protect their rights.

One glaring bottleneck in the current regulatory landscape is the inadequate empowerment of European citizens to protect their rights in the face of chemical hazards. Even the ‘right to know’ about the presence of SVHCs in articles is in practice scaled back to a mere right to ask. Industry can provide no or insufficient information, usually without legal consequence. European citizens lack the necessary power to demand public preventive action or to request compensation from polluters for damages suffered.

This lack of empowerment creates a significant barrier to effective chemical control, as it undermines the ability of affected individuals and communities to advocate for their health and wellbeing. Without robust mechanisms for citizen engagement and recourse, the regulatory framework remains deficient in its ability to address the concerns and interests of those directly impacted by chemical pollution.

⁹⁵ ECHA, EU Agencies: more work needed to make chemicals safe and sustainable, April 2024. Available at: <https://echa.europa.eu/-/eu-agencies-more-work-needed-to-make-chemicals-safe-and-sustainable>

⁹⁶ Antonia Reihlen, Mariana Goulart, Tatiana Santos and Michael Warhurst, Waiting for REACH The negative impacts of delaying reform of EU chemical laws, EEB and CHEM Trust, March 2023. Available at: https://eeb.org/library/waiting-for-reach/?utm_source=T%26E+EEB+super+list&utm_campaign=6b437709fe-EMAIL_CAMPAIGN_2022_01_31_01_15_COPY_02&utm_medium=email&utm_term=0_7a91882d26-6b437709fe-

Recommendations for the new Commission's chemicals policy objectives

1. Speed Up Regulation of the Most Hazardous Chemicals. Make Safe and Sustainable Products the Easy Choice: Use the available information to expedite the regulation of the most hazardous chemicals by adopting group-based approaches. Banning the most hazardous chemicals in both consumer and professional uses, as well as non-essential industrial uses. Prioritise the classification of persistent chemicals and EDs under the CLP regulation. Leverage the recent successful revision of the CLP Regulation to streamline hazard identification for these groups of chemicals.

2. Give REACH teeth, ensure industry liability: Strengthen REACH to ensure robust, dissuasive sanctions, including a revocation mechanism, and harmonised enforcement. Establish clear provisions to hold chemical companies accountable for any harm caused by their chemicals. Enforce financial responsibility on companies to cover the costs associated with monitoring, enforcement, addressing adverse effects of their chemicals, including compensating affected individuals and communities, and remediating contaminated sites. Integrate the Polluter Pays Principle in the legal text.

3. Deliver Swiftly on Pending CSS Promises: The above points already refer to some commitments outlined in the Chemicals Strategy for Sustainability. Additional pending actions to be implemented promptly include:

- Banning the most harmful chemicals in consumer and professional uses by 2030;
- Adopting and implementing the essential use concept;
- Implementing mixture assessment factors in all chemical safety assessments;
- Ensuring the identification and regulation of endocrine disruptors;
- Executing the PFAS action plan;
- Stopping the exports of banned chemicals.

4. Enhance Authorities' Accountability: Strengthen accountability mechanisms for the European Commission and national competent authorities responsible for chemical regulation. Empower and mandate authorities to duly consider the costs of inaction, take swift and decisive actions to address chemical risks and ensure timely compliance with regulatory requirements. Establish a clear process for authorities to take timely action following the identification and reporting of early warnings within the early warning and action system for emerging chemical risks.

5. Empower Citizens and Establish Compensation Mechanisms: Provide citizens accessible information about chemical risks, opportunities for public participation in decision-making processes, mechanisms for reporting pollution and access to justice. Introduce compensation mechanisms for victims of chemical pollution to provide redress for harm caused by exposure to hazardous chemicals, employing adapted burden of proof rules to give victims a real procedural chance at justice. Ensure that individuals and communities affected by chemical contamination have avenues for demanding action and seeking compensation and remediation.

6. Mainstream intrinsically safe and sustainable chemicals, materials and products, and promote substitution: mainstream inherently safe and sustainable chemicals, materials and products across all sectors of industry and daily life. Implement policies and economic instruments that encourage the use of these alternatives while promoting substitution strategies. Strong regulatory incentives such as clear phase-out rules are best placed to give predictability to companies required to substitute and suppliers of alternatives. Establish an EU-wide substitution support centre to facilitate the transition to safer and more sustainable alternatives.

7. Solve the Data Gap: Fill the chemical data gap by ensuring that companies provide under

REACH comprehensive information on hazards, specific uses in products and processes, and exposure of chemicals and polymers. Make information readily available to authorities and all actors across the supply chain to enhance transparency and traceability of chemicals present in materials, products and waste.



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