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

Templates for Rapporteurs

1 March 2024

Morning session Question Template for Rapporteurs

Question 1. Refining the Problem Definition

Challenges hindering effective and efficient substitution under the current regulatory framework [Outlined in the background paper]

1. Substitution requires time and resources; these needs are highly varied across uses and users of the hazardous substances
2. Downstream customers and upstream value chain characteristics can hinder substitution.
3. Uniform transition periods may result in unintended hinderances to substitution.
4. Risk of regrettable substitution.
5. No obligation for involvement amongst all value chain actors.

Question 1 (In-person): **Refining the Problem Definition.**

(1) Key additional insights or experiences on the 5 Commission identified challenges related to substitution and (2) What challenges hindering substitution were missing.

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Key Themes

- **Drivers to substitution:**
  - **Regulation or financial incentives, rest is marginal; how to reward and support front runners;**
  - **We need to look much more into perspective of alternative providers: difficulties to get data, difficulties in relationships with potential clients, need for "safe" environment**
- **Hurdles to substitution:**
  - **Price disadvantage**
  - **Technical feasibility**
  - **Lack of data (hazard, exposure and market info), data transparency**
  - **Information/interest asymmetry: chemicals producers vs. downstream users vs. OEMs – sometimes synergy/sometimes clash of interests;**
  - **Lack of co-ordination/collaboration – trade off with competition/competition law**
  - **International competition (EU and non-EU)**
  - **Unclear regulation/problems with predictability**
  - **Performance**
  - **Sustainability trade-offs and thus, resources**

Question 1 (In-person): **Refining the Problem Definition.**

(1) Key additional insights or experiences on the 5 Commission identified challenges related to substitution and (2) What challenges hindering substitution were missing.

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Key Themes

- **Role of regulation:**
  - **Regulation must be predictable; level playing field vs. specificity of use (for same use same rules + credibility important, but escape clauses?), granularity is a discussion point – one size for all?**
  - **Consistency of legislation and conflicts with e.g. circularity/other environmental parameters than chemical safety**
  - **Can green listing work? Can SSbD be a basis for green listing? Can SSbD be used as early warning system?**
  - **Speed of regulation vs thorough analysis - investments stop when analysis/regulatory debate too long – sometimes: is there a problem at all (controversial); is hazard data key point, or do we need to look more into detail of uses; can essential use bring more speed/or the opposite?**
  - **Uniformity over legislations, uniformity in terminology.**

Question 1 (In-person): **Refining the Problem Definition.**

(1) Key additional insights or experiences on the 5 Commission identified challenges related to substitution and (2) What challenges hindering substitution were missing.

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Primary areas of agreement/disagreement

- **Agreements**
  - **Regulation and financial incentives are driving substitution**
  - **Main obstacles for substitution are lack of information and co-ordination; market rigidity; technical issues**
  - **Regulation must be clear and predictable**
  - **Perspective of different actors is important**
  - **There is a need to strengthen co-operation between actors, start with early information and co-ordination on alternatives - but that must be balanced with competition issues/solutions need to be found (third parties etc.)**
  - **Agreement that collaboration is possible even with competitors when an alternative is sought for the technology used and not for the end product itself.**

- **Disagreements**
  - **What is the level of granularity at which regulatory uniformity/clarity apply - Flexibility**
  - **How much analysis do we make before we take decisions?**
  - **Look into situation of alternative providers (for some key issue, others did not identify this)**

Question 1 (virtual): **Refining the Problem Definition.**

(1) Key additional insights or experiences on the 5 Commission identified challenges related to substitution and (2) What challenges hindering substitution were missing.

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Key Themes

- **Lack of support to alternative providers** or to make a business case with the costs of alternatives being higher. Inhibits spreading of the alternative. How to better support innovators?
- **R&D timeframes need to connect better with regulatory timeframes** (example of RoHS where authorities and stakeholders get together)
- **Certification** and other regulatory/market requirements in certain sectors make substitution longer and more difficult to achieve
- Difficult for **authorities** to actually challenge substitution plan because **lack of knowledge and capacity**
- **Awareness across supply chain is key**. Particularly important for users in the middle of the supply chain because they rely on actors upstream and downstream.
- **Collaboration** needs to be encouraged
- Need for **predictability and reliability in the timelines set in the regulation** (need to know precisely "when is the hard stop").
- Multiple overlapping sustainability requirements on companies (phase out hazardous substances, reduce CO2 emissions, reduce water consumption,…)

Primary areas of agreement/disagreement

- Agreement with all 5 challenges (but REACH works) and further identified: **lack of information on authorities side and also across value chains.** Is it a problem with the regulatory system or rather how things work alongside the system?

Question 2 - Objectives in the Background Paper

Natural Capital

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.

Question 2 (In-person): **Validating the objectives of the substitution framework.** ***(1) Are the objectives identified the right set? What's missing/should be removed? (2) Which are priorities?***

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Key themes

- **Missing objective of creating and making available of information:** may be implicit and underlying many already identified objectives – but there seemed to be consensus on making an objective of creation and availability of information on hazard, risk and on alternatives more explicit. This new objective would address a key problem with current substitution framework.
- **Missing objective of communication and early engagement:** communication along the supply chain, including early engagement on substitution issues could be added to the objectives.
- **Taking a holistic approach to substitution, yet involving trade-offs and prioritisation of targets**
  - Broaden objectives to more than just hazard or risk. Other targets of circularity, net zero, climate change, social and economic sustainability could be considered as well.
  - EU legislation and standards include several targets already – there may not be one perfect substitute that address all EU targets. Trade-offs should be considered, and targets should be prioritised (e.g. first removal of hazard, then other targets of circularity, net zero, etc.)
  - To make objectives wider than hazard/risks, links could be made to the CSS, European Green Deal, Safe and Sustainable by Design, etc.
  - Harmonisation of legislation: reminder to ensure coherence across EU legislation, rather than a fully separate initiative.

Question 2 (In-person): **Validating the objectives of the substitution framework.** ***(1) Are the objectives identified the right set? What's missing/should be removed? (2) Which are priorities?***

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Key themes

- **Earlier and higher standards:** Objective 2 could be split as *earlier* and *higher* standards for environment and human health cover different elements. Some discussions around whether high or higher is more appropriate – maybe standards are quite high already, but could they be 'clearer' in terms of what is expected for substitution?
- **Flexibility vs predictability:** Concerns over references to 'flexible solutions', which may not align well with objective of 'predictability'. Predictability involves setting clear regulatory objectives with clear timetable, unlike a flexible approach. Flexibility may imply losing in terms of effectiveness of the initiative.
- **Scope for objectives?**
  - **Substances:** at the moment, unclear scope in objectives in terms of substances under scope. Focus should be on all most harmful chemicals, as per the CSS objectives and definitions, which are a priority for phasing out.
  - **Essential uses:** recurring references to including the concept of essential use in the objectives and scope of substitution planning. There were suggestions to replace the concept of complex cases by looking at essential uses. Another suggestion was to first look at essential uses, and then, among those, consider those that are more complex cases.

Question 2 (In-person): **Validating the objectives of the substitution framework.** ***(1) Are the objectives identified the right set? What's missing/should be removed? (2) Which are priorities?***

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Key themes

- **Refine the objective of competitiveness:**
  - When referring to competitiveness of industry, the creation of market for alternatives and the uptake of alternatives must not be undermined. Focus often on incumbents and them losing market share.
  - Include references to level-playing field (between incumbents and alternative providers, but also between EU and non-EU players). Enforcement is a key tool to ensure level-playing field, including checks of imported articles.
  - Difficult to purely *avoid* negative impacts as disinvestments from certain substances will take place: *minimisation* of negative impacts may be a better wording.
  - **Efficiency** of regulation in objective 4 should be extended to industry – not just EU and MS authorities.

Question 2 (In-person): **Validating the objectives of the substitution framework.** ***(1) Are the objectives identified the right set? What's missing/should be removed? (2) Which are priorities?***

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Priority objectives to guide the study (top 3)

- Overall, all objectives were deemed relatively important across groups. However, views were polarised when it comes to which objectives are priority ones.
  - For industry, the one key objective was competitiveness. Other stakeholders emphasised more on health and environmental protection (objective 2), as well as speeding up the pace of substitution (objective 1).
  - There were some concerns over the hierarchy of objectives, that protection of environment and health should be further at the top – at the moment, emphasis is on economic objectives. Noted that environmental and health protection are more universal objectives as well, while economic ones could lead to non-representative outcomes.

Question 2 (virtual): Validating the objectives of the substitution framework. *(1) Are the objectives identified the right set? What's missing/should be removed? (2) Which are priorities?*

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Objectives: Key themes

- **Overall, the objectives are right but quite broad. They would benefit from greater detail.**
- **Important to emphasise in objectives that the framework is harmonised with other initiatives (e.g. Safe and Sustainable by Design)**
- **Framework should aim to provide clarity and transparency over regulatory timelines – links to objective 3c.**
- **Key part of enabling innovation and substitution is facilitating communication and understanding across the supply chain – both up- and down-stream. Communication and collaboration is crucial.**
- **Perhaps the framework should also track substitution efforts (including success stories) to see what lessons can be learned.**
- **Promotion of knowledge-sharing to support substitution activities – especially for SMEs.**
- **Focus the framework specifically on incentivising substitution and promoting market opportunities. Innovative action in EU industry should be rewarded - . 'Speeding up' substitution and innovation (objective 1) cannot be done directly.**
- **Important that the framework recognizes the variety in different industries and applications, and the challenges they face.**
- **Costs versus benefits of the framework?**

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Question 2 (virtual): Validating the objectives of the substitution framework. *(1) Are the objectives identified the right set? What's missing/should be removed? (2) Which are priorities?*

Priority Objectives to Guide the Study (top 3) – General consensus on top 3 priorities. But in what order?

- **Speed up innovation and substitution – Should this have a greater, specific focus on incentivisation and promoting market opportunities?**
- **Promote earlier and higher standards – Suggestions protection of human health and the environment is the overarching framework objective and should this come first.**
- **Enhance competitiveness of involved EU companies – If this includes incentivisation of innovation and substitution efforts, then perhaps objective 1 is not needed.**

Question 3 (In-person): **Information needs to support speeding-up regulatory substitution timelines.** *How information on uses, exposure and alternatives speed up substitution of targeted hazardous chemicals in advance of regulatory requirements? What information is needed and how should it be provided?*

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Key Themes

Key words: Regulatory certainty, better access to better information, collaboration

- **Clear and early information on proposed restrictions and bans (including precise information on what will be restricted and banned (what uses, what substances (note impurities)).**
- **Not enough available data (on SVHC) from REACH registration dossiers – more precise on use pattern, to understand what uses may be restricted. Especially difficult for SMEs**
- **Blockages in the market to get to sell alternatives – industry develops alternatives, but can be slow uptake because of long regulatory process.**
- **Need consistent ways (methods/templates) to assess and compare hazards of substance – to find alternatives.**
- **Need for matching substance function to use (to identify alternatives).**
- **Coordinated 'platforms' (voluntary) to discuss possibilities for alternative replacements**
- **Clear 'roadmaps' for R&D (it is not possible to test everything).**
- **Working together (on sector basis) enhances progress (rather than auth/industry 'pulling in different directions').**
- **Supply chains are global – this needs to be considered – change is necessarily global**

Question 3 (In-person): **Information needs to support speeding-up regulatory substitution timelines.** *How information on uses, exposure and alternatives speed up substitution of targeted hazardous chemicals in advance of regulatory requirements? What information is needed and how should it be provided?*

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Primary areas of agreement/disagreement

(These are issues where there was not necessarily agreement in the groups)

- **Notification of substances by DUs on uses of SVHCs – legal or voluntary?**
- **Inclusion of a substitution plan in REACH registration dossier (for SVHC substances)**
- **More detailed information (e.g. on uses) in REACH registration dossiers – but need to simplify information that can be easily understood by users in the supply chain.**
- **Risk that sharing of R&D gets close to breach of competition law.**
- **Risk that very detailed use information is potentially sharing sensitive business information that DUs do not want shared (business critical that detailed and specific uses are not public).**
- **Other lists of substances (such as SIN list) help to give early warning.**
- **The changing landscape of hazard – developing new products can take a long time – substance selected on the basis of a good hazard profile some years ago now may have a 'bad 'profile and no longer be acceptable.**
- **Not enough info on risky substances (for restriction) leads to wide scope of restriction - which then captures uses that maybe should not be restricted - better information (in REACH dossier) would help target restriction proposals.**
- **Define the substance (both that being restricted and those that are alternatives) CAS can be poor descriptor, impurities and production process can be important.**

Question 3 (virtual): **Information needs to support speeding-up regulatory substitution timelines.** *How information on uses, exposure and alternatives speed up substitution of targeted hazardous chemicals in advance of regulatory requirements? What information is needed and how should it be provided?*

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Key Themes

- **Early triggers:**
  - **Regulatory considerations: RMOA, hazard classification, candidate list, registry of intentions for restrictions, member state lists (e.g. PRIO in Sweden), OEL**
  - **NGO awareness rising initiatives: e.g. SIN List (ChemSec)**
  - **Supply chain dialogues/conversations**
  - **Rewards/fees**

- **How to make triggers work:**
  - **Awareness raising, change of mindset, "success stories"**
  - **Mechanisms to support supply chain communication**
  - **Capacity building**
  - **R&D funding, especially for non-commercial sectors (e.g. defense ministries) and SMEs**
  - **Collaboration between different DGs/agencies and DGs and across legislation**

Question 3 (virtual): **Information needs to support speeding-up regulatory substitution timelines.** *How information on uses, exposure and alternatives speed up substitution of targeted hazardous chemicals in advance of regulatory requirements? What information is needed and how should it be provided?*

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Key Themes

- **Information (needs) to support substitution planning:**
  - **Data platforms and information portals (e.g. Zero PM, French Substitution Portal)**
  - **Positive lists**
  - **Case studies**
  - **Use-specific R&D**
  - **Information flow in the supply chain**
  - **Networks to share best practice**
  - **Information from the side of alternative providers**

Primary areas of agreement/disagreement

- **Overall agreement**
- **Slightly differing views on the existing level of awareness regarding substitution and the need for additional triggers**

Afternoon Session Question Template for Rapporteurs

Question 4 (Face to face)
Facilitator: Pete Simpson. Rapporteur: Monique Pillet

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

- ***Primary Question:*** Should the regulatory use of substitution planning remain limited to provisions in current policy (e.g., its current role under REACH authorisations) or be extended to other applications (e.g., as a precondition for derogations from REACH restrictions)?
  - *Early data on substitution will help to chose the regulatory actions that are appropriate*
  - *Other legislation have provisions coming supporting substitution. To be considered too.*
  - *Tools for substitution planning are needed for different actors and their scales with different aims*
  - *Companies have to take into account other legislation when thinking about substitution*
  - *Candidate listing not sufficient signal*
  - *Should consider substance/use combination*
  - *Compulosry or not – different views.*

Question 4 (virtual): **Legal/voluntary substitution planning requirements.** *Should the regulatory use of substitution planning remain limited to provisions in current policy or extended? How can voluntary use of substitution planning complement existing regulatory provisions?*

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Key themes:

- **Definition and content of 'substitution planning'** would influence its use (REACH: authorization only or also restriction / voluntary vs mandatory)
- Need to distinguish between substitution strategy at **sector level versus** substitution plan at **company level**
- **REACH perspective:** if **company-specific** substitution planning, it would not work for restrictions; **sector-wide** substitution planning could play a role in restrictions but need to be mindful of complexities, process and resources , link it to new early information requirements
- **Sector-wide substitution planning**: exchange of confidential business info is an obstacle
- **Fees:** could be usage fees (i.e. economic incentive that would influence prices) or administrative fees to cover regulatory work to support substitution work (Massachusetts model)
- If substitution planning is meant to work for other legislation than REACH, **needs to be general enough**
- Important to **avoid one-size fits all approach** with substitution planning
- **Importance of collaboration between regulators and companies** – example of substitution of titanium dioxide in pharma, cooperation with EMA

Question 4 (virtual): **Legal/voluntary substitution planning requirements.** *Should the regulatory use of substitution planning remain limited to provisions in current policy or extended? How can voluntary use of substitution planning complement existing regulatory provisions?*

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Primary area of disagreement:

<u>Voluntary actions</u>

- EU level **voluntary agreements** from the past (e.g. ACEA) not successful and no evidence that voluntary action leads to substitution
- Protection of health and environment from most harmful substances cannot be left to voluntary action, **regulation is key to trigger substitution**
- issue of **free-riders** under voluntary use of substitution planning

versus

- voluntary programmes for substitution are needed, can be triggered already by classification
- **ESPR voluntary initiatives** could be looked at as examples

<u>Extend substitution planning to other policies/ legislation</u>

- No consensus on whether substitution planning should have an increased role in the regulatory framework

Question 5 (In-person): **Focus of the substitution plan.** *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?*

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Key Themes

- **Individual companies faces different conditions and concrete substitution in their products is assessed in their own capacities - companies also start from different substitution points**
- **Companies with similar/same supply chains could easier collaborate – but not for competitors**
- **No universal experience on joint approaches – there are a number of cases where joint approaches work, especially in early phases of substitution, and where an obvious solution exists, but as soon as innovation kicks in, in reality companies go on their own**
- **For such cases, individual substitution plans are easier to prepare, coordination will be an effort**
- **Under REACH no experience with joint approaches**
- **Experience under RoHs is different, where joint approaches are required, which work quite well**
- **Companies find RoHS easier, as it allows them to interact with the development of derogations, while under REACH restriction development is a black box**

Question 5 (In-person): **Focus of the substitution plan.** *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?*

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Key Themes

- **A joint platform to have exchanges could be conceivable. However, it should not result in delaying the process**
- **Competition issues seen by some as a major barrier, others see rather limited problems that can be overcome with relevant mechanisms**
- **Regulatory measures could be more efficient than non-binding substitution planning**
- **Allowing some flexibility in the substitution planning could be needed but can be seen as backdoor option and hamper efficiency**
- **Under a joint approach, different interests could also slow down joint efforts and discussions**
- **Bigger joint substitution planning efforts could result in less ambitious substitution**
- **Under a joint approach, confidentiality of data could complicate exchanges**
- **If applied to restrictions, a multitude of individual substitution plans would be very difficult to be handled by enforcement authorities**

Question 5 (virtual): **Focus of the substitution plan.** *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?*

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Key Themes, Primary areas of agreement/disagreement

- One-size fits all does not work for substitution planning – combined approach
- Collaborative SP will always be subject to CBI and competition issues, might need regulatory oversight etc to ensure legality etc; involvement of regulator to ensure standards met
- Collaborative SP only high-level, since final decisions have to be made at the company level? Collaboration can then provide peer-review, performance checks etc, strategic direction.
- Collaborative SP can help regulator identify outliers (laggards, difficult cases) for direct action
- Collaboration more possible where competition is less related to chemistry/substance. Chemistry might be key to company survival or generic across product sector
- Non-PFAS water repellant fabrics as a case study – clothing manufacturers (non-chemistry competitive) signalled desire to substitute and provide market – business case for substitution
- Regulation easier when substitutes can service larger portion of the market (codification of existing progress e.g. formaldehyde). More difficult when alternatives are niche and/or few performance/price advantages
- Look at CFCs and how that substitution progressed and was managed – relevant to PFAS
- Need for central (COM) funding targeted at priority areas/substances etc
- Need to ensure SMEs are informed and not excluded from collaborative activities – depends on nature of technology

Question 6 (In-person): **Who prepares, reviews and monitors implementation of plans?** *Who should be the actors involved in the preparation of substitution plans and how should decisions on their appropriateness be taken?*

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Key points

- **Clear consensus that industry has to lead. But in implementation other 3rd parties can intervene**
- **Substitution centres entity to support, researcher, academia..**
- **3rd party neutral entity to secure level playing field, CBI. Some mention ECHA Could fit in that role**
- **Views about communication across DU - value chain - that it is important..**
- **Benefits on value chain and discussing**
- **Sometimes sector wide plan, and in others company by company**
- **It needs to have a committee that it is monitored**
- **Thre was not agreement on how to monitor, how this 3rd parties have to lead and how to keep it ambitious**
- **Member States authorities might have capacity problems.**

Question 6 (virtual): **Who prepares, reviews and monitors implementation of plans?** *Who should be the actors involved in the preparation of substitution plans and how should decisions on their appropriateness be taken?*

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Key Themes

- Acting early

- Need to recognise nuances - sector / company specific substitution plans + nature of substance, use and release pathway in question?

- Structured approach enabling collaboration

- Uncertainty on success of substitution plans (need to foresee review moments / milestones)

Primary areas of agreement/disagreement

- A: Knowledge predominantly within industry

- A: Scope for bringing more stakeholders together:

    - Implementation -> Industry collaboration / stakeholder platforms

    - Assessment -> Can authoritative scope of expertise be expanded?

    - Monitoring -> Can be enhanced

*Voluntary action vs regulation as a driver

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