19 September 2024

Workshop for substitution of targeted hazardous chemicals – supporting background document

1. *Context for the second study workshop*

This background paper provides context and information for the second workshop taking place in relation to the study on **Strengthening the role of substitution planning in the context of REACH and other EU chemicals legislation**. The study assesses challenges in the context of chemicals substitution so as to identify, evaluate and assess the impacts of options to better address substitution planning, to advance and expedite the replacement of hazardous substances with safer, more sustainable alternatives that are technically and economically feasible[1]. Conceptually such options may go beyond current legal provisions or build non-regulatory mechanisms to advance substitution such as support infrastructure and/or financial incentives.

The overall goal of the study is to inform the Commission on various measures that could **accelerate safe substitution** and enable **efficient use of industry and authority resources**.

Overall objectives include: to **accelerate safe substitution** and enable **efficient use of industry and authority resources within a simplified regulatory system which supports EU innovation and investment**. 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 so as to speed up innovation and support the competitiveness of European companies.

At this second workshop, we will briefly present the 'problem definition' which is our assessment of the current challenges with substitution based on a literature review, stakeholder interviews, and discussions at the first workshop. The main part of the workshop will be dedicated to presenting and discussing potential "policy options" to strengthen substitution planning in the context of REACH.

For the purpose of preparing stakeholders for the workshop, three hypothetical policy options are described at a conceptual level in the subsequent sections. These will be explained further during the workshop presentations. The options are a structured set of possible measures or approaches, intended to allow discussion and a subsequent analysis of impacts of those options**. They are <u>not</u> endorsed by or formal proposals of the contractor or the Commission.** The various elements have been defined to show the assumptions of the analysis only. This should in no way pre-empt later policy decisions which may diverge from the assumptions used for this analysis.

At the workshop, we wish to obtain stakeholder input on these policy options. That input will allow us to further develop and refine hypothetical options and enable an impact assessment of their significant costs and benefits, advantages and disadvantages for different stakeholders. This assessment will be undertaken after the workshop.

[1] In the study this is referred to as safer, more sustainable and suitable alternatives

It is important to note that the concepts set out in this paper have undergone a process of discussion and iteration subject to the agreement of Commission services, but neither are the conclusions of the contractor alone, nor reflect the opinion of the Commission. They merely serve to illustrate the impacts of potential policy options. They focus on specific elements of substitution; notably how to operationalise and implement substitution planning within practical, legal, political and resource constraints and reflecting the policy priorities of the new Commission. The final report for the study is expected to contain discussion on a wider number of possible measures to support substitution more generally. Whilst these will be considered by the Commission, they are not intended to be the focus of discussion at the current workshop.

In the following sections we:

- define concepts used in the study;
- briefly summarise the key issues examined in the problem definition;
- describe at a high level the policy options; and
- set out key questions for discussion at the workshop.

Participants, especially those attending the smaller on-line and face-to-face discussion groups (described below) are asked to read the remainder of this document prior to the workshop, to maximise contributions to discussions. After the workshop, minutes summarising the overall outcomes of the discussions will be prepared.

Workshop format and agenda

The workshop will take place in a 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 session in the morning to provide relevant background and context for discussion and a closing session for conclusions and reflections in the afternoon. The plenary sessions will be held in person in a conference room hosted by the Commission and web streamed[2]. This plenary conference room has a capacity of 140 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. These sessions are designed to engage stakeholders on a possible set of policy options. The deliberately envisage different levels of ambition, intervention and oversight for the purposes of further examination and assessment. The hypothetical options consist of (1) a set of *voluntary* measures which could operate outside of current regulatory provisions; (2) a set of *voluntary* measures based on new regulatory provisions; and (3) a set of *mandatory* measures based on new regulatory provisions.

As with the first study workshop, physical space constraints will limit small discussion groups to a total of around 80 attendees, of which around 40 in person groups and around 40 in on-line groups.

Participants in the discussion sessions will be allocated to discussion groups of up to 15 persons. Each group will discuss the proposed policy options and will be facilitated by a representative of the organisers alongside a rapporteur to summarise discussions.

Unfortunately, registrations for physical and online participation in the discussion sessions exceeded the number of available places. However, there will be opportunity to join the plenary sessions - both in person – for those who have registered and been accepted – and web streamed online for anyone

[2] For registered participants attending remotely, the links will be provided closer to the event date.

else who is interested. For the smaller breakout sessions, participants were 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

A recording of the two plenary sessions will also be published on the Commission´s website after the workshop. But the smaller discussion sessions will be accessible only to the participants of that group on the day. Any thoughts or contributions during the discussion sessions will serve as input to the further study work and to refine the options in the study. Only a brief 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.

An indicative agenda for the workshop is provided as part of the bundle of workshop documents. **Please note** this is subject to confirmation and agreement with the Commission and may be amended.

2. Why is substitution planning being considered?

Substitution planning seeks to address a specific set of problems. These include cases where it is extremely difficult to establish beyond doubt whether alternatives exist and whether those are safer, more sustainable and suitable for all affected users. Typically, such cases relate to important uses, where substitution possibilities are uncertain and/or diverse depending on exact use patterns and technology readiness levels.

In such cases, appropriate regulatory decision making requires very detailed analysis, often of company specific performance needs which are difficult for regulators to judge objectively and consistently, such as the acceptable level of performance loss of an alternative compared to the use of the affected substance. The result of these complexities are lengthy and controversial discussions which delay necessary action to protect health and the environment, and which lead to uncertainties for both users of the substance and alternative providers, prevent investments in Europe, and may lead to relocation of business activities outside of Europe. Such “complex regulatory cases” therefore share a number of common characteristics but involve a degree of judgement. They need to be identified on a case-by-case basis. Examples of such cases are uses of PFAS in technical applications such as semiconductors, batteries, hydrogen production or in membranes, or uses of chromium(VI) in hard chrome plating.

The purpose of substitution planning is to investigate whether for such cases, the use of fora for enhanced information exchange as part of a more collaborative approach between authorities and industry (both users and alternative providers) that is promoted by financial and technical support where appropriate, holds greater promise for advancing towards safer, more sustainable and suitable alternatives earlier, more efficiently and whether that approach would be able to provide a higher degree of investment certainty for both current users of the substance and for alternative providers, thus promote innovation and investment in Europe.

3. Definitions and key concepts used for the study

Targeted Substances in scope

For the purpose of this study, the term "targeted substances" is used for any substance which may be of interest for substitution based on its intrinsic hazard properties and due to regulatory, market, or scientific reasons. The study itself does not provide any analysis of which substances, or groups of substances, could or should be targeted for substitution planning.

What is substitution planning, what is a substitution framework and what are the policy objectives?

In the context of this study, substitution planning seeks to promote the substitution of targeted substances by other substances or technologies using plans. These plans consist of a series of documented and verifiable time-based activities specifically developed by multiple stakeholders for the purpose of substitution. Planning starts with an analysis of alternatives to map potential alternatives, to assess their safety, suitability and sustainability and to identify trade-offs linked to different choices.

Whereas the substitution plan and the R&D plan under REACH are about individual authorisation applications, the concept of substitution planning in the context of this study is wider. This may also comprise industry/use-wide planning (such as multiple users of a substance for a specific use, for example chrome plating).

Substitution planning seeks to:

- **Protect human health and the environment** – through the accelerated substitution of certain targeted substances with safer, more sustainable and suitable alternatives. This should increase the level of protection and achieve the associated human health and environmental benefits.
- **Facilitate and enhance early action on substitution** to increase the efficiency, predictability and where appropriate the flexibility/adaptability of the regulatory system both for companies using targeted substances, alternative technologies and front-runner companies providing or using safer alternatives.
- **Support and enable efficient use of resources for industry and authorities within a simplified regulatory system** – improving data and knowledge-sharing to identify and evaluate potential alternatives allowing for informed decision-making, technical discussion of details and trade-offs with substitutes.
- **Boost investment and innovation in the EU** – providing investment certainty to both users of the substance and the alternative providers.
- **Foster enhanced cooperation and communication** - between actors across complex value chains, including users of targeted substances and potential alternative providers as well as supporting and enabling all actors to operate on a level playing field, whilst respecting rules on competition.

To operationalise substitution planning in a regulatory context, it is recognised that a wider substitution framework of actions, requirements and incentives are likely to be required. Such a substitution framework may include regulatory, voluntary measures and/or economic incentives which seek to accelerate effective substitution activities more broadly.

4. Problem analysis –key messages

This study includes a "problem definition" examining the underlying causes and resulting problems for the substitution of targeted substances with safer, more sustainable and suitable alternatives in a regulatory context. This is a standard methodological requirement in policy analysis for the Commission. The key elements are summarised below.

- The **central problem** is that the substitution of targeted substances with alternative substances or technologies that that are safer, more sustainable and suitable is not happening fast enough.

- There are **several underlying causes** of this problem, which affect both industry who conduct the substitution efforts and authorities in their regulatory decision making.
    - **Gaps in knowledge and awareness amongst industry and authorities** of substance function, usage as well as alternatives within supply chains.
    - **Differences in incentives for substitution for supply chain actors.** Different actors along a supply chain, even for the same substance and use have different incentives.
    - **Capacity and resource constraints both for industry and authorities.** All actors have resource constraints. This means focusing on/selecting priorities for investment, on specific cases for regulatory decision-making. Both have constraints on their capacity to identify and evaluate alternatives.
    - **Complexity of use profiles and substitution possibilities.** The number of substances and use combinations, differences in hazard, risk and substance functionalities all combine with *differences in substitution possibilities* and *differences in capacity to substitute* for industry. This makes regulatory decision making extremely difficult and resource intensive, particularly for a select number of cases where these issues predominate, and which involve complex trade-offs.

- The **consequences** are:
    - Ongoing risks to human health and the environment alongside external costs to society from exposure.
    - Delayed or lost investments and innovation benefits to EU companies and citizens, with specific challenges for SMEs; often amongst the most innovative.
    - A lack of communication and transparency among supply chain actors which can constrain action, investment as well as efficient and effective collaboration.
    - Risks of an unlevel playing field between certain actors in supply chains.
    - Complexities have driven resourcing challenges for industry and authorities. Such resources cannot then be used for other the pressing matters and have caused delays in decision-making, with reduced predictability and investment certainty for industry.

Informed by the problem analysis and in extensive discussion with the Commission, the contractor has developed three initial options to support considerations for an updated substitution framework. A baseline option (i.e., a "do nothing") reference scenario will be used in the final impact assessment but is not the focus of discussion during the 1 October Workshop. Thus, it is not described further in this background paper.

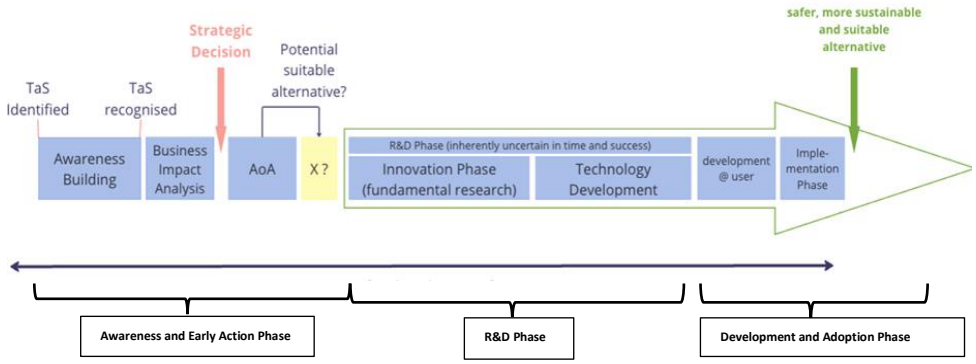
Principles and foundational context for the options

The options have been developed based on several principles, provided by the Commission services:

- Where the options foresee mandatory substitution planning arrangements, these are not expected to be applied for all – or even most - substances/use combinations. These **arrangements are foreseen for a relatively small number of "complex regulatory cases"** where the use of standard approaches under restriction or authorisation under REACH or similar processes under other legislation are not deemed to be suitable. The working assumption for the impact assessment is that between three and up to five complex cases using targeted substances combinations may go via this route per year.
- To increase the level of protection and achieve the associated human health and environmental benefits, it is envisaged that **substitution shall be made to safer, more sustainable alternatives that are technically and economically feasible**. This will require dialogue both within industry and between it and the authorities.
- **No options mandate that companies must collaborate** on research and development activities, collaborate in the detailed design and development of alternatives or adopt the same alternative substance or technology in any given situation. Companies may wish to do so, where such collaboration pools the risk and reduce the costs, but they are not required to. Financial support could be applied to fund specific support and/or direct it toward e.g. SMEs, where feasible.
- No options require companies to disclose *to other market participants*, competitors or future competitors any confidential business information (CBI) on alternatives, potential alternatives or details of intellectual property (for example, new products/techniques technologies that are under development or being considered).
- Where company CBI may be required, for example in the context of individual company substitution activity, the options envisage **submission of CBI information to a third party only who will act as trustee and protect such information**. The above points have been incorporated to reflect possible competition/anti-trust issues.
- Different actions and obligations in the policy options depend on whether safer, more sustainable, and suitable alternatives are available. The requirements and actions differ, depending on whether this is the case or not.
- We are envisaging delivery of the options – at least in a REACH context - **via the restriction process**. This is for reasons of simplicity and clarity of explanation and to ensure a manageable scope for the study.
- Under all three options, we envisage the overall process can be supported and coordinated via a newly designated **"(network of) substitution centre(s)", in cooperation with national, regional or stakeholder institutions,** but other tools and mechanisms can also come into play.

Terminology used in the options:

- **The substitution journey:** The starting point for developing the options has been to consider the various sequential steps that are necessary for industry to successfully substitute. We refer to this as the substitution journey. The precise steps will differ per company/substance/use and may involve a degree of trial and error. As such the policy options consist of a package of measures across three substitution journey phases. We refer to these phases as the Awareness and Early Action Phase, the R&D Phase and the Development and Adoption phase. Two out of three options are based on the logic that instead of restricting a particular use of a substance or submitting it to authorisation, continued use of that substance may remain possible in exchange for commitments in the form of substitution planning to do research and to invest into safer and more sustainable alternatives, where this is feasible. This is without prejudice to the outcome of the assessment and discussion whether or not substitution planning should be applied in this context.
- The journey, displayed below, reflects the *experience of industry actors* and the time course of actions needed to substitute a targeted substances with a safer, more sustainable and suitable alternative. The journey reflects distinct stages at which different activities advancing substitution can occur. Thinking in terms of these phases has been useful for organising measures and the related policy options, some of which focus on how regulation can most effectively interact along the phases, recognising that the journey differs for each company and in each case.



  - **Awareness and Early Action Phase**: This phase is the time needed for a user to realise there is a concern and that action may be required. The user typically makes a business impact analysis by evaluating the necessity of the substance in the production process, the exact functional requirements and the risks. During this phase, measures are taken that increase awareness and provide information about the uses, functions, applications, and risks of targeted substances to support future risk management actions by authorities. In addition, measures in this phase target making information about alternatives more widely available and enhancing capacity among users of targeted substances to analyse alternatives to support determinations regarding their safety, sustainability and suitability.
  - Awareness and early action measures are needed to support earlier substitution efforts as part of a comprehensive substitution framework in the EU. These measures have been already assessed in earlier impact assessment studies and hence are not examined in detail here. They are considered, however, to be a key element of the overall process. These initiatives could include additional information – available at an earlier stage than

currently - of specific substance /use combinations, associated risk and assessments of the availability and feasibility of alternatives.

- **R&D Phase:** Where no safer, more sustainable and suitable alternatives are determined to be available, research and development (R&D) is needed. The stage and type of innovation needed to develop a suitable alternative may vary and, thus, so will the time needed. Innovation is commonly characterised by Technology Readiness Levels (TRLs). Alternatives that are at an early stage of R&D (e.g., TRL 2-3) will inherently take more time to be widely commercialised than alternatives that are at a later stage of development (e.g., TRL 6-7). The R&D phase is described as the innovation phase (laboratory and pilot testing, TRL 1 to 5) and the technology development phase (TRL 6 to 9). The result of the R&D phase is the identification of a safer sustainable and suitable alternative(s), for the targeted substances.

- **Development and Adoption Phase:** Once one or several safer, more sustainable and suitable alternatives have been identified either during the Awareness or the R&D phase, additional development and validation may be needed before they can be widely used or adopted. For example, obtaining necessary customer, legal certifications or re-engineering of industrial processes at industrial sites may be needed. These activities, in addition to other adoption needs, such as employee training and time to secure the necessary supply of alternatives to support full-scale adoption are addressed in this final phase of the substitution journey.

- **Substitution pathway:** In the context of this study, a substitution pathway is a document that contains an overall analysis of challenges and opportunities in and gives an overall direction for substituting the substance/use combination.
  - We envisage that these pathways would be concretised via *action roadmaps* and that during the substitution activities the exposure risk from ongoing use is minimised and regularly monitored.
  - The substitution pathway is dependent on the availability and technology readiness level of potential safer, more sustainable and suitable alternatives. Thus, it may include R&D activities (like in the R&D plan under REACH), or, if a safer, more sustainable and suitable alternative already exists, then it includes development and implementation (like in the substitution plan under REACH). The substitution pathway may thus differ depending on the maturity of the alternative.
  - These plannings can involve activities of one company or stakeholder, or potentially several working together.
  - There must also be assessment of the safety and sustainability of alternatives. An EU (network of) substitution centre(s), including national, regional, and stakeholder institutions, could act as advisor to help to define the availability of alternatives.

- **Action roadmap:** A series of agreed actions to be undertaken by stakeholders, companies, users of the substance, actors upstream or downstream the value chain acting alone and/or in combination with others which document the actions necessary, by when, by whom and involving actions and efforts to substitute. The action roadmap should be a public document summarising the overall action planning. It would only contain non confidential business information and focus on the overall strategy and sought outcome of the substitution exercise

for a group of companies (or an individual company if they opted-out of the collaborative elements). These roadmaps may need to be complemented by industry pledges or company specific substitution plans, which would likely contain commercially confidential information; as such the details would be kept confidential.

- **Industry Pledges:** Comprise a series of verifiable actions by specific participants of the action roadmap acting alone or together to share costs and pool risks to contribute to the road map.

- **Co-operation group of stakeholders:** To facilitate efficient and transparent information exchange between the participants (stakeholders, companies, users of the substance, actors upstream or downstream the value chain) on the current safety, sustainability and "technology readiness" of alternatives, subject to the protection of CBI and in line with competition law, specific co—operation groups or fora would be required. The objectives of the groups are to identify the specific use, to make an alternatives assessment, to develop action roadmap(s) for substitution and coordinate industry pledges, and to benchmark the risk minimization. The groups could also undertake actions together, such as a call for evidence on the use of targeted substances. The groups are to be considered a 'safe space' for stakeholders to find together alternatives and innovative approaches to the use of the substances in line with and subject to the requirements of competition law and protection of CBI.

5. *Options considered for the analysis*

The options considered for the analysis are described in the attached set of slides and will be further explained at the workshop. The options are a structured set of possible measures or approaches, intended to allow discussion and a subsequent analysis of impacts of those options. **They are not endorsed by or formal proposals of the contractor or the Commission.** As such, this background paper has deliberately not provided extensive written details of the options at this stage. It is the principles and building blocks, their advantages and disadvantages that we wish to explore and gain feedback on at the workshop, prior to a more detailed assessment of the costs and benefits for different stakeholders.

Questions for option 1 - voluntary substitution pathway

a) *What are the advantages and disadvantages for a fully voluntary approach to substitution planning, outside any specific regulatory requirement?*
b) *How could stakeholders agree to work together in "co-operation groups"? What steps are needed to effectively set up those groups on a voluntary basis? What measures would be needed to ensure the protection of CBI and compliance with competition law?*
c) *What practical steps would be needed for stakeholders to prepare a substitution pathway, including an action road map, in cooperation with/in line with guidance from authorities?*
d) *How could co-operation groups provide a "safe space" for alternative providers for discussions about potential alternatives? What additional support might be needed?*
e) *How could maximum engagement be achieved and risks of "free rider" behaviour be tackled?*
f) *Would individual "pledges" from industry be a useful complement to voluntary substitution pathways?*

Questions for option 2 - voluntary substitution pathway reviewed based on new regulatory provisions

(in addition to questions already addressed for option 1:)

a) *What are the advantages and disadvantages of focussing voluntary substitution pathway initiatives to a regulatory context?*
b) *How could early discussions between various industry stakeholders and authorities be launched on voluntary substitution planning as a way to adequately address concerns for which restrictions are being considered?*
c) *What measures might be necessary to ensure the voluntary substitution pathways are sufficient to address regulatory concerns and what role could e.g. scientific committees play?*
d) *How could monitoring of implementation of voluntary substitution pathways be organised? What role might a substitution centre or networks of substitution centres play to establish the state of the art for alternatives, to support companies, in particular SMEs and to provide a "safe space" for alternative providers exchange information, raise awareness and find partners for their ideas for alternatives?*

Question for option 3 – mandatory substitution pathway based on new regulatory provisions

(in addition to questions already addressed for option 1:)

a) *Do you think compliance, at least with the main principles substitution pathway, developed for a specific substance/use combination should be mandatory? Why? How?*
b) *What role could individual action roadmaps and individual substitution plans (i.e. company) play to concretise those main principles?*
c) *Would there be a need to monitor and enforce the implementation of the substitution pathway? Should that also apply to individual substitution plans?*
d) *Does this option raise concerns over implications for resource intensity/administrative burden for stakeholders? Do you consider this would simplify such complex cases, in practice? If so, how could this option be kept as simple and least resource intensive as possible?*
e) *What advantages would a mandatory system bring? What would this mean for the role of a substitution centre or networks of substitution centres play in establishing and validating the state of the art of alternatives, to support companies, in particular SMEs and to provide a "safe space" for alternative providers to exchange information, raise awareness and find partners for their ideas for alternatives?*

General and common questions

a) *What are the advantages and disadvantages of the options compared to each other?*
b) *Are there key elements missing in any of the three options or should there be other options/elements of options introduced?*
c) *Would combining one or more options with the baseline, i.e. standard restrictions be an option? How could that work?*
d) *What should be the role of EU, national or regional funding instruments to support substitution?*
e) *Do you think that the policy options properly address the specificities of e.g. SMEs and downstream users of substances?*