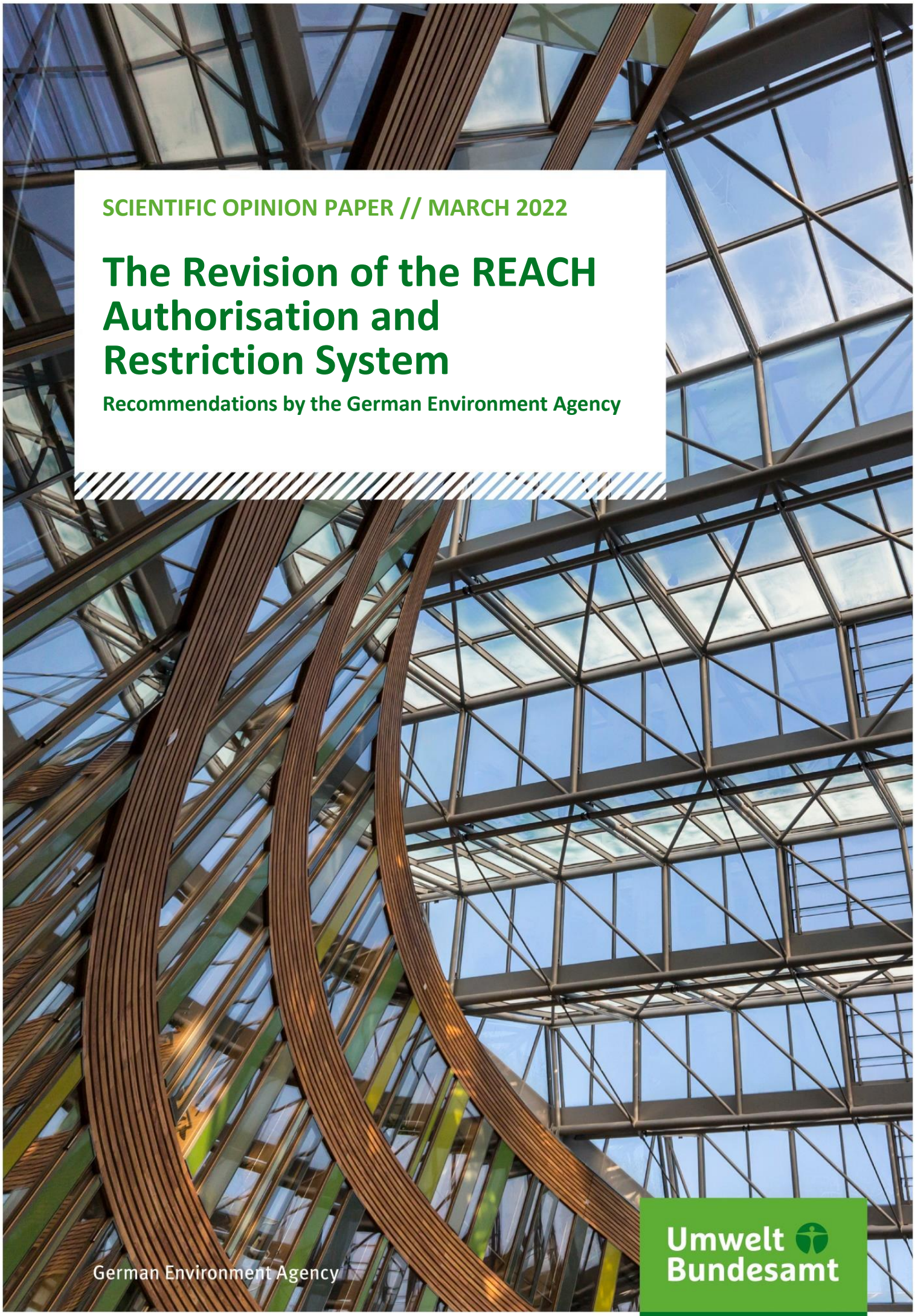

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The Revision of the REACH Authorisation and Restriction System

Recommendations by the German Environment Agency

German Environment Agency

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The Revision of the REACH Authorisation and Restriction System

Recommendations by the German Environment Agency

by
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On behalf of the German Environment Agency

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Summary

The European Green Deal´s zero pollution vision to 2050 and the Chemicals Strategy for Sustainability have raised the level of ambition of the European Union´s policies on chemicals. Against this background, the targeted **revision of the REACH regulation** offers a unique and timely opportunity to further strengthen the legislative text.

This paper focuses on the **revision of the REACH authorisation and restriction system** from an environmental perspective. Both systems are central for the regulation of the continued use of the most hazardous substances, as well as the manufacture, placing on the market or use of substances when there is an unacceptable risk. While this paper deliberately does not take a position vis-à-vis the policy options discussed by others, our recommendations mostly support what has been proposed by the European Commission so far.

Based on an analysis of the strengths and weaknesses of the current REACH authorisation and restriction system, this paper recommends **six objectives** and **ten building-blocks** as well as **procedural steps** for the revised REACH authorisation and restriction system. Building-blocks offer a flexible approach that can be adapted easily to different policy options.

The **availability and accessibility of data** should be improved through compliance checks of all registration dossiers and additional information requirements for certain hazard classes. Applications for authorisation that do not fulfil minimum quality standards should be rejected.

The Candidate List should be maintained to ensure **legal certainty and predictability** and to drive substitution. The **level of environmental protection** should be strengthened through incentives for substitution, such as research and innovation for safe-and-sustainable chemicals.

The **level-playing field** with non-European companies should be improved by increasing regulations through restrictions. Cooperation and coordination across legislation should be enhanced to ensure **policy coherence**, for example by aligning reporting obligations.

The simplified procedure for identifying substances of very high concern (SVHC) that have a harmonised classification should be extended to certain hazard classes, in order to enhance **efficiency and effectiveness**.

Preventive measures, including the extension of the generic approach to risk management to additional hazard classes and uses, and the introduction of derogations from restrictions for uses that are essential for society and necessary for health and safety when alternatives are not available, should contribute towards further simplifying current procedures.

In conclusion, the German Environment Agency proposes in this paper a set of ambitious revisions to the REACH authorisation and restriction system, that will bring about some of the **transformative changes needed** to come a step closer to a toxic-free environment.

Table 1: Summary of recommended objectives and building-blocks for the revised REACH authorisation and restriction system

Objectives	Building-blocks
A) Improve data availability and accessibility	1) Information and notification requirements
B) Enhance efficiency and effectiveness	2) The simplified procedure for the identification of SVHC
C) Increase legal certainty and predictability	3) The Candidate List
D) Strengthen the level of environmental protection via preventive measures	4) The authorisation system 5) The specific approach to risk management 6) The generic approach to risk management 7) The essential use concept 8) Incentives for substitution
E) Introduce a level-playing field with non-EU companies	9) The regulation of substances in articles
F) Ensure policy coherence	10) Cooperation and coordination across legislation

1 Background

1.1 The management of chemicals is essential for the achievement of sustainable development

Chemicals are everywhere in our daily lives. They are essential for the functioning of our society and economy. They are critical for the production of pharmaceuticals, electrical and electronic equipment, or for the production, transport and storage of renewable energy. The global production of chemicals is expected to double within a decade until 2030 (UNEP, 2019) (Textbox 1).

At the same time, chemicals can pose a risk for **human health and the environment**. They are continuously released into air, water and soil and many are found ubiquitously in the environment, causing biodiversity loss (Johnson *et al*., 2020). It is estimated that 2 million human lives were lost worldwide in 2019 due to exposure to selected chemicals (WHO, 2021).

The sound management of chemicals throughout their life cycle is essential for the achievement of **sustainable development**. It contributes to most, if not all, sustainable development goals (SDG), including combatting climate change (SDG 13), biodiversity loss (SDG 15), and protecting human health and well-being (SDG 3). Environmental pollution, including chemical pollution, has been declared as one of the three environmental emergencies to be addressed jointly to achieve sustainable development (UNEP, 2021).

Current actions on chemicals throughout their life cycle are insufficient and must be stepped up. Against this background, the **European Green Deal** (COM, 2019) sets an ambitious **zero pollution vision for 2050**. The overall objective is to reduce the pollution of air, water and soil to levels that are not harmful to human health and the environment in order to achieve a toxic-free environment. The Chemicals Strategy for Sustainability contributes towards the achievement of the Zero Pollution Ambition (COM, 2021a).

Textbox 1: The need to take ambitious actions on chemicals and waste across sectors


The global production of chemicals is expected to double within this decade until 2030, with emerging economies making up the largest share (UNEP, 2019).


Toxic pollution from contaminated sites affects over 200 million people worldwide. Tens of thousands are poisoned each year (IOMC, 2021).


It is estimated that the total deposition input of mercury to the oceans in 2008 was 3.700 tons (IOMC, 2021).


Waste generation is projected to increase from 1.3 billion tons per year to 2.2 billion tons per year by 2025, with high increases in middle-income developing countries (IOMC, 2021).


2 million lives were lost in 2019 due to exposure to selected chemicals (WHO, 2021).


Approximately one quarter of workplace deaths result from exposure to hazardous substances (IOMC, 2021).


Around 1 in 3 children – up to 800 million globally – has blood lead levels at concentrations that require global interventions (UNICEF, 2020).

1.2 The Chemicals Strategy for Sustainability is a new vision for the European Union´s policies on chemicals

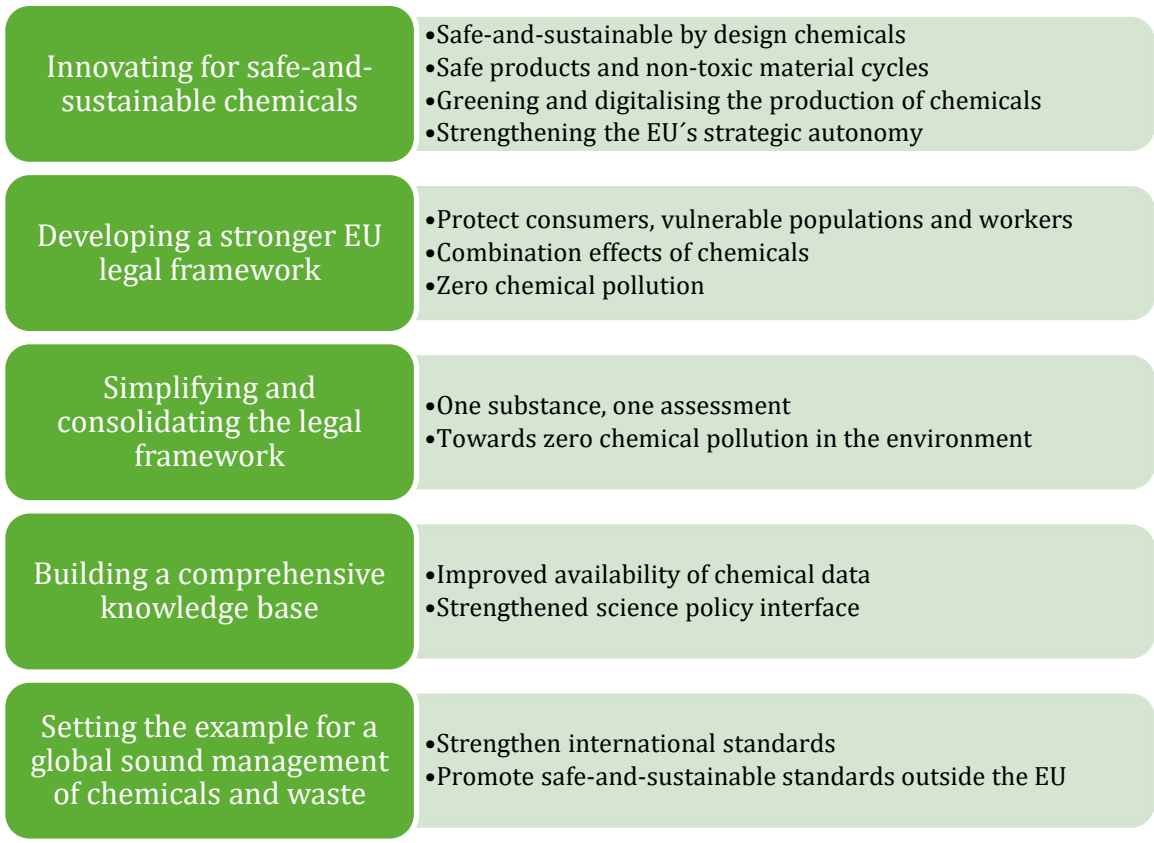
The **Chemicals Strategy for Sustainability** is a new vision for the European Union´s policies on chemicals (COM, 2020). Its overall objective is to ensure better protection of human health and the environment from hazardous chemicals, while boosting innovation for safe-and-sustainable chemicals and enabling the transition to safe-and-sustainable chemicals by design.

The **five pillars** of the Chemicals Strategy for Sustainability include: 1) innovating for safe-and-sustainable chemicals, 2) developing a stronger EU legal framework, 3) simplifying and consolidating the legal framework, 4) building a comprehensive knowledge base, and 5) setting the example for a global sound management of chemicals and waste (Figure 2).

The Strategy will be **delivered** through legislative proposals, including a revision of the European Union chemicals legislations, the development of new methodologies, and financial support for research, innovation and capacity building. A high-level roundtable was set up, bringing together representatives from government, intergovernmental organisations, industry and civil society (COM, 2021b).

The European Commission has announced a targeted **revision of the REACH regulation**. An impact assessment will be carried out to verify whether the actions outlined in the Chemicals Strategy for Sustainability address the challenges and gaps in the REACH regulation. The European Commission aims to finalise the legislative proposal for the revision of the REACH regulation by the end of 2022.

Figure 2: The Chemicals Strategy for Sustainability´s objectives and targets



1.3 The REACH regulation allows for the regulation of the most hazardous substances and unacceptable risks via the authorisation and restriction system

The European Union has one of the most comprehensive and ambitious **legislations on chemicals** globally. The Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (EU, 2006) and the Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging of Chemicals (CLP) (EU, 2008) are the two horizontal legislations on chemicals in the European Union.

The **REACH regulation** entered into force in 2007. Its overall objective is to ensure a high level of protection of human health and the environment from hazardous substances, to promote alternative test methods, the free circulation of substances on the internal market, as well as the promotion of competitiveness and innovation. The regulation applies to the manufacture, placing on the market or use of substances on their own, in mixtures or in articles.

The **REACH authorisation and restriction system** is key for regulating unacceptable risks and the most hazardous substances in the European Union (Textbox 2). The authorisation process addresses the risk management and progressive substitution of substances of very high concern (SVHC). The restriction process aims to restrict the manufacture, placing on the market or use of substances when there is an unacceptable risk to human health or the environment from a substance.

Textbox 2: The REACH authorisation and restriction system

The **authorisation process** involves the identification and inclusion of substances of very high concern in the "Candidate List", based on proposals by ECHA (in request of the European Commission) and Member State competent authorities, followed by their prioritisation and inclusion in the authorisation list (REACH Annex XIV). Manufacturers, importers or downstream users may apply for authorisation, demonstrating that the risk arising from continued use can be adequately controlled or that the socio-economic benefits from continued use outweigh the risks and no suitable alternatives are available. The European Commission is responsible for granting authorisations, based on the opinions developed by the ECHA´s committees for risk assessment (RAC) and socio-economic analysis (SEAC).

The **restriction process** involves the restriction of the manufacture, placing on the market or use of substances when there is an unacceptable risk to human health or the environment from a substance. The European Commission and Member States decide on the restriction proposals prepared by ECHA or Member State competent authorities based on the opinions provided by ECHA´s RAC and SEAC.

To date, more than **100.000 registrations** have been made with ECHA for about **23.000 substances** (ECHA, 2022). 239 entries have been included in the candidate list of SVHC, and 54 entries in the authorisation list in Annex XIV (ECHA, 2022). 46 entries have been listed in the registry of restriction intentions until outcome resulting in about 27 new or revised restrictions so far (ECHA, 2022). Multiple entries can be made per substance.

2 The Need for a Revision of the REACH Authorisation and Restriction System

2.1 The REACH review concluded that improvements in the REACH regulation were needed

The REACH regulation includes the obligation for **a review** every five years to monitor progress in the achievement of its objectives against five criteria: effectiveness, efficiency, relevance, coherence and EU added value (EU, 2006).

The latest REACH review (COM, 2018) concluded that while the regulation was effective overall, some **improvements were needed**. With regard to the authorisation and restriction system, the recommendations can be summarised as follows:

(1) ***Non-compliance of registration dossiers***: address data gaps and update registration dossiers;

(2) ***Simplification of the authorisation process***: clarify requirements, make the process more predictable, and step-up efforts to substitute SVHC;

(3) ***Level-playing field with non-EU companies***: assess the need for a restriction on imported articles containing substances listed in Annex XIV, reinforce enforcement activities by Member States on imported goods;

(4) ***Ensure policy coherence***: clarify the coherence between REACH and other EU legislation, in particular on Occupational Safety and Health (OSH) and waste;

(5) ***The number of restrictions has so far not met the original expectations***;

(6) ***There is room for improvement of the restriction process***: review the requirements (criteria) for the conformity check, continue efforts to obtain a maximum of information through the public consultation, ensure compliance with the REACH provisions across the EU.

Against this background, the German Environment Agency commissioned a research project to assess the REACH authorisation and restriction system (UBA, 2021a+b) (Table 2).

2.2 The strengths and weaknesses of the authorisation system

Regarding the REACH authorisation system, the research project concluded that overall, the authorisation system has driven the **phasing-out of SVHC** (UBA, 2021a). However, its effect on **substitution** remains unclear, due to the lack of quantifiable data (UBA, 2021a).

Data on substance properties, which are needed for the identification of SVHC, is generally available from registration and evaluation dossiers, especially when those properties are subject to **harmonised classification** (UBA, 2021a). However, challenges may arise from disagreement about the interpretation of data or when case-by-case evaluations are needed (UBA, 2021a). Moreover, the identification of substances with an **equivalent level of concern** (ELoC) (REACH Article 57 (f)) can be challenging, where data often do not yet fall under standard data requirements compared to the other SVHC criteria (REACH Article 57 (a-e)) (UBA, 2021a).

Information on substance uses, alternatives and market impacts is often lacking. Therefore, the ability of authorities to conduct the risk management option analysis (RMOA), the evaluation of applications for authorisation, and the prioritisation of SVHC is hindered (UBA, 2021a).

The **RMOA** has been a valuable tool for determining the best option for regulating a substance for certain cases (UBA, 2021a). The **Candidate List** has been a valuable tool for triggering information and notification requirements. While the **prioritisation of SVHC** for inclusion in Annex XIV has been clear and concise, the prioritisation criteria may be insufficient to put forward the substances for which authorisation provides significant risk reduction (UBA, 2021a).

Upstream applications for authorisation have alleviated the administrative burden on authorities (UBA, 2021a). Multiple applications for authorisation for similar uses of small quantities of SVHC have been particularly burdensome for authorities (COM, 2021a).

Finally, the **scope of authorisations** does not apply to the manufacturing of SVHC nor to SVHC in imported articles, thus affecting the competitiveness of companies based in the EU.

2.3 The strengths and weaknesses of the restriction system

Regarding the restriction process, the research project concluded that overall, **it achieved its aim** to restrict the manufacture, placing on the market or use of substances when there is an unacceptable risk to human health or the environment (UBA, 2021b) (Table 2).

Case studies showed that restrictions on substances with cancerogenic, mutagenic or toxic to reproduction (CMR) properties in consumer articles caused largely more efforts via REACH **Article 68(1)** than 68(2), although the use scenarios were similar (UBA, 2021b).

Broad scope restrictions are more burdensome for authorities, in terms of data collection, demonstration of unacceptable risks, assessment of alternatives, socio-economic analyses, as well as stakeholder consultations. Restrictions with a narrow scope have been better accepted by market actors, possibly because they impact fewer stakeholders (UBA, 2021b).

The **demonstration of an unacceptable risk** has been challenging for submitters of restriction dossiers. Justifying the grouping of substances may be complex, demonstrating hazardous properties on a case-by-case basis for an equivalent level of concern, and assessing the effects of the continued use of a substance or group of substances on the environment (UBA, 2021b).

Information on substance uses and exposure, as well as on the availability and feasibility of alternatives is often missing but needed by dossier submitters. There is also a lack of knowledge about the wide range of sector specific measures for emission abatement and their specific efficiency. Furthermore, public consultations have not closed the information gap (UBA, 2021b).

Regarding the **assessment of alternatives**, authorities need to evaluate whether drop-in alternative substances exist, their technical performance, application conditions for alternative families of chemicals, or the existence of alternative technologies. Authorities also need to predict the costs for articles and products and to estimate transition periods until when alternatives can be applied. Specific expertise is not accessible to authorities.

Cost-effectiveness assessments are increasingly accepted in cases where damage/benefits cannot be quantified, so that the emission reduction is used as a proxy for benefits, and costs are evaluated against the achievable emission reduction (UBA, 2021b).

Specific exemptions are often introduced late during the public consultation, when RAC and SEAC opinion making is ongoing or shortly before the Commission´s decision-making (UBA, 2021b). Thus, authorities face challenges in assessing and justifying specific exemptions. This may also delay the decision-making by the Commission.

Finally, restrictions have been the **preferred regulatory option** for SVHC in imported articles and to address consumer risks (UBA, 2021b).

Table 2: Strengths and weaknesses of the REACH authorisation and restriction system

	Strengths	Weaknesses
Authorisation	The **phasing-out of SVHC** The **RMOA** has been a valuable tool for determining the best regulatory option in certain cases The **Candidate List** has been a valuable tool for triggering information and notification requirements **Data on substance properties** is generally available from registration and evaluation dossiers, especially when those properties are subject to **harmonised classification** **Upstream applications** for authorisation have alleviated the administrative burden on authorities	The **effect on substitution** remains unclear **Information on substance uses, alternatives and market impacts** is lacking The **ability of authorities** to conduct the RMOA, the evaluation of applications for authorisation, and the prioritisation of SVHC is hindered The **prioritisation criteria** for inclusion of SVHC in Annex XIV are insufficient The identification of SVHC can be burdensome when there is disagreement about the **interpretation of data** or when **case-by-case evaluations** are needed The **identification of substances with an equivalent level of concern (ELoC)** (REACH Article 57 (f)) can be challenging, as data do not fall under **standard data requirements** The **scope of authorisations** does not apply to manufacturing of SVHC nor to SVHC in imported articles
Restriction	**Restrictions under REACH Article 68(2)** have required less efforts The **grouping of substances** has been an advantage **Cost-effectiveness assessments** are increasingly accepted in cases where damage/benefits cannot be quantified Restrictions have been the **preferred regulatory option** for SVHC in imported articles and to address consumer risks The **scope of restrictions** applies in principle to all substances, including polymers There is a **wide range of targeted risk management options**	**Restrictions with a broad scope** are generally more burdensome for authorities than those with a narrow scope Sometimes the **demonstration of an unacceptable risk** has been challenging **Information on substance uses and exposure**, as well as on the availability and feasibility of **alternatives**, which is key for justifying a restriction, is missing The **assessment of alternatives** is complex and specific expertise is not accessible for authorities **Specific exemptions are often proposed late** during the public consultation

3 Recommended Objectives and Building-Blocks

3.1 Objectives of the revised system

Based on the conclusions of the REACH review (Chapter 2), the German Environment Agency proposes the following **objectives for the revision** of the REACH authorisation and restriction system (Table 3):

A) Improve **data availability** and accessibility,

B) Enhance **efficiency** and effectiveness,

C) Increase **legal certainty** and predictability,

D) Strengthen the **level of protection** of the environment via preventive measures,

E) Ensure a **level-playing field** with non-EU companies, and

F) Ensure **policy coherence**.

The effectiveness of the revised REACH authorisation and restriction system should be assessed against these objectives.

3.2 Building-blocks of the revised system

Furthermore, based on our analysis of the strengths and weaknesses of the REACH authorisation and restriction system (Chapter 2), and in order to achieve the objectives listed above, the German Environment Agency proposes the following building-blocks for the revised system (Table 3):

(1) Information and notification requirements

Basic information on hazards, substance uses, alternatives and socio-economic impacts are essential for the decision on which substances need further regulatory action (i.e. authorisation or restriction). Improvement of the availability of information is needed in order to decide on the most appropriate measures and the scope of restrictions in an efficient and effective way.

We propose that compliance checks of all registration dossiers should be conducted in order to ensure that relevant information is provided. The revocation of registration numbers should be allowed in cases of enduring non-compliance. Regular updates of registration dossiers should be mandatory. Procedures for filling data gaps should be improved, such as grouping of substances and mandating authorities with testing.

Moreover, downstream users and manufacturers of articles should provide extended information on substances classified as endocrine disruptors (ED), persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT), very persistent and very mobile (vPvM) or CMR. The same should apply to SVHC with an equivalent level of concern identified under REACH Article 57(f).

Extended information requirements should include information on substance volumes, uses, alternatives, as well as risk and waste management measures. Furthermore, downstream users and manufacturers of articles should be obliged to provide additional information to authorities upon request and within a reasonable timeframe. Authorities may use this information to grant applications for authorisations or derogations from restriction.

The proposed extended notification and information requirements should improve the overall availability and accessibility of data, so as to allow authorities to make decisions on the most appropriate regulatory measures.

(2) The simplified procedure for the identification of SVHC

Substances can currently be identified as SVHC when they have CMR (Cat. 1A, 1B), PBT or vPvB properties, or when they are identified as substances with an equivalent level of concern (REACH Article 57). Substances meeting the criteria for classification in the hazard classes CMR (Cat. 1A, 1B) in accordance with CLP Annex I may be identified as SVHC and included in REACH Annex XIV in a simplified procedure. In these cases, the Annex XV dossier may be limited to a reference to an entry in CLP Annex VI (i.e. harmonised classification and labelling for certain hazardous substances).

The simplified procedure for identifying SVHC that have a harmonised classification as CMR (Cat. 1A, 1B) should be extended to PBT, vPvB, PMT, vPvM and ED substances. It would also be possible to automatically identify substances with such harmonised classifications as SVHC. Thus, ECHA would automatically supplement the Candidate List without the need for a dossier. This would reduce the administrative burden and increase transparency.

At the same time, the procedure for identifying substances with an equivalent level of concern, and for those without harmonised classification, should be maintained in parallel. Moreover, separate letters for PMT, vPvM, and ED should be added to REACH Article 57. The link with the planned new hazard classes of the CLP regulation should be developed. Finally, listing of substances in the Candidate List could be linked to entries into the database for information on substances of concern in articles or products (SCIP).

The proposed simplified procedure for the identification of SVHC should enhance the overall efficiency and effectiveness of the REACH authorisation and restriction system.

(3) The Candidate List

Substances that are identified as SVHC are currently listed on the Candidate List. Listing triggers information and notification requirements for suppliers as well as the need to implement operational conditions (OCs) and risk management measures (RMMs) to minimise emissions into the environment. ECHA proposes a prioritisation of substances on the Candidate List for inclusion in the authorisation list.

The Candidate List should be maintained in the revised system. It could be used by authorities as a source for prioritising substances, as well as to ensure transparency, predictability and to drive substitution. Moreover, the continued use of substances included in the Candidate List should be linked to a “fee” for manufacturers, importers and downstream users (paragraph (8)) and should trigger extended notification and information requirements for downstream users and manufacturers of articles for substances, in the same way as for substances classified as CMR, vPvB, PBT, vPvM, PMT, or ED (i.e. identified via Article 57 (f)) (paragraph (1)).

(4) The authorisation system

The authorisation system should be maintained in the future. The assessment of alternatives should be carried out on an overarching level by authorities (UBA, 2021a). Moreover, RAC and SEAC should be allowed to reject applications for authorisation which do not fulfil the minimum requirements and quality standards (UBA, 2021a), and to withdraw granted authorisations if requested information has not been generated.

RAC and SEAC resources should not be used to generate information during the evaluation process, which should have been provided prior to the application (UBA, 2021a). Instead, RAC and SEAC resources should focus on demonstrating the risk, costs and benefits for society from continued use of a certain SVHC.

(5) The specific approach to risk management

The specific approach to risk management currently involves the restriction of the manufacture, placing on the market or use of substances when there is an unacceptable risk to human health or the environment from a substance (REACH Article 68(1)). The European Commission and Member States decide on the restriction proposals prepared by ECHA or Member State competent authorities based on the opinions provided by ECHA´s RAC and SEAC.

The specific approach to risk management for restrictions should be maintained for substances and/or risks that cannot be regulated under the generic approach or for cases where more flexibility is needed. These substances should preferably be restricted as a group rather than individually (UBA, 2021a).

Derogations from restrictions should either be derived in line with the current procedure (proposal by dossier submitter, further processing in RAC/SEAC processes, decision in comitology) or the dossier submitter may open up the possibility for applications from industry. Joint applications should be given priority over individual applications. Furthermore, elements of generic approaches to risk management, for example the use of emissions of SVHC as a proxy for risk, should remain possible as part of specific risk management approaches.

(6) The generic approach to risk management

The generic approach to risk management (GRA) currently only applies to the restriction of substances with CMR (cat. 1A or 1B) properties and only for consumer uses (REACH Article 68(2)). The generic risk approach is a simplified decision-making tool, since the procedural steps laid out in REACH Articles 69-73 (i.e. restriction proposal, RAC opinion, SEAC opinion, proposal submission) do not apply. Moreover, the generic risk approach is a preventive measure, because it allows for the general ban of substances with certain hazardous properties.

For certain hazards there are no safe concentration limits, so that the risk cannot be quantified based on a classical risk assessment (i.e. PEC versus PNEC relation for the environmental risk assessment). From an environmental perspective, this applies to PBT, vPvB, PMT, vPvM and ED substances. Any release of these substances into the environment throughout their lifecycle poses a risk for the environment.

Emissions of **PBT and vPvB substances** into the environment are considered as proxy to risk under REACH and must be minimised. Moreover, a safe level of exposure that would be protective for all species and ecosystems cannot be determined for **ED substances** in the environment, based on the current knowledge. Regarding invertebrates, there is still no agreed guidance which clearly defines biologically plausible links between endocrine modes of action and adverse effects for invertebrate taxa and knowledge is still scarce in light of the large number and variety of invertebrates and their endocrine systems. Transferability of vertebrate data to invertebrates is hence very limited. Furthermore, even transient exposure to endocrine disruptors during sensitive life stages can have severe consequences in later life stages or even in later generations. This decoupling between exposure and adverse effects in

time is difficult to assess with the available ED specific test guidelines and hence, predictions of future effects and safe exposure levels for the environment are not possible. Validated test guidelines exist so far only for a limited number of adverse ED specific endpoints in various species. For example, thyroid related adversity cannot be assessed for fish species at the moment.

Regarding **PMT and vPvM substances**, it is specifically their persistency causing concern for an irreversible and increasing presence in the environment which justifies a generic risk approach with regard to REACH. Once a PMT or vPvM substance is emitted into the environment, it is the combination of persistency and mobility causing the substance to be transported over long distances. Effects might occur far away from its point of emission. These intrinsic substance properties make purification of water and remediation difficult. If purification of the aquatic environment is possible at all, the costs commonly need to be paid by society. Continuous presence in water results in continuous exposure of humans and the environment.

The generic risk approach should be extended to PBT, vPvB, PMT, vPvM and ED substances. Moreover, the generic risk approach should be extended to professional and industrial uses. Consumer and professional uses are wide dispersive uses, except those under strictly controlled conditions. For consumer and industrial uses, it is often not possible to implement measures that would avoid releases of substances throughout their lifecycle into the environment.

Derogations from the extended generic risk approach should only be possible for essential uses (paragraph (7)) when no alternatives are available. Member States should have the possibility to initiate restriction proposals under the generic risk approach procedure. The REACH regulation should clearly describe the regulatory approach for the types of substances mentioned above. The policy objectives for dealing with the most hazardous substances need to be defined in law. For example, in order to implement the generic risk approach, it should be clarified that REACH Annex I, point 6.5, applies to all substances with any of these hazardous substance properties. It should also be made clearer that when substitution is not possible, adequate measures to minimise emissions into the environment from continued use must be implemented. Finally, REACH Article 55 could be further developed into an overarching objective for REACH Titles VII and VIII.

The proposed extension of the generic approach to risk management for restrictions should contribute towards the overall objective of strengthening the level of protection of the environment via preventive measures.

(7) The essential use concept

The essential use concept originates from the Montreal Protocol on substances that deplete the ozone layer (UNEP, 1987). It should be integrated into the REACH restriction system. A derogation for a use would only be granted when the use is necessary for health and security or critical for the functioning of society and when technically and economically feasible alternatives are not available. Derogations may be granted for a limited time, for example until alternatives become available.

The effectiveness of the essential use concept is based on the fact that the decision on the essentiality of a use should be based only on screening steps and a simplified evaluation procedure, rather than on a detailed cost-benefit analysis.

When the generic risk approach within the restriction system is combined with the essential use concept, every use which is not critical for society will not be granted as derogation. Thus, it will be effective to base a decision on a derogation only on the criticality of the use for society and the availability of alternatives. Consequently, a detailed cost-benefit analysis to grant or refuse a derogation for a use, will only be necessary for the specific risk approach within the restriction system.

The integration of the essential use concept as a derogation from restrictions is a preventive measure which should contribute towards the overall objective of strengthening the level of protection of the environment via preventive measures.

(8) Incentives for substitution

A "fee" should be introduced for the continued use of SVHC, with a gradual increase of the costs over time to avoid internalisation of costs (e.g. into product prices). Moreover, a sunset-date is needed for derogations from restrictions. Incentives for regulating groups of substances rather than individual substances should be provided, in order to prevent regrettable substitution. Research and innovation on safe-and-sustainable by design alternatives should be supported through relevant programmes (e.g. Horizon).

(9) The regulation of substances in articles

Manufacturers of articles in the European Union should have a level-playing field with their non-EU counterparts importing articles in the European Union. This can be achieved by increasing the use of restrictions (including by extending the generic risk approach) but also by further developing the authorisation system to cover substances in articles (UBA, 2015; UBA, 2020).

(10) Cooperation and coordination across legislation

Cooperation and coordination across legislation should be ensured in order to address substances that are used in various sectors (UBA, 2021c). For example, a cross-sectoral coordination body with representatives from European and Member State authorities could be established. Reporting obligations and common tools to access information (on properties, uses, exposures, alternatives, existing regulatory measures) could be aligned across legislation to assess progress towards the achievement of common objectives. Coordination should only take place where it really makes sense. It must also be ensured that this does not delay necessary regulatory measures, but results in faster and targeted measures. In particular, this should not lead to the installation of additional formal barriers.

Synergies and trade-offs should be identified at an early stage of policy making, for example in terms of achieving circularity for climate neutrality. In the context of authorisation and restriction, it should be possible to take full account of risks at the waste stage. Restrictions and not authorisations should also be possible with the aim of recyclability and prevention of contaminated waste streams.

Finally, cross-linkages with international conventions and instruments should be strengthened (e.g. Basel, Rotterdam and Stockholm Convention).

Table 3: Recommended objectives and building-blocks

Objectives	Building-blocks
(A) Improve **data** availability and accessibility	(1) **Information and notification requirements** - **Compliance check** of all registration dossiers - **Revocation** of registration numbers for enduring non-compliant dossiers - **Regular update** of registration dossiers mandatory - **Filling of data gaps** (group assessment, testing by authorities) - **Information requirements** apply to manufacturers and downstream users of PBT, vPvB, PMT, vPvM, ED, ELoC and CMR substances and include information on volume, use, alternatives, risk and waste management - **Provision of additional information upon request**
(B) Enhance **efficiency and effectiveness**	(2) **The simplified procedure for the identification of SVHC** - Identification as SVHC of substances with a **harmonised CLP classification** as CMR extended to PBT, vPvB, PMT, vPvM and ED substances - **Annex XV dossier** may be limited to a reference to an entry in CLP Annex VI or the inclusion may be automatic **without dossier** - The procedures for the demonstration of an **ELoC** and identification of SVHC **without harmonised classification** are maintained - Inclusion of separate letters for PMT, vPvM, and ED to REACH **Article 57** - Link to entry in to the **SCIP database**
(C) Increase **legal certainty and predictability**	(3) **The Candidate List** - Listing triggers a **"fee"** for manufacturers and DUs - Listing triggers **information requirements** for manufacturers and DUs
(D) Strengthen the **level of protection** of the environment via **preventive measures**	(4) **The authorisation system** - **Assessment of alternatives** on an overarching level - RAC and SEAC can **reject low-quality applications** - RAC and SEAC can **withdraw granted authorisations** if requested information has not been generated - **Link with CLP** new hazard classes (5) **The specific approach to risk management** - Maintained **for substances and/or risks that cannot be regulated under the generic approach** or for cases where more flexibility is needed - **Grouping approach** preferred - **Joint applications for derogations** prioritised - can include **aspects of the generic risk approach** (6) **The generic approach to risk management**

Objectives	Building-blocks
	- Extension to **PBT, vPvB, PMT, vPvM and ED** substances - Extension to products for **professional and industrial use** - Extension of the **right to initiate generic risk approach restrictions to MS** - **Definition of the regulatory approach** in the REACH text (7) **The essential use concept** - Integration as **derogation from restriction** - **Derogations from restrictions** granted only for uses that are critical for society and necessary for health and safety when alternatives are not available - Derogations granted for a **limited time** - The decision based on **screening steps** and a simplified evaluation procedure, rather than on a detailed cost-benefit analysis (8) **Incentives for substitution** - **"Fee"** for the continued use of SVHC with gradual increase of costs - **Sunset-date** for derogations from restrictions - **Grouping of substances** - **Research and innovation** for safe-and-sustainable by design chemicals supported through relevant programmes
(E) Introduce a **level-playing field** with non-EU companies	(9) **The regulation of substances in articles** - Extended generic risk approach for **restriction of substances in articles** - **Authorisation system to cover substances in articles**
(F) Ensure policy **coherence**	(10) **Cooperation and coordination** across legislation - Establish cross-sectoral **coordination bodies** - Set **common objectives** across legislation - Align **reporting** across legislation - Assess **impacts and trade-offs** across legislation - Strengthen **cross-linkages with international conventions** (e.g. Basel, Rotterdam, Stockholm and Minamata Conventions)

4 Recommendations for Procedural Steps

The German Environment Agency proposes a number of **simplified procedural steps** that should enhance the overall efficiency and effectiveness of the REACH authorisation and restriction system.

We propose the following procedural steps for the identification of SVHC:

- Substances with a **harmonised classification** as PBT, vPvB, PMT, vPvM, ED and CMR (Cat 1A, 1B) are identified as SVHC in a simplified procedure.
- The procedures for the demonstration of an **equivalent level of concern** and identification of SVHC without harmonised classification are maintained.
- Inclusion of these substances in the **Candidate List**.
- Inclusion in the Candidate List triggers **notification and information requirements** for manufacturers and downstream users, as well as certain operational conditions (OCs) and risk management measures (RMMs) to minimise emissions into the environment.
- Inclusion in the Candidate List triggers the obligation to provide additional **information upon request** for manufacturers and downstream users.
- Inclusion in the Candidate List triggers a "**fee" for the continued use of a SVHC** for manufacturers and downstream users, with a gradual increase of the costs over time.

We propose the following procedural steps for the revised restriction system (Table 4):

- The **generic risk approach** for restrictions is the preferred route of regulating PBT, vPvB, PMT, vPvM and ED substances of environmental concern.
- The **specific risk approach** for restrictions applies when unacceptable risks to the environment cannot be addressed by the generic risk approach.
- Member State competent authorities have the right to **initiate generic risk approach restrictions.** They should have the right to submit a restriction proposal to the Commission, which must set aside sufficient resources to process it within defined deadlines. The Annex XV dossier may be limited to a reference to an entry in CLP Annex VI.
- Derogations from restrictions for PBT, vPvB, PMT, vPvM and ED substances for consumer, professional and industrial uses (except under strictly controlled conditions) are only permitted when **uses are necessary for health and safety or critical for society** and when **no alternatives** are available.
- Manufacturers, importers or downstream users may apply for derogations from restrictions of substances in Annex XVII via **joint or individual applications** for similar uses. The area for possible derogations can be limited by decision of the European Commission supported by a positive opinion of the REACH Committee or in the REACH Annex XVII entry.
- Manufacture, use or placing on the market of substances of concern is **prohibited** (if no derogation applies) after [X] years.
- **Support for research and innovation for substitution** with safe-and-sustainable alternatives.

Finally, we propose that SVHC that cannot be addressed in a restriction should be regulated via the authorisation system (Table 4).

Table 4: Overview of recommendations

	Restriction via generic risk approach (GRA)	**Restriction via specific risk approach (SRA)**	**Authorisation**
Precondition (from an environmental perspective)	PBT, PMT, vPvB, vPvM, and ED properties	Unacceptable risk for the environment	SVHCs (not addressed under restriction)
Scope	Manufacturing, placing on the market or use (except industrial use under strictly controlled conditions)	Manufacturing, placing on the market or use	Uses of substances, import of articles containing the substance
Dossier	Shorter dossier	Annex XV dossier	/
Proposal for derogation	1.Dossier submitter 2. Users can propose specific derogation (limit to the scope described in Annex XVII)	1.Dossier submitter 2. Users can propose specific derogation (limit to the scope described in Annex XVII)	Applications by industry
Decision process	COM (ECHA opinion only on request) regulatory procedure with scrutiny	COM based on RAC/SEAC opinion; regulatory procedure with scrutiny	Examination procedure

5 Outlook

The REACH authorisation and restriction system is a centrepiece for regulating the most hazardous substances in the European Union. However, the latest REACH review concluded that some improvements were needed, in terms of legal clarity, efficiency and policy coherence. The revision of the REACH authorisation and restriction system offers a window of opportunity to tackle these deficiencies.

The German Environment Agency proposes in this paper a set of ambitious objectives and building-blocks, as well as procedural steps for the revised REACH authorisation and restriction system. With a simplified procedure for the identification of SVHC, the extension of the generic risk approach to further hazard classes and the integration of the essential use concept as a derogation from restrictions, some deeply transformative revisions are recommended, that largely support current proposals in the European Union.

The Chemicals Strategy for Sustainability has set a long-term vision for a toxic-free environment, where chemicals are produced and used in a way that maximises their contribution to society, including achieving the green and digital transition, while avoiding harm to the planet and to current and future generations (COM, 2020). It is also a major contribution towards the European Green Deal, and towards achieving the 2030 Agenda for Sustainable Development.

List of abbreviations

CARACAL	Competent authorities for REACH and CLP
CEFIC	European Chemical Industry Council
CLP	Regulation on the Classification, Labelling and Packaging of Chemicals
CMR	Carcinogenic, mutagenic and toxic to reproduction
COM	European Commission
CSS	Chemical Strategy for Sustainability
EC	European Council
ECHA	European Chemicals Agency
ED	Endocrine disruptor
EGD	European Green Deal
ELOC	Equivalent level of concern
EP	European Parliament
EU	European Union
IOMC	Inter-Organization Programme on the Sound Management of Chemicals and Waste
MSC	Member State Committee
OC	Operational conditions
OSH	Occupational safety and health
PBT	Persistent, bioaccumulative and toxic substances
PFAS	Per- and polyfluoroalkyl substances
PIC	Regulation on the Prior informed consent procedure
PMT	Persistent, mobile and toxic substances
PNEC	Predicted no-effect concentration
POP	Persistent organic pollutant
RAC	Risk assessment committee
REACH	Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk management measures
RMOA	Risk management option analysis
SCIP	Substances of concern in articles or products
SEAC	Socio-economic analysis committee
SIEF	Substance information exchange forum
SVHC	Substance of very high concern
UBA	German Federal Environment Agency
UNEP	United Nations Environment Programme
UNICEF	United Nations Children´s Fund
vPvB	Very persistent and very bioaccumulative substances
vPvM	Very persistent and very mobile
WHO	World Health Organization
WTO	World Trade Organization
ZPA	Zero Pollution Ambition

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