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Directorate-General for Internal Market, Industry, Entrepreneurship and SME's
Ecosystems I: Chemicals, food and retail
REACH

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Workshop for substitution of targeted hazardous chemicals supporting background document

1. Context of the workshop and Commission expectations

Regulation (EC) No 1907/2006, REACH, provides a framework to regulate the risks related to the use of hazardous substances. Where those risks are significant and cannot be adequately controlled by risk management measures, the regulatory framework aims at substituting those substances with safer and feasible alternatives, mainly via REACH *authorisations*, Title VII of REACH, or *restrictions,* Title VIII of REACH.

REACH has been successful in speeding up the substitution of such substances compared to its predecessor legislation. Nevertheless, the existing authorisation and restriction processes remain very resource intensive, both for companies and authorities. The pace of addressing those risks through substitution is still slow[1, 2] and has addressed only a limited number of substances and uses to date.

Lengthy procedural requirements along with complexities, such as the aggregation of heterogenous uses into a single use, have resulted in a significant regulatory challenge to the efficient transition to safer, sustainable and feasible alternatives. Such examples include authorisation of hexavalent chromium (Cr(VI)) substances, and challenges in preparing a broad restriction of PFAS substances. Both involve a wide range of uses and a high number of downstream users. The outcome of these challenges risk delaying actions to substitute the substance and missed opportunities for uses where earlier substitution may be possible.

In the course of the preparation of the impact assessment to support a revision of the REACH Regulation, various options to simplify authorisation and restriction were discussed. During those discussions, strengthening the role of substitution plans was identified as a potential tool to address the observed complex substitution cases, potentially using a more flexible and collaborative approach. This takes inspiration from existing voluntary models such as the industrial transition planning framework outlined in the recent *Transition Pathway for the Chemicals Industry*[3] to achieve EU climate goals that include a safer and sustainable chemicals dimension, as well as required substitution planning frameworks, such as under the Massachusetts Toxics Use Reduction Act (TURA)[4]. Other legislation could also provide lessons for more decentralised and collaborative processes supporting

[1]The need for speed, EBB, July 2022 Need-for-speed_Online_Final.pdf (eeb.org)
[2] Socio-economic impacts of REACH authorisations, A meta-analysis of the state of play of applications for authorisation, ECHA 2021, Socioeconomic impacts of REACH authorisations (europa.eu)
[3] European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, *Transition pathway for the chemical industry*, Publications Office of the European Union, 2023, https://data.europa.eu/doi/10.2873/873037
[4] TURI - TURI - Toxics Use Reduction Institute

substitution. These include the *substitution principle* under occupational safety and health legislation, such as Directive (EC) No 2004/37 or the Industrial Emissions Directive (EU) No 2010/75.

The potential role of substitution planning in achieving chemicals policy goals was insufficiently analysed in the study supporting the REACH impact assessment[5]. Thus, the Commission has launched a Study on ***Strengthening the role of substitution planning in the context of REACH and other EU chemicals legislation***. The study was awarded to a consortium of expert consultants, led by Logika Group[6].

The study will identify, evaluate and assess the impacts of options to better address substitution planning, to advance and expedite the replacement of hazardous substances with safer and more sustainable alternatives. Such options may involve changes to the REACH legislation or additional non-regulatory mechanisms to advance substitution such as support infrastructure and/or financial incentives.

The overall goal is to **accelerate safe substitution** and enable **efficient use of resources**. Specific objectives include:

- increasing the level of protection of human health and the environment;
- reducing resource intensity for authorities;
- providing greater predictability and, where appropriate, flexibility, both for companies using current substances and technologies and front-runner companies providing safer alternatives;
- enhance planning and co-operation between companies to speed up innovation and support the competitiveness of European companies.

The study is expected to be conducted over 12 months, with final outcomes by end of 2024. It will be supported by two workshops, organised by the Commission. This first workshop on 1 March 2024 is intended to:

- Discuss this document, which contains a thought starter setting out the Commission's initial analysis of the problem ("the problem definition") with the current regulatory system advancing substitution under REACH. It is intended to provoke reflection before the workshop and discussion during it. A final problem definition will form part of the study outputs.
- Exchange experiences with the analysis of alternatives and substitution plans in EU Member States and worldwide.
- Validate and refine the objectives of a substitution framework that aims to advance substitution goals envisioned under REACH.

Note that although options for substitution planning will arise in discussions, this workshop will not focus on concrete options at this stage. A second workshop will be organised later in 2024 to obtain feedback on *draft options* which will be developed based on additional research, consultation and analysis alongside your feedback at the current workshop.

2. *Workshop format and organisation*

The workshop will take place in hybrid format. This format has been chosen to obtain maximum engagement from diverse stakeholders, within logistical constraints.

Two plenary sessions will take place: An introduction in the morning and a closing session for conclusions and reflections in the afternoon. The plenary sessions will be both held in person in a

[5] REACH_Workshop report_21_03_2021.pdf (europa.eu)
[6] https://www.logikagroup.com

conference room and web streamed[7]. This plenary conference room has a capacity of 160 attendees. Web streaming will be available to all who wish to listen and watch.

Smaller discussion sessions will take place in between the two plenary sessions based on a modified *world café* format. These two discussion sessions will include a total of three in-person small groups that include a selection of attendees who expressed interest. Logistical constraints mean that physical spaces are limited to a total of 39 attendees. An additional three virtual discussion groups for a further 39 participants will also be conducted.

In case registrations for the physical participation in the plenary session, or for physical or online participation in the discussion sessions exceeds the number of available places, participants will be selected from the expression of interest using the following criteria:

- Balanced representation of stakeholder groups (Member States, industry, NGOs, academia…)
- Broad representation will be favoured over specific interest groups.
- Specific knowledge on substitution and provision of alternatives
- Geographical balance

Participants in the discussion sessions will be allocated to discussion groups of no more than 13 persons in each. Each group will discuss three specific topics in the morning and three specific topics in the afternoon. The groups will be facilitated by a representative of the organisers.

This background document is intended to serve as a basis for the discussions at the workshop. ***Participants, especially those attending the modified world café discussion groups are asked to carefully read this document prior to the workshop, to maximise contributions to discussions.*** After the workshop, minutes summarising the overall outcomes of the exchanges and discussions will be prepared.

A recording of the two plenary sessions will be published on the Commission´s website. The *world café* tables will be accessible only to the participants of that table. Any thoughts or contributions during the discussion sessions will serve as input to the further study work and to refine the options for possible solutions in the study. Only a summary of the discussion, keeping names of individuals and who they represent confidential, will be reported in the closing session and included in the minutes.

3. Regulatory context for substitution

The REACH Regulation, in particular, aims at securing a high level of protection of human health and the environment, while enhancing competitiveness and innovation. The assessment of alternatives and substitution plans have been key aspects in the regulatory process to address the risks and the use of hazardous substances. Key provisions addressing substitution within REACH include those for authorisation and restriction.

- **Title VII Authorisation** describes in detail the process for how the Commission can grant an authorisation to specific companies for the continued use of a substance listed in Annex XIV of REACH (authorisation list) and the conditions of that use for a specified period. The applicants, i.e., manufacturer(s), importer(s) and/or downstream user(s) of the substance, shall file an application for authorisation that includes an analysis of alternatives and, in many cases, a substitution plan. The application is reviewed by ECHA's scientific committees SEAC[8]

[7] For registered participants attending remotely, the links will be communicated closer to the event date.
[8] The Committee for Socio-economic Analysis (SEAC) prepares the opinions of ECHA related to the socio-economic impact of possible legislative actions on chemicals in the following REACH processes. The final decisions are taken by the European Commission. Committee for Socio-Economic Analysis - ECHA (europa.eu)

and RAC[9] that produce an opinion on the application. The Commission considers the committees' opinions and, if it concludes that the required conditions are met, grants a temporary authorisation for a use, via an implementing decision via the *comitology* procedure. Applications for renewed authorisations and review reports may be submitted before the end of the granted period if the applicant could not transition to an alternative. The average time between the submission of an application for authorisation to ECHA and delivery of the opinion to the European Commission for a decision is currently around 3 years.

- **Title VIII Restriction** describes the process for restricting dangerous substances resulting, for instance, in specific conditions of use, or maximum thresholds for content of substances in articles or mixtures. A restriction can regulate the manufacture, use or placing on the market of the substances (or group of substances) if it applies as a harmonising measure across the EEA. For restrictions based on specific risk management, the process requires filing a restriction dossier, that is prepared by Member State competent authorities or ECHA (on request of the Commission). The mandatory content of this is described in Annex XV of the REACH Regulation. The dossier includes a socio-economic analysis of the proposed measure, and may discuss the availability, suitability, and technical feasibility of alternatives. The dossiers are then subject to consultation and evaluated by ECHA's scientific committees SEAC and RAC that develop an opinion and send it to the European Commission. The Commission considers the committees' opinion and, if it concludes that there is an unacceptable risk to human health or the environment that needs to be addressed on a EU-wide basis, adopts an implementing regulation via the *comitology* procedure. The whole process of restriction takes on average 3 to 5 years[10].

Provisions for substitution in other chemicals legislation are also useful to consider as these experiences inform both challenges as well as opportunities for substitution planning under REACH.

- Under the **Cosmetics Products Regulation (EC) No 1223/2009** and the **Toys Safety Directive (EC) No 2009/48**, applicants are required to demonstrate that no suitable alternatives exist when applying for derogations from the ban of carcinogenic, mutagenic or toxic for reproduction, CMR, substances category 1.
- The **Restrictions of Hazardous Substances Directive** takes into account the availability, practicability and reliability of alternatives and the impacts of substitution on the environment, health and consumer safety as well as socio-economic impacts including innovation. Its scope are substances in electrical and electronic equipment. It is possible to file applications for exemptions from substance bans that shall include an analysis of possible alternative substances, materials or designs, as well as proposed actions to develop possible alternatives, including a timetable for such actions by the applicant.
- The **end-of-life vehicles** Directive (EC) No 2000/53 addresses the use of substances of concern and aims to limit those substances in vehicles with the aim to reduce and control their use in vehicles, in order to prevent their release into the environment, to facilitate recycling and to avoid the disposal of hazardous waste. Furthermore, the **Ecodesign for Sustainable Products Regulation** proposal COM/2022/142 aims to increase the information on substances of concern used in products, beyond their chemical safety and food safety, and limit the use of those substances if products' sustainability impacts are affected negatively, in particular recyclability and reuse among other aspects.

[9] The Committee for Risk Assessment (RAC) prepares the opinions of ECHA related to the risks of substances to human health and the environment in the following REACH and CLP processes. The final decisions are taken by the European Commission. Committee for Risk Assessment - ECHA (europa.eu)

[10] The preparation of a restriction dossier by MSCAs or ECHA has taken often two years. From the assessment by ECHA Committees until adoption of the restriction, it takes around three years but for complex restriction dossiers covering many substances, it might take even longer.

- **The Biocidal Products Regulation** and the **Plant Protection Products Regulation** (EC) No 1107/2009 foresee specific provisions for active substances that are identified as 'candidates for substitution' according to certain criteria. The placing on the market or use of such substance may only be approved for a shorter period of time than active substances not identified as candidates for substitution and all approvals are time limited. Before granting an authorisation for the placing on the market and use of a product containing the active substance, competent authorities are required to perform a comparative assessment to evaluate if the product can be substituted by other adequate alternatives, restricting or prohibiting the placing on the market or use if alternatives are available.
- The **Persistent Organic Pollutants Regulation (EU) No 2019/1021** obliges Member States to develop action plans which shall include measures to promote the development of substitutes. The Regulation also encourages exchange within the Union and with third countries of information relevant to the phase-out of persistent organic pollutants. The Commission, ECHA and the Member States shall promote awareness programmes, inter alia on alternatives. Derogations can only be included for essential uses for which safer alternatives do not exist and where the efforts undertaken to find safer alternatives have been reported on.
- The **Industrial Emissions Directive**, IED, aims to achieve a high level of protection of human health and the environment, by regulating pollutant emissions from industrial installations (emissions to air, water and land) as well as generation of waste, use of raw materials and water, energy efficiency, noise and prevention of accidents. Activities falling under the scope of the IED are required to operate in accordance with a permit which should contain conditions set in accordance with the principles and provisions of the Directive. Under the IED, the Best Available Techniques, BAT and associated environmental performance, are the reference for setting permit conditions by the competent authorities. Under the revised IED, each installation must have an Environmental Management System, including an inventory of hazardous substances, a risk assessment of these substances and an analysis of the possibilities to substitute them with safer alternatives or reduce their use or emissions.
- The **Carcinogens, Mutagens or Reprotoxic substances Directive (EC) No 2004/37**, CMRD, sets out the minimum requirements for protecting workers against risks to their health and safety - arising or likely to arise - from exposure to carcinogens, mutagens or reprotoxic substances at work. It lays down preventive and protective measures, as well as (binding) occupational exposure limits. To implement these measures, employers are obliged to reduce the use of a CMRs at the place of work by replacing it by substances, mixtures or processes which, under its conditions of use, are not dangerous or are less dangerous to workers' health or safety. When a replacement is not technically possible, the CMRD obliges the employer to ensure that the substances are manufactured and used in a closed system or, where a closed system is not technically possible, the risk for workers is reduced to a minimum by other means.

4. Substitution concepts and frameworks in the EU and worldwide

Although REACH implementation provide**s** lessons regarding needs and opportunities to more effectively and efficiently advance substitution, there are a range of additional models for substitution and substitution planning to consider in developing options in the future.

Transition pathways

As laid out in the Updated 2021 Industrial Strategy[11], transition pathways are lists of actions and conditions needed to achieve the green and digital transition of EU industry. The Transition Pathway for the Chemical Industry published in January 2023 highlights about 190 actions needed to achieve the twin transition and increase the resilience of the EU Chemical Industry. These actions are

[11] https://ec.europa.eu/commission/presscorner/detail/en/ip_21_1884

organised in eight building blocks, including sustainable competitiveness, research and innovation, regulation and governance, access to energy and feedstocks, infrastructure, skills and the social dimension of the twin transition. The pathway was developed in cooperation with chemical industry stakeholders[12], Member States, NGOs, and other interested parties. The actions needed to achieve the transformation require investments and measures by EU institutions, Member States, trade unions and industry stakeholders.

Massachusetts Toxics Use Reduction Act, TURA

TURA is a law in U.S. state of Massachusetts that requires users of large quantities of specific toxic chemicals (with smaller quantities for highly hazardous chemicals) to evaluate their operations and plan for toxic use reduction opportunities, including substitution options. TURA created a substitution support infrastructure by establishing the Office of Technical Assistance and Technology (OTA) and the Toxics Use Reduction Institute (TURI). From 2000 to 2020, Massachusetts companies reduced toxic chemical use by 75%, waste by 67% and releases by 91%. Reductions in the use of specific toxic chemicals have been even more remarkable. For example, from 1990 to 2020, the use and release of a known carcinogen, trichloroethylene (TCE), was reduced by 95% and 97%, respectively.

SUBSPORTplus Portal[13]

This web-based portal is a reliable source of information on regulations and safer alternatives for hazardous substances. The portal is supported and hosted by the German Federal Institute for Occupational Safety and Health (BAuA)[14] and is the result of a LIFE project[15] in which environmental and safety institutes of EU Member States and other experts participated. The portal includes a database on legislation, lists of hazardous substances, substitution tools as well as a repository of case studies and offers tailored assistance about the safe use of substances that cannot be replaced.

Swedish Centre for Chemical Substitution

Established in 2018/2019 and run by RISE – the Centre acts as a hub for promoting chemicals substitution. The Centre offers customized training and resources on substitution as a concept as well as substitution planning, including adapting ECHA's training program on the assessment of alternatives for Swedish companies and organizations. The Centre also stimulates and support the identification and use functional substitutes; develops positive lists of alternatives; and support R&D on alternatives using safe-by-design and circularity thinking.[16]

Economic instruments to incentivise substitution of chemicals of concern

The Organisation for Economic Co-operation and Development (OECD) has performed extensive research on policies and initiatives to identify alternatives and substitute hazardous chemicals[17]. According to the OECD's publication *Economic instruments to incentivise substitution of chemicals of concern – a review*[18] economic instruments can provide continuous incentives for industry to innovate and substitute hazardous chemicals with safer alternatives. The lack of transparency along the supply

[12] EU Chemical Industry Transition Pathway (cefic.org)
[13] BAuA - SUBSPORTplus - Startseite - Bundesanstalt für Arbeitsschutz und Arbeitsmedizin
[14] German Federal Institute for Occupational Safety and Health, BAuA - Startseite - Bundesanstalt für Arbeitsschutz und Arbeitsmedizin
[15] LIFE08 ENV/D/000027
[16] RISE. Welcome to the Swedish Centre for Chemical Substitution.
[17] OECD webpage *Alternatives assessment and substitution of harmful chemicals* Alternatives assessment and substitution of harmful chemicals - OECD
[18] OECD (2023), Economic instruments to incentivise substitution of chemicals of concern – a review, OECD Series on Risk Management, No. 79, Environment, Health and Safety, Environment Directorate, OECD. Economic instruments to incentivise substitution of chemicals of concern – a review (oecd.org)

chain is still a bottleneck, as the integration of safety and sustainability considerations into a product's pre-market design phase can be complex and requires the involvement of all actors in the supply chain and potentially other stakeholders, such as competent authorities. Economic instruments can incentivise substitution without stipulating what technology or action each actor should take.

Chemical substitution processes can be complemented by third-party approaches that mainly aim to distribute information on chemical substances and substitution options and efforts among governments and other stakeholders.[19] The range of third-party approaches includes tools and frameworks to help practitioners to conduct alternatives assessments, implement training, capacity building via professional networks, stimulate market demand for retailers and manufacturers, and help consumers make informed purchasing decisions via transparent labelling and awareness-raising advocacy.

5. *Problem definition – thought starter*

To achieve the goal of minimising the use of and substituting the most harmful substances while safeguarding and promoting the competitiveness of EU industry, the transition to safer and more sustainable alternatives – namely different substances, or changes in process, material or technology – is crucial. Although industry has an interest to act responsibly and avoid damages to health and the environment from their activities or products, they must be successful on the market, make profits and sell their products. Where substitution requires moving to alternatives which are more expensive or require product reformulation, may not achieve the same performance as the substance to be substituted, or where there is simply less experience with the use of the alternative, substitution is unlikely to happen in the absence of regulatory measures.

Understanding the problems with substitution under the current regulatory system of authorisation and restrictions under REACH is the first step towards identifying options for substitution planning that mitigates those challenges. Outlined below are 5 primary problems, based on the Commission's analysis, that are hindering substitution goals under REACH. Together, these start to *define the problem* to be addressed in the current study. The workshop offers an opportunity to review the problem analysis and discuss refinements to ensure that options pursued in the study focus on these underlying challenges and reflects views of all stakeholders.

1. Substitution requires time and resources; these needs are highly varied across uses and users of the hazardous substance. This complicates current efforts to make regulatory substitution processes and decision making efficient and effective for all stakeholders.

The technical, economic or legal feasibility of alternatives and their availability often depends on a set of company- and utilisation-specific considerations. Those considerations can evolve over time, as technology and production capacities are being developed. However, variation in substitution needs as outlined in A-E below complicates regulatory decision making, can constrain industry and slows substitution.

A. *Performance testing is generally needed to support substitution requirements but needs are not the same for all uses of a hazardous substance.* It may not be clear from the outset whether the alternative works in a particular product, so testing and building prototypes may be necessary. For instance, replacing PFAS in semiconductor production will require testing

[19] OECD (2023), Lessons Learned from Third-Party Approaches that Support Substitution of Chemicals of Concern, OECD Series on Risk Management, No. 78, Environment, Health and Safety, Environment Directorate, OECD. Lessons Learned from Third-Party Approaches that Support Substitution of Chemicals of Concern (oecd.org)

whether the necessary quality of chips can be achieved with the alternative, or whether undesired effects of alternatives (e.g. foaming during production) prevent a switch to the alternative. Depending on where a component produced with a hazardous substance ends up, a different level of loss of performance due to the switch to an alternative may be acceptable. For example, alternatives to hexavalent chromium (Cr(VI)) substances providing less corrosion protection may be acceptable for aeroplane seats but not necessarily for safety relevant machinery parts on the outside of an aeroplane.

B. *The financial, technical and resource constraints of companies to implement product, process and/ facility redesigns to accommodate alternatives greatly varies and is costly.* Often it is possible to use a substitute in new products, but it is much more difficult to switch to alternatives in products that are already on the market or in existing installations (e.g. industrial production sites), in particular if the use is only a small element of a much bigger production process. Companies differ in available space and resources to change production processes. For example, some companies may not have spare capacity to build a parallel production line, or need to seek permits to expand the factory, others might not have the financial capabilities to change to another machine or train staff on how to handle an alternatives. For instance, certain cooling systems require the use of a hexavalent chromium (Cr(VI)) substance, while others do not. Therefore, the only way for such companies to replace the hexavalent chromium (Cr(VI)) substance would be to build a new cooling installation, while the old one has the potential to last for decades more. For other companies, such as manufacturers and formulators of chemical substances with specialisation in a certain type of chemistry, shifting their production to a different substance requires additional time and investment.

C. *Getting alternatives to scale in the volumes needed takes time.* It may take time to build up the necessary production capacities for supplying the entire EU market with an alternative. For example, even if the switch to alternative chrome plating technologies is considered technically feasible for certain utilisations and the alternative is already applied, it may take years to build the necessary production capacities for the alternative technologies to serve the entire EU market.

D. *Legal approvals and specific industry/product certifications take time*. Legal requirements (hazard assessment of newly developed alternatives, medicine approvals, airworthiness certification etc.) may take time. For instance, new products introduced to the aeronautic sector need to obtain an aeronautic certification, which proves that the properties of the new product are in line with safety requirements. Similarly, some medical devices are used for very specific treatments of only a limited number of patient's needs. As development of such devices is expensive and requires certification, it may not be economically feasible to redesign such devices, even if, in new devices, another substance or technology could be used.

The above variations in needs and resources means that it is very difficult or almost impossible for authorities (without looking into company and process/product specific data) to establish whether an alternative exists and whether and by whom it can be used. Given these constraints, earlier substitution planning by companies to accommodate realistic time and resource needs associated with innovation, redesign/reengineering, testing and scaling of alternatives may be necessary. Such earlier planning may support authorities with timely decision making at the same time as wider

efficiencies in the regulatory process for industry alongside improved health and environmental outcomes.

2. Downstream customers and upstream value chain characteristics can hinder substitution

In some value chains, customers' preferences can prevent substitution; there are cases where one supplier provides the same or similar products to many clients who may have different requirements. For example, even if a company producing chromium-plated components for aircrafts understands the benefits associated with moving to an alternative, they may not be able to switch the (entire) production to that alternative, if their biggest customer insists on chromium plating. Similar effects may also occur the other way around, i.e. downstream users may have difficulties influencing their supplier. For example, a paint company might want to use a dispersing agent without a specific hazardous substance, but suppliers do not produce or develop it as the demand is too low. This means that availability of the alternative at sufficient quality and often from multiple suppliers is needed to ensure supply chain resilience. The level of knowledge to understand these challenges may not be easily available to authorities in making regulatory judgements.

3. Uniform transition periods may result in unintended hinderances to substitution

Authorities can make allowance for the time required to substitute in their decision making via setting transition periods. For some uses, setting one transition period is sufficient to enable timely substitution and without excessive cost. However, for other uses setting a uniform transition period may not be the most appropriate solution, in particular if a use covers a wide range of different utilisations and if company-specific barriers predominate. If the transition period is set "early", i.e., when only some users can substitute the substance, this may cause disruptions, as companies may have no choice but to cease manufacturing of the product or move production outside the EU, to serve markets where the use of the substance is still allowed. Or a company may switch to a regrettable substitute given a limited timeframe to substitute and the limited options at sufficient scale. So this may risk avoidable societal costs and/or regrettable substitution.

Conversely, if the transition period is set "late", this may provide insufficient incentive to substitute the substance earlier than the end of the transition period, wherever the use of the targeted substance is cheaper, gives a higher quality of the process or product or is simply better tested or accepted.

However, defining differentiated transition periods to reflect such differences requires a level of regulatory detail, resource and time that appears impracticable. In the worst case, such situations can lead to prolonged and inconclusive discussions. Non-governmental organisations and alternatives producers may highlight the existence of alternatives, while companies may highlight their inability to substitute. In such cases both views may be right for specific utilisations and the problem lies in the difference between the considered utilisations. This risks suboptimal outcomes for all concerned.

4. Risk of regrettable substitution

Yet another, major consideration is "regrettable substitution". In other words, there may be alternatives, but these may be equally bad or even worse from a health and environmental point of view than the targeted substance in the considered use. Where pressure exists to substitute the substance, without due consideration of the risks of alternatives or adequate time to substitute, this may de facto worsen health and environmental impacts. In the absence of regulatory pressure or support from the authorities, industry may be inclined to use well-established solutions rather than alternatives with uncertainties and risks with respect to their performance and market acceptance. Sometimes, there may also be better alternatives but that require more time to implement than short term solutions. In the absence of clarity on which solution to prefer, responsible companies will face dilemmas which they cannot resolve on their own.

It is noted that currently there is no agreed system to make detailed comparison between the safety of a substance in use (for which detailed information on exposure and emissions is available) and the safety of using an alternative substance (or technology), for which limited exposure or emissions data may be available. As a result, often the analysis is limited to the comparison of the hazard profiles of the substances. Whereas a certain prioritisation between different hazards exist, this may not fully take into account trade-offs about the potency of a particular substance (there are carcinogens with low carcinogenic potency that may be preferred over a potential alternative with a high skin sensitisation potency), nor the functionality (a minute use of a carcinogen that has a high functional performance may actually be preferable to the use of a skin sensitiser, which, due to its limited functional performance, would have to be used in much larger quantities).

5. No obligation for involvement amongst all value chain actors

A problem with current regulatory approaches is that they are focused on analysing substitution possibilities by the actor actually using the substance, but substitution often requires the involvement of other actors in the supply chain. Therefore, current regulatory approaches might not address the needs of substitution in complex value chains effectively and efficiently[20]. In such cases, minimising the use of or substituting targeted hazardous substances, while safeguarding and promoting the competitiveness of EU companies in complex value chains and products, needs to be coupled with the actual way industrial sectors approach innovation, research and development.

Complex industrial value chains, for example automotive, aerospace, high-tech, semiconductor, or industrial machinery are heavily interlinked. The use of specific mixtures, the design of parts, and the use of a particular production process is carefully defined to reply to highly demanding technical specifications and ensure the products' safety and performance. Often, producers of a specific article or mixture in the middle of the value chain have a very limited capacity to propose alternatives to the use of targeted hazardous substances. The producer of a part may have little knowledge on whether a specific performance or design can be modified or adapted in order to use an alternative substance or process by their customers.

As such, innovation on alternatives in complex value chains seldomly occurs in isolation. Multidisciplinary teams of experts, from providers, customers, suppliers and final users are put in place to design alternatives and move towards, lighter, stronger, or cost-efficient solutions. A framework that is effective in achieving substitution for uses in such circumstances is likely to require a similar approach; involvement of all actors across complex value chains to find the best alternative for each use of targeted hazardous substances.

Examples illustrating the above problems and potential solutions

Two examples below: (a) authorisation of hexavalent chromium substances; (b) universal PFAS restriction reflect some of the challenges s identified above. A third example, use of substitution plans under RoHS may provide insights on options to address several of the problems identified.

Example A. Authorisation of hexavalent chromium (Cr(VI)) substances under REACH

The current procedures under REACH authorisation are very complex, time consuming and have proved controversial. Court cases[21] have clarified the legal requirements for granting authorisations for those substances, in particular with regard to the analysis of alternatives and the suitability of alternatives. Retrospectively, particular uses (e.g. uses with mainly decorative functions, or uses as an

[20] For example, answers from companies to the ECHA's consultation on the U-PFAS restriction highlight difficulties in substituting PFAS in complex value chains. See: Comments submitted to date on restriction report on PFAS - ECHA (europa.eu)

[21] Cases T-837/16 and C-144/21

anti-corrosion agent in cooling equipment) where the main factors in the decision making process were comparatively clear and where use is homogenous, could have been decided faster.

Nevertheless, most applications have concerned uses which pose complexities (e.g. uses in aeroplanes, machinery or equipment where safety or longevity is relevant and depends on use/company specific factors). The criteria and the issues the Court cases have examined raise questions on the feasibility of the process with respect to the amount of available resources to analyse applications for authorisation. Moreover, even with the best possible applications, many factors remain unclear. In particular, the current process insufficiently takes into account the risks of alternatives and how to precisely determine the acceptable loss of performance of an alternative.

Experience shows that despite the complexity of the procedure, and the time and resources needed to take decisions on the relevant authorisation applications, substitution has not taken place where it might have been possible long ago in some complex cases. In addition, the delay of decisions has negatively affected investments, both in development of alternatives and in products requiring current uses of hexavalent chromium (Cr(VI)) due to the uncertainties of the legal situation. Banning all uses of hexavalent chromium (Cr(VI)) substances would however not provide an adequate solution either, as it is clear that many uses do not have alternatives yet and still need to continue in the foreseeable future and societal needs would be negatively affected by such disruptive bans.

Example B. Universal PFAS restriction

Another example is the ongoing REACH restriction of PFAS substances[22]. Uses of PFAS substances are incredibly heterogeneous. For some uses, substitution options have been developed and are available, for example uses such as food packaging, anti-sticking pans, ski waxes, outdoor clothing. For other uses, alternative solutions are more complicated given technical needs and the lack of readily available alternatives that meet performance standards (though these standards could be questioned), such as uses within semi-conductors, membranes in technical uses such as hydrogen production, in medical devices such as heart pacemakers, or uses in automotive and aerospace parts. As analysing all factors on such uses takes substantial time, there is a risk of delaying measures when all uses are aggregated within a single restriction. Moreover, it remains to be seen to what degree it will be possible to set uniform phase-out dates for more complex substitution cases, due to the large variation of uses and requirements for those uses.

Example C. RoHS substitution plans

The time-limited exemptions under the RoHS Directive can be seen as an instrument to promote substitution, where alternatives are already available and reliable.

The regular re-application and review of exemption entries should eventually result in a phase-out of using hazardous substances in electrical and electronic equipment. To plan the phase-out, the applicant has to include a substitution plan within the submitted application. Past experience has shown that some recurring applications repeat the same arguments and time periods needed as in previous applications, even many years later. This partly reflected external circumstances, but a plan that is not implemented can hamper efforts to substitute hazardous substances.

Narrowing the scope of exemptions under RoHS over the years lead to an increased technical complexity and level of detail. Instead of focusing on larger and general application areas, as was the case at the beginning of the Directive's implementation, exemptions focused on specific applications, where substitution was not easily applicable, and thus were split into sub-exemptions. This trend also

[22] ECHA published the PFAS restriction dossier prepared by five national authorities in February 2023, All news - ECHA (europa.eu)

leads to greater expense and more difficult argumentation for the applicant, which might be one of few manufacturers with the relevant technical expertise. This practice, of setting intermediate steps, often applied to applications which exhibited the complexities described above. Experience showed that before removing the last sub-exemption, the argumentation mainly referred to socio-economic impacts and a majority of the industry made the transition.

For applications where substitution was technically straightforward but intensive in terms of time (e.g., redesign and requalification of the electrical and electronic equipment), time-limited exemptions without narrowing the scope have been required. This experience demonstrates that high requirements for granting of exemptions favours early substitution. Depending on the case, long lead times for the expiry of exemptions are important for the adaptation of industry and applying clear expiry dates allows stakeholders time to prepare.

Besides the exemption procedure under the RoHS Directive, other initiatives and measures in the field can significantly contribute to substitution:

- Labels/certificates for manufacturers of products (such as Blue Angel, the Nordic Swan, Austrian Ecolabel, EU Ecolabel, Cradle to cradle certificate, TCO Certified);
- Requirements for the public sector (e.g., EU Green Public Procurement, Minimum Environmental Criteria in Italy).
- Financial incentives for producers and importers (e.g., eco fee modulation with a bonus/malus system; taxes with deduction mechanism);
- Internal company declarations for suppliers (Product Content Declaration for IBM Suppliers, Hewlett-Packard's environmental standard);

6. Overview of the objectives of the study

The aim of the study[23] is to identify, evaluate and assess a series of options (a "framework") utilising substitution planning to better address the replacement of hazardous chemicals with safer, more sustainable and feasible alternatives. Such a framework should seek, on the one hand, to provide more flexibility and predictability for industry in the transition process to safer alternatives, supporting innovation and the long-term competitiveness of EU industry. And on the other hand, reduce the resource intensity for authorities to regulate complex uses, allowing them to tackle a wider range of substances more quickly with better and faster outcomes for human health and environmental protection.

As such, in line with the terms of reference of the study, the initial objectives of a substitution framework may comprise the following:

1. speed up innovation and substitution of targeted substances and uses (allowing different competitive solutions, where possible);
2. promote earlier and higher standards of health and environmental protection from chemical risks;
3. enhance competitiveness of involved EU companies (both companies using the targeted substance and alternative providers), by
    a) avoiding economic disruptions and delocalisation of economic activities out of the EU and allowing more appropriate, proportionate and flexible solutions for the continued use of

[23] Tender specifications available at CIRCAB CARACAL 50 Circabc (europa.eu)

targeted substances during complex substitution processes, where suitable alternatives are not available;

b) promoting new market opportunities and fostering market uptake of alternatives where and when they become available, avoiding undercutting by free-riders;

c) creating more predictability and investment security for European industry;

4. render regulation on substituting substance uses with complex use patterns more efficient, effective and manageable for EU authorities and Member States.

When an agreed list of objectives are finalised, they will form a critical component of the study as they will provide the criteria by which options to enhance substitution and the use of substitution planning can be assessed. The workshop offers an opportunity to review the above objectives in light of the problem definition outlined in the prior section and discuss whether those objectives are appropriate, need to be amended or further specified.

7. Questions to be discussed at the workshop.

Participants attending the world café discussions will be asked to respond to the following questions during the morning and afternoon sessions. Each question is allotted 30 minutes for discussion. Please come prepared to provide succinct remarks, recognising both the complexity of the issues and the need for us to hear from all participants. Please reflect on perspectives and analyses provided in this background paper as well as your own experience in order to provide useful input to the study.

Morning session:

Question 1. Refining the Problem Definition. The background paper identifies 5 primary challenges with the current REACH substitution regulatory framework and/or its implementation that is hindering the replacement of hazardous substances with safer, more sustainable and feasible alternatives.

- *Please offer additional insights or experiences on these challenges particularly with regard to the current regulatory framework and its implementation. Does this experience differ based on experience with substitution or substitution planning requirements under different regulations or with different sectors/product types (e.g., REACH RoHs, biocides)?*
- *What challenges/additional problems with the current regulatory framework are missing?*

Question 2. Validating objectives of the substitution framework. The background paper outlines 4 primary objectives (along with sub-objectives) of a substitution framework to advance policy goals under REACH. These objectives are important to clarify and prioritize as they will serve as criteria used in the study to evaluate the merits of policy options focused on the use of substitution planning.

- *Are these the right set of objectives? What's missing? Should any be removed?*
- There are likely trade-offs across the options**.** *If you had to prioritize 3 objectives for a substitution framework, what would they be?*

Question 3: Information needs to support speeding-up regulatory substitution timelines. Experience to date reveals that research, evaluation/testing and redesigning products/processes to support substitution takes time. How can early information on uses, exposure and alternatives speed up substitution of targeted hazardous chemicals in advance of regulatory requirements?

- *How can early discussion on alternatives be triggered and implemented and burden on companies, especially SMEs, be minimised? What information is needed or would be useful to support early substitution planning and how should it be provided?*
    - Please draw in experiences from use of substitution planning/regulatory programs in the EU and globally to the extent possible.

Afternoon Session

Question 4. Legal/voluntary substitution planning requirements. Existing models demonstrate a range of required and voluntary uses of substitution planning.

- *Should the regulatory use of substitution planning remain limited to provisions in current policy (e.g., its current role under REACH authorisations) or be extended to other applications (e.g., as a precondition for derogations from REACH restrictions)?*
- *How can voluntary use of substitution planning complement existing regulatory provisions supporting the substitution of targeted substances and uses?*

Question 5. Focus of the substitution plan. Considering both your reflections in advance of the workshop and the group's discussion in Question 4, how can substitution planning be most effectively and efficiently implemented?

- *Should individual companies create their own substitution plans? Is there value in pursuing an industry/use/value-chain wide substitution planning approach? Or a combination of both?* Please draw in experiences from use of substitution planning in the EU and globally.
    - If per company, how can the appropriateness of company-based substitution plans be exhaustively assessed without overstretching authority resources?
    - If industry/value-chain wide, how can joint plans be elaborated/co-ordinated? How can anti-competitive practises between companies be avoided; how can innovators best be protected; and how can confidential business information be managed?

Question 6. Who prepares, reviews and monitors implementation of plans? Existing models demonstrate various substitution planning structures and these vary whether the plans are mandatory or voluntary.

- *Who should be the actors involved in the preparation of substitution plans and how should decisions on their appropriateness be taken?*
    - Should the implementation of substitution plans be left to industry, or should there be continuous/periodic monitoring of the implementation and adjustment of the substitution plans over time?
    - How should third parties (alternative providers, NGOs, substitution centres, academia) be involved in the preparation and assessment of substitution plans and the monitoring of their implementation?
    - What role could periodic workshops take and by whom/how would those be managed?