Report

Study on strengthening the role of substitution planning in the context of REACH and other EU chemicals legislation

Workshop Report: Workshop 1

For the European Commission (DG GROW)

3 May 2024

Document control

Project Title:	Study on strengthening the role of substitution planning in the context of REACH and other EU chemicals legislation
Project Number:	J11/12140C/11
Client:	European Commission (DG GROW)
Principal Contact:	David Tyrer davidtyrer@logikagroup.com
Document Title:	Workshop Report: Workshop 1
Document Number:	J11/12140C/11-001
Prepared By:	Marko Ristić-Smith, David Tyrer
Reviewed By:	David Tyrer

Revision History

01	03/04/2024	First draft
02	03/05/2024	Final draft

Registered Office: 23 Coldharbour Road, Bristol BS6 7JT Tel: +44(0)117 974 1086

24 Greville Street, Farringdon, London, EC1N 8SS Tel: +44(0)20 3873 4780

First Floor, Patten House, Moulders Lane, Warrington WA1 2BA Tel: +44(0)1925 937 195

Avenue du Port, 86c Box 204, 1000 Bruxelles Tel: +44(0)20 3873 4784R

Contents

1 Executive summary

Purpose of study and workshop objectives

On March 1st 2024. a hybrid workshop was held at the European Commission (DG GROW) as part of a study on "strengthening the role of substitution planning in the context of REACH and other EU chemicals legislation". The study, expected to be completed by the end of 2024, will identify and evaluate options to better address substitution planning. Such planning seeks to expedite replacement of hazardous substances with safer and more sustainable alternatives, efficiently. The study is supported by two stakeholder workshops. The first workshop on 1 March 2024 sought input on challenges with the current regulatory system advancing substitution under REACH and to refine policy objectives for any potential revision of the substitution process or "framework". It did not focus on concrete options. This report summarises discussion at the workshop and provides links to background materials.

Workshop questions and feedback

The workshop consisted of opening and closing plenaries. Between these, six breakout groups with balanced stakeholder representation discussed six workshop questions (Qs). A brief summary of the questions and attendee feedback is below.

- **Q1: Refining the problem definition:** The European Commission prepared a background paper with five key challenges, for participants to review and comment on . First, substitution requires time and resources and challenges vary between uses and users of hazardous substances. Second and third, both value chain characteristics and uniform transition periods can hinder substitution. Fourth, risks of regrettable substitution arise and fifth, obligations for involvement in the substitution process amongst all actors are lacking. Participants judged these accurate, but provided further detail, clarification and improvement. They raised additional challenges which included a lack of key data, including from registration dossiers, on exposure, uses to enable efficient and effective regulatory decision-making. Another reflected lack of support for frontrunners and providers of alternatives alongside insufficient predictability in regulatory decision-making.

- **Q2: Validating objectives of the substitution framework**: Four objectives were presented in the background paper for critique and prioritisation, if possible: i) speeding up innovation and substitution of targeted substances and uses; ii) promoting earlier and higher standards for health and environmental protection from chemical risks; iii) enhancing competitiveness of affected EU companies (users of targeted substances and alternatives providers) and iv) an efficient, effective and manageable regulatory system for EU authorities and Member States, including in cases with complex use patterns. Participants validated the objectives but sought further detail and clarification. All were considered important, there was no consensus on priorities. Some felt additional objectives were required on: creation and availability of information on hazard, risk, and alternatives; on communication along the supply chain; on early engagement with substitution activity; and on clarity and transparency over regulatory scope and timelines.

- **Q3: Information needs to support speeding-up regulatory substitution timelines:** Participants agreed regulation is a key driver of substitution, so clear and early information on proposed restrictions and their scope, for example, is key. Some attendees considered further supply chain dialogues were required to trigger earlier substitution efforts, noting requirements of competition law and challenges posed by protection of confidential business information (CBI). Some felt the use of economic instruments would help align incentives, preferably rewarding frontrunner companies. Further information on possible alternatives/greater

involvement of alternative providers was noted and this may be facilitated by a coordinated information platform(s).

- **Q4: Legal/voluntary substitution planning requirements:** Given substitution activity usually reflects multiple policy requirements, attendees felt other legislation should be considered. Some attendees felt earlier provision of data would aid authorities select the most appropriate regulatory action(s) and that better coordination amongst authorities with regulatory oversight for different legislation would also help. There was no consensus on whether new or amended provisions for substitution planning should be mandatory, voluntary or a combination of both.

- **Q5: Focus of the substitution plan:** Participants noted both individual and sector wide approaches may be appropriate, given the diversity of resources, capacity and challenges. Some felt different levels of collaboration may be practicable, for example overall direction and strategy undertaken at a sector level, but specific actions by companies. Others noted the nature of competition between actors affects collaboration, suggesting joint arrangements for certain stages of the value chain may be more appropriate. It was noted lessons may be learned from the greater interaction in the development of derogations under RoHS, for example. Joint platforms to facilitate information exchanges may be required as long as these do not cause delay. Participants identified specific risks with a sector-wide approach, for example free riding and ensuring fair participation of SMEs. Participants emphasised plans should remain suitably ambitious.

- **Q6: Who prepares, reviews and monitors implementation of plans?** Respondents felt three stages be considered. First, it was agreed industry should lead the *preparation of plans*. As above, some participants felt a combination of sector wide and company level plans may be appropriate, with specific measures to ensure plans are both realistic and ambitious. Second, *evaluation of the plan(s)*: challenges for authorities with the current process were recognised and some advocated for an independent assessment centre/entity, at least for more complex cases. An overall theme was that any such approach must be transparent. Third, *monitoring of plans*: Some felt additional monitoring is necessary, but there was no consensus on who undertakes it, nor how it should be done. Some felt a review of plans could be "triggered" if proposed timelines had not been met and/or the situation vis a vis alternatives materially changed.

Next steps

A second workshop will be organised (likely in September 2024) to obtain feedback on draft options developed based on additional research, consultation and analysis, alongside the feedback summarised in this report. Further details will be provided when the date is confirmed. To provide information of use to the study, please contact the European Commission via email at GROW-ENV-REACH-REVISION@ec.europa.eu and David Tyrer at Logika Group davidtyrer@logikagroup.com.

We sincerely appreciate the participation and engagement of participants and those who have sent information subsequently.

2 Workshop background

2.1 Introduction

On March 1st 2024, a hybrid workshop was held at the European Commission (DG GROW) premises on Avenue d'Auderghem 45, Brussels. The workshop was held as part of a study on "strengthening the role of substitution planning in the context of REACH and other EU chemicals legislation". This study is being led by a contractor team from Logika Group[1], alongside partners from Aperion[2], Vitis Regulatory[3], Mayer Brown[4] and experts Molly Lefevre and Professor Joel Tickner. A link to the study terms of reference is available on CIRCABC[5].

This workshop report is intended for all interested stakeholders, both those who participated in the workshop and those who did not. **The European Commission has published the final agenda, the background paper, the presentations from the plenary and feedback sessions as well as a video recording of both the opening plenary and the feedback sessions. All are available here: https://single-market-economy.ec.europa.eu/events/substitution-targeted-hazardous-chemicals-2024-03-01_en**

2.2 Workshop context

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).

During 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, perhaps using a flexible and collaborative approach. It was noted lessons may also be gleaned from other regulations and approaches from within the EU and beyond.

The study will identify and assess the impacts of options to better address substitution planning, with the aim to advance and expedite the replacement of hazardous substances with safer and more sustainable alternatives. Such options may involve changes to the REACH legislation and/or non-regulatory mechanisms to advance substitution, such as support infrastructure and/or financial incentives, or a combination. The overall policy goal is to accelerate safe substitution and enable efficient use of financial and human resources form authorities and industry

The study is expected to be conducted over 12 months, with final outcomes by the end of 2024. It will be supported by two stakeholder workshops. The first workshop on 1 March 2024 had the following objectives:

[1] https://www.logikagroup.com/
[2] https://apeiron-team.eu/
[3] https://www.vitisregulatory.com/
[4] https://www.mayerbrown.com/en
[5] https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/fe49b45f-4c5b-4a44-86f1-39163919aac3/details

- Further discussion on the issues originally set out in a background paper. This was a "thought starter" containing the Commission's initial analysis of the problem ("the problem definition")[6] with the current regulatory system advancing substitution under REACH. This was intended to provoke reflection amongst participants before and during the workshop. 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. Tentative objectives were included in the background paper.

Whilst tangible options for substitution planning arose in discussions, this workshop did not focus on concrete options.

A second workshop will be organised (likely in September 2024) to obtain feedback on draft options which will be developed based on additional research, consultation and analysis alongside feedback summarised in this report.

2.3 Workshop format and purpose

The workshop was undertaken in a hybrid format. A call for registrations was issued for interested participants, via the contractor and European Commission websites as well as social media. The opening and closing plenary sessions were live web streamed, with recordings available afterward. All registrants could also join the opening and closing plenaries in person if they wished.

Thereafter a total of six breakout groups were organised. Three online and three in person. Each had diverse stakeholder representation, a facilitator and a rapporteur, along with some observers from the European Commission services and/or agencies. Each breakout group discussed a total of six workshop questions – discussed further below - as the facilitator and rapporteurs rotated between the groups. Interest in these groups outstripped available spaces. We sought to ensure balanced representation from different stakeholders. Spaces were allocated based on the criteria below. Information on these were collected via the registration form and these criteria were communicated in advance via the workshop report:

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

[6] This is a specific analytical task recommended in the European Commission Better Regulation Guidelines and Toolbox. https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation/better-regulation-guidelines-and-toolbox_en#:~:text=The%20better%20regulation%20guidelines%20set,of%20the%20law%2Dmaking%20cycle.

2.4 Agenda

2.4.1 Opening plenary session (09.30-10:30)

The first session involved an opening plenary session between 9:30 and 10.30. This was both open to physical attendees who expressed interest and livestreamed and accessible to all. The plenary speakers along with a brief recap of the focus of their remarks are below:

- **DG GROW** provided welcome remarks along with practicalities and a reminder of the format of the workshop.
- **DG GROW** provided remarks on the study context and on the need for a modern substitution framework. Key points were:
    - Key challenges with the existing REACH processes and procedures include a lack of efficiency. For example the time and resources required examining specific uses, alternatives, and implications of adoption for users. This has contributed to backlogs in decision making with the associated delays to protection as well as innovation opportunity costs for the EU economy.
    - There are challenges where substitution is particularly complex and/or takes time. Industry wide substitution planning may be a promising option.
    - Conclusions from the study could flow into voluntary actions or amendments to regulation, but the purpose of the current workshop is not to debate options, but examine the problems in more detail.
- **DG ENV** provided further remarks on the challenges associated with substitution, outlining:
    - The challenges with the substitution process and that companies have a key part to play.
    - The advantages of regulation are well demonstrated and there is good evidence that Authorisation, for example, has been an important driver in substitution. However, processes have been resource intensive, time consuming and hindered by a lack of some specific information to authorities.
    - Strengthening voluntary action can act as a further driver, incentivising companies to act ahead of regulation, gain competitive advantage and spur innovation. However, without regulatory support these may not be sufficient.
- **Logika Group** set out the study objectives and scope, methodology and timelines, including opportunities for further stakeholder input:
    - The study seeks to identify and assess options to better address substitution particularly in the context of REACH authorisation and restriction. A range of possible options will be considered and currently all are on the table.
    - The starting point for any proposed improvement is a careful assessment of the current problem: what issue are we trying to solve? The key purpose of the workshop is to listen to and learn from stakeholders, to improve this part of the analysis.
    - The methodology consists of a series of steps. First, a careful review of existing information, case law, specific applications for authorisation and restriction. We will also look at existing activities from companies. Second, condensing this into a

problem definition and an agreed set of objectives for a revised substitution framework. Third, we develop a longlist of options for a revised substitution framework. These may comprise "measures" (i.e., individual actions) which are combined into "options". This will be followed by an impact assessment of up to three options. These will be communicated to stakeholders at a second workshop for feedback. This is likely to take place in September 2024.

- The session was followed by **questions and comments** from participants in the auditorium. These included:
    - **Q:** Substitution is at the heart of the objectives of authorisation and has been discussed for a long time. What concrete outcomes can we except from the current study? **A:** REACH has achieved a lot, but we wish to remedy issues and improve the system, we want faster substitution of targeted substances, but also to make the process clearer and more predictable so companies can plan and make investments etc, with the associated competitive advantages to the EU economy. The specific outcomes are to be developed; the exercise is open. We are looking at coordinated/voluntary objectives to regulatory action. We may borrow from existing initiatives (e.g., the Transition Pathway). The purpose of this workshop is to collect evidence on themes. Where we end up is open, but a key question is - are we really exploiting all the potential for substitution planning?
    - **Q:** Incentives play a key role. At what point do we discuss the prevailing incentives for actors in the process more broadly? **A:** This issue will be brought up throughout the day and is relevant to all questions. The main aim is how can we make substitution work faster and in a way that is more beneficial to the economy. It was agreed that incentives are an important element.
    - **Q:** How is "substitution" being interpreted in the study – is this when a substance is replaced by a different substance. Or are we also looking at the function of that substance and how that function can be replaced, including via alternative technologies? **A:** It is both. We are looking at solutions for problems in the widest sense.
    - **Q:** We hope for a dialogue, will there also be a consultation and when can we provide input? **A:** The key way is via the current workshop and the second workshop. We welcome email correspondence; position papers and research and we will explain how we take that into account in the second workshop. A limited number of interviews will be undertaken to fill gaps.
    - **Q:** We have been working on these issues for a long time, it is important to have a range of multidisciplinary views "around the table". These should include frontrunner companies. We will also need legal expertise, investors as well as companies etc. **A:** This is agreed, we are particularly interested in specific problems areas, i.e., where substitution is complex, takes time, there are a larger number of diverse actors involved. Here there may be a particular need for a planned substitution exercise. A related issue is about regrettable substitution. Early planning may mitigate risks but we do not want to define one solution, and there is a need to use all the creativity and input available to define solutions. The issues encountered by industry need to be examined alongside the challenges for regulators.
    - **Q:** The background paper is a good start and described the situation, in at least some sectors, accurately. In terms of next steps, how will parties be selected to be interviewed. **A:** We cannot interview everyone, and the main stakeholder

consultation approach is via the workshops. There are no set criteria, but this will focus on addressing specific gaps and for example to ensure assumptions in the impact assessment are realistic.

2.4.2 Discussion groups (11.00 – 16.00)

After the opening plenary session, three face-to-face and three online breakout discussions commenced. In the morning, each group discussed questions 1-3 (11.00-12:45) and in the afternoon questions 4-6 (14.00 – 15.45). A total of six teams, consisting of one rapporteur and one facilitator, rotated between the face-to-face and online groups. Rapporteurs focussed on drafting the slides and on feedback during the afternoon plenary sessions. Facilitators guided the discussions. Breakout session attendees were provided with a 1 pager supplementary briefing for each of the six workshop questions to aid reflection, alongside the background paper. A summary of the discussion groups is in section 3.

2.4.3 Closing plenary session (16.00 – 18.00)

The session consisted of feedback on each of the six workshop questions. First from the face to face rapporteurs and then from the online rapporteurs for questions 1- 6. This feedback is summarised in section 3.

The feedback session was followed by questions from participants. These were:

- **Q:** Will the study look at competition law issues? Will study outputs include guidelines to deal with competition issues? **A:** DG GROW is in discussion with DG Competition on this. They have advised that this is an issue we need to consider, and also that there are tools available to avoid issues/mitigate these risks. The study will consider competition issues in the potential options. The Commission cannot promise a guidance document (and this does not form part of the study outputs).

- **Q:** One participant felt there was a perception that most of the actions are likely to be voluntary, was that accurate? The same participant was confused by the reference to "capacities of MS competent authorities" in the feedback. **A:** Clarification was provided that all options are on the table, regulatory or voluntary and there was no preference implied at the present time. The resources point related to specific challenges in decision making, for example arising from assessment of a large number of company specific substitution plans, and/or if they contained uses/supply chain specific technical detail.

Closing remarks were provided by DG GROW. Key points were:

- Whether or not we propose a voluntary or regulatory framework is an open question for the purpose of the study. It is also a political decision for the new Commission which will discuss how to address this work and take it forward.

- The workshop has helped us better reflect on the current challenges. We heard a lot of good ideas, via lively and interactive discussion, for which we are very grateful. The next steps in the project are to consider and further formulate the problem definition, the objectives of a new framework and r the options and impacts of those options.

- All are invited to send submissions on your own initiative, there will also be some targeted interviews and of course the second workshop, which we expect in September. For the second workshop, all those who have registered will be notified once a date is agreed. A notice will also be placed on CIRCA_BC.

3 Summary of feedback from discussion groups

A summary of key themes which emerged from both the online and face to face breakout sessions are below. We identified areas of consensus among attendees, as well as aspects where views were divergent. These summaries are based on notes taken by rapporteurs at the workshop. They do not exhaustively detail all feedback.

3.1 Question 1: Refining the problem definition

Attendees were sent a copy of the European Commission's background paper as well as a series of further one-pagers on each workshop question (Appendix A1). Both documents contained an initial assessment of the challenges with the current REACH regulatory framework, for further discussion. In the documents, five primary challenges were identified:

- Substitution requires time and resources; these needs are highly varied across uses and users of the hazardous substances.
- Downstream customers and upstream value chain characteristics can hinder substitution.
- Uniform transition periods may result in unintended hinderances to substitution.
- Risks of regrettable substitution arise.
- There are no obligations for involvement amongst all value chain actors in the substitution process.

Participants were asked to offer additional insights or experiences on the challenges with the current regulatory framework and its implementation. They were asked to comment on any that were missing.

Overall participants felt all challenges were relevant and accurate. Attendees highlighted that given numerous hurdles, **regulation and financial incentives are the primary current drivers of substitution**. There remains a **lack of key data**, including from registration dossiers, on exposure, uses. Moreover, what data exists is not always transparent.

Additionally, actors may have different challenges, information and interests. Whilst there is a need for coordination and collaboration, there is a delicate balancing of constraints: for example, commercial business information (CBI) and competition, including international competition, implications of substitution on performance and the wider trade-offs required to meet various environmental objectives such as circularity or reductions in Green House Gas (GHG) emissions.

A focus for strengthening substitution should be on **rewarding and supporting frontrunners**. Regulatory action sends a clear signal to motivate substitution. But a key obstacle to substitution arises from the position of providers of alternatives, and the difficulties they face in making a business case for their products and establishing a position in the market. Strengthening substitution would need to consider **how to better support these innovators** and the problem definition should reflect their views, experiences, and challenges as well.

Discussion group attendees were in agreement that effective and efficient **regulation must provide predictability to stakeholders** to facilitate decision making on a level playing field**.** It was recognised that there are challenges in application, for instance providing future certainty for substances given an evolving science base. However, a key issue relates to regulatory delays in decision making.

Some noted **research and development timeframes should better connect with regulatory timeframes**, through greater collaboration between authorities within different jurisdiction and

affected stakeholders. However, in certain sectors, specific regulatory requirements, standards and certifications for products make substitution more protracted and technically difficult (e.g., aerospace, or medical devices).

Attendees were in agreement there is a **need to strengthen co-operation and coordination between actors, raise awareness and share information earlier and across supply chains (e.g. of upcoming restrictions)**. This is particularly important for actors in the "middle" of the supply chain who are reliant on both upstream and downstream actors. Participants were generally of the view that collaboration is possible, even among competitors, where technology development is not the main factor. Such cooperation could facilitate earlier substitution of hazardous substances.

Participants indicated that **lack of information on alternatives across value chains** is a challenge. Additionally, authorities' lack of knowledge on available alternatives limits their ability to challenge substitution plans associated with derogations applications.

3.2 Question 2: Validating the objectives of the substitution framework

Four initial objectives for a substitution framework were presented as background to the discussions. These were:

1) Speeding up innovation and substitution of targeted substances and uses.

2) Promoting earlier and higher standards for health and environmental protection from chemical risks.

3) Enhancing competitiveness of involved EU companies (both companies using targeted substances and alternatives providers).

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

Participants were asked if they agreed these are the right objectives, if any were missing or should be removed? Given the trade-offs, participants were asked to prioritise objectives if they could.

The consensus of discussion group participants was that the given objectives are generally correct but are broad in scope and would benefit from greater detail and clarification. All objectives were considered important.

Stakeholders felt an explicit objective should relate to the **creation and availability of information on hazard, risk, and alternatives.** Participants indicated that the framework could also track/monitor substitution efforts, including success stories, to help identify and disseminate best practice and 'lessons learned'. This promotion of knowledge-sharing was highlighted as particularly important for SMEs. Participants suggested objectives should also include **facilitation of communication along the supply chain and early engagement** on substitution issues.

Commenting on objective three, participants indicated the framework should **seek to provide clarity and transparency over regulatory timelines** to facilitate greater predictability and investment security for European industry. Participants noted a lack of compatibility between the flexibility needed to address the diversity of substitution challenges, and the predictability required by industry. This may mean a combination of approaches is needed. Stakeholders requested clarity on the scope of substances in the study (for example are they the same as listed in the Chemical Strategy for Sustainability (CSS), and recurring references were made to including the essential use concept in the objectives and scope of substitution planning.

Stakeholders provided various clarifications and challenges to wording of the objectives. For example, earlier action and higher standards are different. With respect to the first objective, some participants suggested substitution and innovation cannot be 'sped up' directly, and that the objective should focus instead on **incentivising substitution and promoting market opportunities**. Some participants emphasised that discussion on economic competitiveness should focus not only on incumbents but on new market entrants, whilst also considering non-EU actors.

Participants were broadly of the view that the objectives should emphasise **harmonisation and coherence** of the substitution framework with other initiatives and legislation, including Safe and Sustainable by Design, the Chemicals Strategy for Sustainability, and the European Green Deal. Some participants further stated that there is scope to broaden objectives to beyond just hazard and risk, and to **consider other targets such as circularity, net zero, climate change, social value, and sustainability** more generally.

There was no consensus in the discussions about the prioritisation of the objectives. Some participants indicated the overarching purpose of a substitution framework is the protection of human health and the environment, and that objective two should be prioritised accordingly. Other stakeholders suggested that if the incentivisation of innovation and substitution efforts falls within the scope of objective three, the this would also deliver objective one.

3.3 Question 3: Information needs to support speeding-up regulatory substitution timelines

Participants were asked to consider how early discussions on alternatives could be implemented and burdens on companies, especially SMEs, be minimised? What information is needed or would be useful and how should it be provided?

It was agreed that regulatory and pre-regulatory measures, in particular Regulatory Management Option Analysis (RMOA), hazard classifications, Candidate Listing of substances and restriction proposals, are a key driver of substitution. Other non-regulatory triggers were also mentioned, such as initiatives and listings launched by EU Member States (e.g., PRIO in Sweden)[7] and NGO tools (e.g. ChemSec's SIN list[8]. Moreover, **clear and early information on proposed restrictions and bans (including specific uses and substances targeted)** is key to facilitating substitution. However, whilst authorities and NGOs generally felt more information on uses and exposure were needed to better design regulatory measures, the type of information needed by authorities to determine regulatory measures is different from the information needed by companies to substitute. Clearer and earlier definitions of the substance(s) subject to regulatory action, for example restriction entries in the Registry of Intentions not being specific enough to determine whether a company is affected by the restriction.. It was recognised that registration dossiers do not provide sufficiently clear information on e.g., uses and exposure and that delays to regulatory procedures/decision making have a corresponding delay on substitution activities.

Some participants indicated **supply chain dialogues** involving alternative providers and downstream users are key to triggering earlier substitution efforts, and that **mechanisms to support supply chain communication** are important in facilitating this. There was no consensus on precisely how this should occur, for example whether additional notification of downstream uses should be mandatory or voluntary, or whether there would be merit in having a form of simplified substitution plan contained in registration dossiers of substances under regulatory scrutiny, accessible to downstream users. It was recognised that such communication needs to go "both ways" i.e., up and down the supply chain

[7] https://www.kemi.se/prioguiden/english/start
[8] https://sinlist.chemsec.org/

and facilitate participation amongst SMEs. A number of points were raised about the risks with such dialogue with respect to **CBI and competition law**.

A key information need highlighted by participants is the **possible alternatives**, their hazards, as well as information matching **substance functions to uses**. This can be facilitated by independent but **coordinated information platforms**, such as the Zero PM information portal[9] or French Substitution Portal.[10] Stakeholders felt alternative providers would be a key stakeholder, that the platforms should be independent and **case studies on substitution success stories and best practice** can provide useful information to facilitate substitution efforts.

In terms of incentives for substitution, some suggested making the use of SVHC subject to a fee (tax) associated with use. This would be separate to the regulatory submission fee which covers some costs of authority processing and decision making and would be consistent with the polluter pays principle. Others felt frontrunners should be rewarded for their efforts. R&D funding was mentioned as essential to promote substitution, especially for non-commercial sectors and SMEs.

3.4 Question 4: Legal/voluntary substitution planning requirements

Participants were asked to consider if regulatory use of substitution planning should remain limited to provisions in current REACH policy or be extended to other policy applications? How could voluntary use of substitution planning complement existing regulatory provisions supporting the substitution of targeted substances and uses?

Participants indicated that **early data on substitution would help choose the most appropriate regulatory action(s).** Other legislation beyond REACH should be considered in the framework, given that companies substitution activity reflects multiple regulatory requirements. However, it was felt by some that better coordination amongst authorities with regulatory oversight for different legislation would also help coordinate action. Some participants considered **Candidate Listing of substances is not a sufficiently strong signal** to trigger substitution.

Participants also indicated that **the definition and scope of 'substitution planning'** is key to determining whether mandatory and/or voluntary approaches should be followed. Participants made a distinction between **sector-level substitution strategies** and **company-level substitution planning**. Some felt incorporating substitution planning into REACH restrictions would not be workable on a company-level basis, while sector-wide substitution planning could play a role in restrictions. This could be linked to the provision of information requirements, at an earlier stage in the process than is currently required. However, complexities with respect to exchange of CBI would need to be addressed if considering sector-wide substitution planning. As noted under Question 3, some felt fees linked to usage of the most hazardous substances could play a role. It was felt by most, that a one size fits all approach would not address the problem and that collaboration/communication between regulators and businesses would be important.

Attendees expressed divergent views on the role of voluntary actions in substitution planning. On the one hand, some participants suggested previous EU-level voluntary agreements has not been successful in facilitating substitution, that protection of human health and the environment cannot be left to voluntary actions, and that **regulatory approaches are key to triggering substitution** (see Section 3.1). In addition, voluntary schemes would leave scope for **free-riding**. On the other hand, some participants considered that voluntary programmes, which could be agreed with the public authorities, could play a role, citing the example of voluntary initiative under the ESPR.

[9] https://zeropm.eu/
[10] https://substitution.ineris.fr/en

3.5 Question 5: Focus of the substitution plan

Participants were asked to consider if individual companies should create their own substitution plans? Whether there was value in pursuing an industry/use/value-chain wide substitution planning approach, or a combination of both?

Participants noted individual companies face different conditions/challenges and often start from different substitution points; this, as well as different resources and capacities need to be taken into account. As above, a one size fits all approach is unlikely to address the challenges; **both individual and sector wide approaches may be appropriate**. Again it was noted that CBI/competition law will remain a challenge, which may mean some regulatory oversight/standard setting may be necessary. As such, meaningful collaboration may only be practicable at a strategic level (i.e., setting the overall direction for a sector or supply chain) with more detailed action remaining at company level. Some participants felt that joint approaches may prove more useful where the competition between actors in a sector/supply chain is less related to the chemistry. For example, for water repellent fabrics, clothing manufacturers who do not use PFAS signalled a desire to substitute away from them. This helped to provide a more certain market. In contrast it may provide easier where i) substitution is at an earlier stage and ii) an alternative(s), at least in principle, exist.

Participants noted that under RoHS, joint approaches are often undertaken, some felt these have worked well. Participants also reflected that RoHS permits **greater interaction between industry operators in the development of derogations compared to REACH;** under REACH the precise scope of restrictions were felt as more of a "black box".

To support company-wide and sector-wide substitution planning, participants highlighted that **joint platforms to facilitate information exchanges** might be required, but this should not delay the overall process. Such collaboration may help identify the "laggards" within any supply chain as well as identify the most challenging substitution cases/uses. These should then benefit from targeted central funding.

Participants identified challenges in a sector-wide approach to joint substitution. Some felt these could be overcome with careful policy design. They included;

- A wide umbrella of companies under joint substitution efforts could lead to less ambitious and/ or slower substitution;
- It may de facto penalise frontrunners and or SMEs, especially where there are a small number of major players;
- CBI / competition law could complicate the information exchanges needed to achieve substitution;
- A multitude of individual company-wide substitution plans risks overwhelming authority resources and slowing the process down;

The remaining challenge raised by participants was how to ensure plans remained suitably ambitious in general. Some felt an external peer review of alternatives/performance testing may be helpful.

3.6 Question 6: Who prepares, reviews and monitors implementation of plans?

Participants were asked to consider the actors who should be involved in the preparation of substitution plans and how should decisions on their appropriateness be taken? They were asked to reflect on roles for industry, authorities and third parties (alternative providers, NGOs, substitution

centres, or academia) in the preparation, assessment, and the monitoring of implementation. Merits of "supply chain" workshops were also considered.

Respondents reflected on the three different components, noting that roles and responsibilities would differ under authorisation or restriction.

- **Preparation of the plan:** It was agreed industry has a clear role in leading the process, given the investment, information and detailed technical expertise resides with them. However early collaboration between companies and potentially authorities is key. One approach may involve developing a sector-wide "baseline level understanding", before moving to company-level plans. A suggestion was made that two substitution plans may be developed - one detailed company level plan, which is private and second sector wide plan which is shorter and made public - with key actions, milestones, etc. A key challenge was recognised in ensuring plans were both realistic but also ambitious. Others felt there was a role for competition and market authorities in Member States (or the Commission) to oversee and facilitate cooperation, with a role for supply chain workshops at this stage, alongside independent experts and alternatives providers. Whilst there were existing tools from NGOs and authorities to facilitate this, it was recognised this would require funding. Overall, caution was noted by some on watering down regulatory requirements, but some parallel voluntary actions may be useful. Different views were expressed over the merits of a company by company or sector wide substitution plan, again some attendees noted both may be required. The format must allow communication across the value chain, noting that substitution may not be with a substance but with a technology.

- **Evaluation of substitution plans:** challenges to authorities with the current process was widely recognised. Some noted cases where coordination had taken place between parallel authorities (e.g., the European Chemical Agency and the European Union Aviation Safety Agency, in aviation) had proved successful. Others agreed there was a role for an independent assessment centre, but there was no consensus over what form this should take. For example, some felt a dedicated substitution centre/academic research centre could support, at least with more complex cases and/or to aid SMEs. There was also recognition that a third-party entity was needed to support e.g., CBI/competition and to ensure a level playing field. Some felt that ECHA would be best placed to fill that role. An overall theme was that any such approach must be transparent.

- **Monitoring of substitution plans.** Whilst some felt that there does need to be monitoring of the substitution plans, but there was no consensus on who undertakes it, nor how it should be done. Some concerns were raised, given the risk and uncertainty with innovation and that "success cannot always be planned". But some felt a review of substitution plans should be triggered if proposed timelines had not been met and/or the situation vis a vis alternatives changes. Others felt there should be more regular review and/or monitoring, not just for the purposes of review reports and again workshops were noted as one means to do this.

4 Next steps

4.1 Project timeline and further consultation activities

After the workshop, the contractor team will be carrying out further analysis of the problem definition, and framework objectives before considering a long list of potential policy options. Some targeted interviews will be undertaken, as noted above.

A second workshop in support of this study will be held later this year, we expect this to be September 2024; the exact timeframe remains to be confirmed. The focus of this workshop will be on options to strengthen substitution planning, building on the problem definition developed by the project team (which will draw on the feedback gained from participants in the first study workshop).

The data of the second workshop has now been confirmed as Tuesday 1st October 2024. Further details on this workshop will be made available as soon as they are confirmed. Individuals and organisations that expressed interest in participating in the first workshop will be contacted via email to inform them.

To provide any feedback or information that may be of use to the study, please contact the European Commission via email at GROW-ENV-REACH-REVISION@ec.europa.eu. Please also cc the Project Director from the contractor, David Tyrer at Logika Group davidtyrer@logikagroup.com. Note we have received several documents and submission since the workshop, we politely request any further document to be submitted before June 28th 2024 at the latest.

5 Appendices

A1 Workshop 1-pagers

A1.1 Discussion Question 1 – Refining the problem definition

Options to improve the substitution of hazardous substances under REACH need to offer solutions to current challenges. In the background paper, the Commission has identified 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, including:

- **Substitution requires time and resources and these needs are highly varied across uses and users of the hazardous substances** complicating current efforts to make regulatory substitution processes and decision making efficient and effective for all stakeholders.
- **Downstream customers and upstream value chain characteristics can hinder substitution**. The availability of the alternative at sufficient quantity 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.
- **Uniform transition periods may result in unintended hinderances to substitution**. Setting transition periods "early" when only some can substitute results in manufacturing disruptions or may threaten moving production outside the EU. Setting transition periods "late" results in insufficient incentive to substitute when alternatives are available, but allows for alternatives in the market to "mature" resulting in more favourable cost and more time to vet and optimise performance.
- **Risk of regrettable substitution**. Pressure to substitute the substance without consideration of the risks of alternatives or adequate time to substitute may de facto worsen health and environmental impacts. Current analysis of alternatives processes prioritise considerations of various hazard endpoints, but may not fully take into account trade-offs regarding potency associated with specific hazards nor the quantity needed for functional performance.
- **No obligation for involvement amongst all value chain actors**. The current regulatory approach for substitution focuses on individual users and does not adequately address the role of and the need for the whole value chain in evaluating and identifying the best alternatives for specific uses.

Q. ***Please offer additional insights or experiences on above 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)?

Q. ***What challenges/additional problems with the current regulatory framework are missing?***

A1.2 Discussion Question 2 – Validating objectives of the substitution framework

In the background paper, the Commission has outlined 4 primary objectives (along with sub-objectives) of a substitution framework to advance policy goals under REACH. These include:

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 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.

These objectives are important to clarify and prioritise as they will support the development of criteria used in the study to evaluate the merits of policy options to improve substitution and the use of substitution planning.

Q. ***Do you agree that these are the right set of critical objectives of a substitution framework?*** What's missing? Should any be removed?

Q. There are likely trade-offs across the options. ***If you had to prioritize 3 objectives for a substitution framework, what would they be?***

A1.3 Question 3 – Information needs to support speeding-up regulatory substitution timelines

One of the challenges the Commission identified as part of the problem definition is that research, evaluation/testing and redesigning products/processes to support substitution takes time. As outlined in the background paper, performance testing, product/process and facility redesigns, getting alternatives to scale and obtaining the necessary legal and/or industry/product-level certifications take time. Yet what should be early triggers to begin substitution including the range of planning needs?

A range of substitution frameworks, such as those outlined in the background paper offer experiences about the data and resources needed to efficiently and effectively support substitutions (e.g., the Massachusetts Toxics Use Reduction Program, SUBSPORTPlus, and the Swedish Centre for Chemical Substitution among others). In addition, tools and information repositories to support substitution such as ChemSec Marketplace or Pharos in the U.S. reveal needs for data that need to be scaled and deepened. Having information early about use needs for substitution of hazardous chemicals and availability of alternatives for those uses can speed up the evaluation and implementation process. But clarity is needed regarding data needs, specifically, what is needed, who can provide it and how it can be accessed.

Q. ***How can early discussion on alternatives be triggered and implemented and the burden on companies, especially SMEs, be minimized?*** Please draw in experiences from use of substitution planning/regulatory programs in the EU and globally to the extent possible.

Q. ***What information is needed or would be useful to support early substitution planning and how should it be provided?***

A1.4 Question 4 – Legal/voluntary substitution planning requirements

The background paper briefly outlines the use of substitution planning under the authorisation and restriction provisions under REACH. These include:

- **Authorisation**. Use of analysis of alternatives and in many cases substitution plans in industry applications for authorisation for continued use of an Annex XIV (authorisation list) substance.
- **Restriction**. Analysis of the availability, suitability, and technical feasibility of alternatives in restriction proposal dossiers filed by Member State authorities or ECHA.

The background paper also outlines provisions in other chemicals legislation that inform experiences with use of substitution planning. These include for example:

- Required analyses of substitution options that demonstrate no suitable alternatives when applying for derogations from bans or restrictions under the **Cosmetic Regulation**, the **Toys Directive**, the **Restrictions of Hazardous Substances Directive** and the **Persistent Organic Pollutants Regulation**;
- Comparative evaluations by competent authorities as to whether active substances identified as "candidates for substitution" under the **Biocidal Products Regulation** and the **Plant Protection Products Regulation** demonstrate that such products can/cannot be substituted by other adequate alternatives before granting authorisation for placing on the market such substances.
- Requirements to consider safer and feasible substitutes under the **Carcinogens, Mutagens or Reprotoxic Substances Directive** as well as the **Industrial Emission Directives**.

Lastly, the background paper illustrates a number of programmatic models in the EU as well as policy models outside of the EU that are supporting substitution and substitution planning. These include for example:

- Portals of substitution resources offered through **SubsportPLUS**, and the **Organization for Economic Cooperation and Development**. In addition, the **Swedish Centre for Chemical Substitution** also offers training and support for R&D on alternatives.
- **Massachusetts Toxics Use Reduction Act** is a U.S. state law that requires users of large quantities of specific toxic chemicals (with smaller quantities for highly hazardous chemicals) to pay a usage fee and evaluate their operations and plan for toxic use reduction opportunities, including substitution options. Planning is mandatory, although implementation of the plan is not. Fees are used to support TURA programs, including technical assistance to industry to support implementing its toxic use reduction plans.
- The OECD recently published its, ***Economic instruments to incentivise substitution of chemicals of concern – a review***, which demonstrates the utility of economic policy instruments (e.g., taxes, fees) to provide incentives for industry to innovate and substitute hazardous chemicals with safer alternatives. Such policy instruments can incentivise substitution without stipulating what technology or action each actor should take.

These models as well as others not described in the background paper demonstrate a range of required and voluntary uses of substitution planning.

Q. Should the regulatory use of substitution planning remain limited to provisions in current REACH policy or be extended to other policy applications?

Q. How can voluntary use of substitution planning complement existing regulatory provisions supporting the substitution of targeted substances and uses?

A1.5 Question 5 – Focus of the substitution plan

As outlined in Discussion Question 4, there are a range of policy and programmatic models that inform how substitution planning could be more effectively and efficiently used under REACH to support transitions away of harmful substances and towards those that are safer and more sustainable. These experiences demonstrate uses of substitution planning by industry actors to support derogations from restrictions and bans (e.g., under RoHS, Cosmetics Regulation or Toys Directive); use by government actors to support market authorisation of substances that are "candidates for substitution" (e.g., under Biocidal Products Regulation); support for the voluntary substitution by industry actors and the use of toxic chemical user fees that support substitution assistance programs (e.g. MA TURA); and the importance of substitution-related resources and trainings (e.g., Swedish Centre for Chemicals Substitution) among other experiences.

In addition to the above, experiences informing the "problem definition" (Question 1 from morning discussion) regarding challenges to substitution under REACH provide insights regarding how substitution and the use of planning can be most effectively and efficiently implemented under REACH moving forward.

Q. 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/coordinated? How can anti-competitive practices between companies be avoided; how can innovators best be protected; and how can confidential business information be managed?

A1.6 Question 6 – Who prepares, reviews and monitors implementation of plans?

Existing models demonstrate various substitution planning structures. For example, REACH authorisations, require industry actors to prepare substitution plans while the Commission with input from ECHA's scientific review committees (SEAC and RAC) decides whether or not to give an authorisation and for how long. Under REACH restriction provisions as well as the authorisation of candidates for substitution under the Biocidal Products Regulation/Plant Protection Products Regulation requires competent authorities to assess substitution options to conclude on the availability of - and implications of adopting - safer and feasible alternatives.

The structure for and set-up of substitution planning assessments (e.g., analysis of alternatives among other planning approaches) often dictates the use of specific data as well as content expertise needed to review plans created. For example, analyses of substitution options by government actors are extremely limited in their ability to plan the range of changes needed to accommodate substitutes (e.g., process-level; product-formulation level, facility-level changes) and thus planning is simply a matter of whether commercially available alternatives are available or not. Experience from the Massachusetts TURA Program reveals the importance of involving a range of actors, including research centres, NGOs as well as industry collaborations to support identifying and evaluating alternative solutions. Although substitution plans/analysis of alternatives required by regulations in the EU and elsewhere (e.g., the California Safer Consumer Products Program) require government

authorities to review the validity of such analyses/plans, the background paper argues that at least for some authorisations under REACH, it is very difficult for authorities to efficiently judge the legitimacy of analysis/planning results, especially regarding the technical feasibility of alternatives given operational nuances and needs that are specific to a given company.

Q. 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?