Approaches for Accelerating Substitution under REACH and Beyond: Strategic Options Assessment

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BACKGROUND/CONTEXT

Government authorities have an important role in advancing substitution as one critical risk management strategy. REACH provides a legislative mechanism to drive substitution. However, there are also a number of market drivers for substitution, coming from consumers and major brands and retailers. While regulatory or market policies can be important motivators for substitution, programmatic support is also needed to overcome a number of capacity challenges.

The European Chemicals Agency (ECHA) commissioned the Lowell Centre for Sustainable Production (LCSP) to complete an evaluation of opportunities to enhance capacity for analysis of alternatives (AoA) and substitution in the European Union (EU). That work resulted in a 2016 report, *Improving the Identification, Evaluation, Adoption and Development of Safer Alternatives: Needs and Opportunities to Enhance Substitution Efforts within the Context of REACH.* The evaluation identified a number of examples of authority activities and structures that support or could support substitution, but these are largely unconnected and suffer from resource and technical limitations. The report outlined a series of recommendations to improve substitution capacity in three main areas: building infrastructure; increasing engagement/collaboration; and enhancing technical capacity.

Based on the 2016 report, ECHA requested that the LCSP develop an assessment of and proposal for strategic options to advance priority recommendations in the 2016 report focused on advancing substitution in the EU. The purpose is to engage stakeholder dialogue on the most effective approaches to achieve this goal. This strategic options assessment report outlines a range of possible strategies in the three focus areas. The report does not constitute a single workplan but provides a menu of possible strategies; further selection and refinement will be required for implementation.

In developing these strategies, we have considered existing resource and capacity limitations; where possible, we have sought to leverage existing mechanisms and initiatives that do not currently focus on substitution-related topics, but could. The report outlines challenges and identifies next steps for research, dialogue, and engagement to advance the options. In the near-term, the recommended options are intended to inform ECHA's internal strategy to advance the substitution of hazardous chemicals. However, this strategic options assessment takes a broader view than what ECHA alone can achieve. The strategies outlined in this report require leadership and engagement among a range of stakeholders, including: industry, industry consultants, Member State (MS) authorities, non-governmental organisations (NGOs), Commission authorities as well as ECHA. Moreover, ECHA's substitution strategy needs to for part of a wider Commission-level strategy (participation of several relevant Directorate Generals such as DG Environment, DG Grow, and DG Research among others) that includes a number of instruments (including incentives, capacity building, technical support, and guidance) resources and leadership beyond what ECHA can offer.

Engagement of a broad range of societal stakeholders, authorities and industry in particular, is critical to implementing this strategy. Removal of hazardous substances from manufacturing processes and products without thorough consideration of alternatives can lead to regrettable substitutions. Innovation in safer chemistry – as an innovation and environmental and health strategy – can lead to win-win benefits. Hence these actors have responsibility to support the thoughtful evaluation, design and adoption of safer materials. This means going beyond traditional regulatory approaches to developing a more holistic strategy that engages new actors and a broader range of incentives, research, and supports.

GOAL AND OBJECTIVES

The overall goal of this effort is to enhance the impact of REACH implementation, as well as other government and market policies, in driving, promoting, and supporting the informed substitution of substances of very high concern (SVHC). Critical to this work is an understanding that substitution is not merely a regulatory compliance measure, but a pillar at the heart of the REACH approach to reducing risks:

> *Adverse effects on human health and the environment from substances of very high concern should be prevented through the application of appropriate risk management measures ... and with a view to progressively substituting these substances with a suitable safer substance.*[1]

To achieve this goal, the strategy options outlined in this analysis seek to impact the following six objectives:

- Increase the knowledge about and engagement in substitution activities by actors at all levels, including EU and MS authorities, industry (different sectors and the entire supply chain), and NGOs, creating a cultural foundation for substitution and chemical innovation.
- More effectively connect AoAs and substitution with EU- and MS-level activities on innovation, the circular economy, and the global competitiveness of EU businesses.
- Embed substitution thinking as a core chemicals management approach in firms and agencies so as to accelerate timing of substitution planning and use of alternatives assessment earlier in chemical assessment and management processes.
- Enhance coordination and networking between authorities and other organisations who can provide support for substitution.
- Increase available resources to support firms and others in substitution decision-making.
- Increase the utility and quality of alternatives assessments completed under the authorisation and restrictions processes and beyond regulatory programmes through improved guidance and training.

FOCUS AND APPROACH FOR DEVELOPING STRATEGY OPTIONS

LCSP researchers undertook a number of initial conversations with ECHA staff to develop a set of priority thematic areas for the scoping of strategy options based on recommendations in the 2016 report. These conversations led to focusing the assessment in three targeted areas, leaving open the opportunity to consider additional priority areas based on stakeholder consultation.

The three thematic areas for the scoping of strategy options included:

1. Increasing engagement, networking and collaboration on substitution.
2. Developing mechanisms to support the research and development (R&D) investment on sustainable chemical and technology innovations in support of substitution.

[1] REACH ¶70

3. Enhancing capacity development for authorities and enterprises to support and implement substitution planning and the conduct of AoAs.

Based on these priorities, LCSP staff undertook document research and conducted fact-finding interviews with approximately 20 organisations[2] that provided insights into each of these priority areas regarding existing initiatives, needs and strategy ideas. LCSP staff also drew from their extensive experience in developing, implementing and evaluating substitution support programmes in the US.

KEY LEARNINGS AND OVERARCHING CONSIDERATIONS

Based on our discussions to date and assessment of existing programmes we see some overarching findings that are critical guides to the implementation of any strategy going forward. These include:

1. Substitution must be reframed in a **broader language around innovation**. We observed that some stakeholders use "substitution" and "innovation" terms in almost mutually exclusive ways. Most stakeholders viewed substitution as purely a regulatory activity and not connected to innovation in safer chemistry that creates new business opportunities with environmental and health benefits. This cultural barrier needs to be addressed. There is **a need for a broad mind-set change among decision-makers in enterprises as well as in government agencies regarding sustainable chemistry as an important chemicals management and economic development approach**, possibly by connecting substitution to discussions on the circular economy, sustainability, and innovation.

2. Substitution thinking needs to be expanded beyond its **narrow/ "shallow" form** (a term coined by Netherland authorities)**:** Substituting one chemical with a direct replacement only when required by regulation and only if drop-in substitutes are available. This approach will not address broader functions that chemicals of concern provide or open up the innovation opportunities afforded by a broader framing of "substitution". Moreover, the problems created by narrow/"shallow" view of substitution will be compounded in the context of a circular economy that places additional demands on the sustainability of materials, product and chemicals.

3. **A number of notable findings from our Sept 2016 report were emphasised again during fact-finding conversations with stakeholders, in particular**
   - **The primary motivations for substitution are regulatory** – e.g. the authorisation process. However, the authorisation process will often lead to "shallow" substitutions because the timeline is too short for innovative research and bringing to market.
   - It is critical to **start the substitution planning timeline** earlier (e.g. to Candidate List or even earlier) so that there is proper time for assessment and innovative research on alternatives (ECHA may not have legal authority to require this, but should be able to encourage it in terms of competiveness when regulation is likely to have an impact in the future.)

4. **Authorities and stakeholders that play critical roles in accelerating substitution have not typically been connected**, such as research and innovation agencies and regulatory agencies. Building some

[2] Those interviewed included government authorities in several member states, European Commission agencies, industry consultants, industry associations, non-profits, and academics as well as experts from research institutes and government agencies in the United States.

type of map that develops understanding of the many actors in the substitution space would be helpful.

5. ECHA may be seen (or see itself) primarily as a regulator, but some stakeholders would welcome **ECHA undertaking more programmatic initiatives to promote substitution beyond regulation as a "messenger" for the role of substitution in achieving the vision of REACH**. Indeed, strategies outlined below would require that ECHA take on a broader role than simply implementing and enforcing REACH and other legislation. For example, there remain "cultural mind-set" issues (e.g., understanding of innovation side of substitution among decision-makers) that ECHA can help advance. Early efforts by ECHA on this front were seen as helpful to authorities. However, taking on this broader role would require significantly increasing staff resources available for substitution and parallel leadership on substitution needs to occur as well within other Commission-level and MS authorities.

6. Given resource constraints, **ECHA is better positioned to be a facilitator, convener, and connector** of elements, actors, and strategies required to move forward. For example, ECHA can serve a critical role of connecting projects and stakeholders that might not know about each other and to launch pilot-level demonstration initiatives that can be models for replication in a range of Member States. ECHA may consider specific priority demonstration projects that help build understanding and experience. However, actual projects (for example on innovation) could be more effectively implemented by other agencies and organisations.

PRIORITY STRATEGIES – PROPOSED OPTIONS

The following sections outline strategy options for ECHA to consider in the development of its strategic plan to implement recommendations in the 2016 LCSP. There is no expectation that the strategy options outlined in this report should be adopted in full – these are considered *options*. The report is intended to stimulate thinking on behalf of ECHA and EU stakeholders regarding the range of strategies that could be included in ECHA's (and other governmental and industrial) strategic plan to enhance substitution efforts in the EU balancing considerations of priorities, resources and readiness among collaborating organisations.

This report focuses on the three priority thematic areas outlined in the 2016 LCSP report: (1) Increasing engagement, networking, and collaboration on substitution; (2) developing structures to promote innovation and infrastructure to support research and development and adoption of sustainable chemistry substitutes; and (3) enhancing capacity development for authorities and businesses on substitution. Table 1 summarises the strategy options for consideration for the above three priority areas. For each of the three areas, we examine underlying considerations and context (foundation) for the priority strategic thematic areas, pros and cons of options, and gaps in knowledge that will require additional research and dialogue. Many of the actions, however, cross priority thematic areas.

There was one additional recommendation in our 2016 report that also resonated with stakeholders as a key strategy for enhancing substitution:

> "Develop web-based data resources to aid in the screening and evaluation of alternatives by using and mining data submitted under REACH, including a repository of resources relating to substitution."

This strategy is not addressed in the strategic options below because it was not elevated as a priority in the scoping phase of this strategy options assessment. However, given the data ECHA has collected and its expertise in data management, we encourage further dialog and consideration by ECHA and stakeholders of this recommendation given that substitution processes have been hindered to date by a lack of accessible data on chemical hazards for alternatives, functional use, and applications through the supply chain. Although significant resources have been invested in making REACH data for chemicals accessible, new data access platforms are needed to help stakeholders identify and evaluate alternatives for substitution purposes. A focused initiative is needed to review how chemical registration data as well as information about alternatives that have been included in authorisation applications and restriction proposal can be more accessible for future substitution planning and alternatives evaluation efforts.

Table 1: Summary of Proposed Strategy Options

Objective/Strategy Elements	Benefits	Challenges	Resource Needs and Timing
Engagement 1. Develop a queriable inventory of EU substitution programmatic activities, models and contacts			
Create an electronic resource that outlines the current state of play of EU substitution projects, programmes, and contacts in government, industry, academia and NGOs to assist with network and associated substitution/ AoAs capacity development efforts	Important foundation to build necessary programme contacts and materials; clear project scope and makes for a "quick and easy" project tender; can implement in the near-term	Maintenance and on-going updating; determining scope of projects, initiatives, and programmes to include/not include	Envisioned as a consultant contract; well-defined scope. Tender issued by DG Environment or another EC authority *Near-term strategy*
Engagement 2. Expand the focus of the Network of REACH and SEA and Analysis of Alternatives Practitioners (NeRSAP) to serve as a multi-stakeholder network for strengthening expertise in conducting AoA and related substitution challenges			
Increase the quality of AoA and substitution activities while increasing coordination and collaboration on substitution efforts and needs across the EU • Establish an AoA working group of NeRSAP • Convene/discuss priority topics as identified by an advisory committee	Existing network and structure; a charge that conforms with a focus on AoA/substitution topics; some relevant experts and the range stakeholders are currently engaged; can implement in the near-term	Difficult to maintain momentum via an annual meeting; unlikely to support deep collaborative initiatives among participants; does not currently reach many practitioners involved in substitution; unclear mandate; no binding/formal decisions.	More time/resource commitments among ECHA and NeRSAP participants to plan and facilitate AOA-specific dialog *Near-term strategy*
Engagement 3. Establish a new EU-level AoA and Substitution Stakeholder Forum, as an expansion to NeRSAP			
Increase coordination and collaboration on AoA/ substitution efforts and needs – including innovation research and development – across the EU among stakeholder and integrate into government and industry decision-making. • Establish a new, EU-level AoA and substitution stakeholder forum	Modelled after the UK Chemical Stakeholder Forum; connects substitution initiatives within the context of risk management policy and programmatic discussions; increases attention to and momentum for substitution; provides recommendations for policies and collaborations	Resource intensive; requires Commission-level support and a clear mandate; unclear whether an MS model of the UK forum will work EU-wide; requires regular meetings and calls	Scoping out the need and structure for such a forum could be taken-up by a sub-group at NeRSAP as a first step *Mid to long-term strategy*

Objective/Strategy Elements	Benefits	Challenges	Resource Needs and Timing
Engagement 4. Establish an Inter-authority forum on AoA and substitution			
Enhance inter-authority collaboration, coordination and capacity on substitution implementation and AoAs needs and challenges • Establish a steering committee of EC and MS authorities to develop an understanding of collaborative needs • Develop a background options paper to lay out collaborative opportunities • Convene a 1 to 1.5 day in person meeting organised and facilitated by initial steering committee • Identify a secretariat among authorities to take leadership for the first 2 years of the working group. A rotating MS authority leadership model is envisioned • Convene quarterly to discuss/present priority topics	Informality lessens resource burdens on authorities; authority-only dialogue facilitates learning, improves communication and identification of opportunities that leverage shared chemical substitution priorities and resources	Need to Identify interest by an authority to provide the necessary leadership and infrastructure to support; substitution is not necessarily part of the current workload of many authorities	Requires ECHA/EC/MS authority time and commitment; more resource investment by authority who takes on the Secretariat/ coordination role *Near-term strategy*
Engagement 5. Host a 2018 Substitution and Chemical Innovation Symposium			
Convene government regulatory and funding authorities, industry, NGOs and academic stakeholders to build understanding on a broad range of substitution topics, develop strategies and organise new collaborations to support substitution • Establish a symposium planning committee • Secure symposium sponsors • Plan and host 1-2 day symposium	Useful engagement mechanism to engage a number of networking strategies – multi-stakeholder, inter-authority and supply-chain professional exchange; supports multi-stakeholder engagement in building strategy, projects, and new collaborations; reframe substitution as an innovation activity and not simply regulatory	Needs to be strategically focused and planning is intensive; ensuring broad attendance; strong leadership/coordination/facilitation to include the perspectives of the broad range of sponsors and balancing the overarching needs/aims of the symposium; cost	Requires financial sponsorship by several organisations; Requires organisation (many options here: ECHA, academic institute, or other) to commit to organising responsibility; resource/time investment by a symposium planning committee; and engagement of an event organiser *Near-term strategy*

Objective/Strategy Elements	Benefits	Challenges	Resource Needs and Timing
Innovation 1. Conduct an Inventory and Gaps Assessment for Innovation Research Support Infrastructure for Sustainable Chemistry Development			
Build an inventory of available public and private funding opportunities at the EU and MS levels for innovation research, public/private partnerships for substitution, and innovation support centres to understand gaps and opportunities for supporting safer chemical innovation. Use this Inventory to engage EU-wide and MS funders in substitution R&D and application	Develops a baseline understanding of available funding; facilitates opportunities for collaborations among funding institutes in support of substitution needs	Funding is not well coordinated; there are distinctions between basic funding, technical support for adoption, and private public partnership funding	Envisioned as a consultant contract; broad scope may need to be narrowed *Near-term strategy*
Innovation 2A. Develop early alert database			
Provide early notice of possible regulatory changes to relevant actors throughout supply chain.	Disseminates information widely, especially to downstream users who are less likely to be tracking specific chemical regulation; motivates research and possible action on alternatives at a much earlier timeline and by upstream and downstream users	Need to identify interested parties and communicate clearly to them; will require research to establish and to maintain; probably relies on intermediaries (e.g. trade organisations) in most cases	ECHA or consultant staff time for research and outreach. Consider starting with the REACH Centre's CHEMTRAC offerings as a possible model *Mid-term strategy*
Innovation 2B. Develop connection-making database			
Provide direct connections between actors with substitution needs and those with potential alternatives	Allows for connections to be made between unconnected actors, rather than relying on existing connections; promotes connections within internal market; increases competitiveness	Some development time/cost; requires active buy-in by many users to become viable.	ECHA or consultant time and research; investigate success of EEN database or ChemSec Marketplace as a model *Mid-term strategy*

Objective/Strategy Elements	Benefits	Challenges	Resource Needs and Timing
Innovation 3. Enhance industry-academic research partnerships to advance innovative solutions to substitution challenges			
Enhance research and development partnerships among academic research institutes and industry on substitution challenges by leveraging existing collaborative models such as ME310 Global and Member State eco-innovation funding models	Important mechanism to advance R&D on substitution challenges among enterprises that lack R&D capacity; leverages existing academic-industry innovation partnership models	Requires expanding models such as ME310 beyond a focus on mechanical and materials engineering; requires investment by Member States to prioritise innovation for substitution challenges in existing Eco-funding/subsidy programmes	ECHA and MS authority facilitation support *Near-term strategy*
Innovation 4. Convene Sector-Specific Supply Chain Dialogues			
Leverage supply chain engagement at EU and MS level to both communicate needs in substitutes and demonstrate demand as well as accelerate development and scale of sustainable chemistry solutions. Demonstrate viability of substitution options. Educate supply chains on value of and resources for analysis of alternatives and substitution.	Important strategy to gain the interest and engagement of supply chain actors, particularly downstream users/SMEs. Broad range of companies/researchers/ expertise involved may surface innovative alternatives not previously identified from within the supply chain.	Often focused on single application/single chemical of concern; difficult to advance broad-scale engagement and change	ECHA plays a relatively limited convener/facilitator role, in collaboration with other actors (especially trade organisations); some travel/conference resources required *Near-term strategy*
Innovation 5. Establish Substitution Support Office and network of Substitution Support Centres			
Establish technical support infrastructure for SMEs to undertake substitution	Assists SMEs and downstream users in overcoming technical barriers to substitution; links them with resources necessary for adoption of sustainable chemistry solutions	Funding is needed to support such a network; would have to be distributed around Europe as language will be a challenge for many SMEs	Substantial funding commitments required from ECHA to establish substitution support office, or from Member States to establish centres *Long-term strategy*

Objective/Strategy Elements	Benefits	Challenges	Resource Needs and Timing
Capacity 1. Align and update ECHA AoA guidance with best practices, developing resources for those conducting AoAs or investigating alternatives			
Improve the quality and consistency of AoAs, including but not limited to those for authorisation and restrictions proposals. • Establish a best practice working group • Review informative AoA frameworks/literature • Establish best practice metrics • ID case examples to serve as models • Develop "best practice briefs" to provide updated guidance	Establishes standards of practice in response to developments in the field of AoA to better align practitioners; improves quality and consistency of AoAs; needed to guide and focus AoA trainings	Inherent methodological and consensus challenges regarding establishing best practices	Convened and facilitated by ECHA; Includes participation and effort by experts knowledgeable about the range of AoA topics *Near-term strategy*
Capacity 2a. Develop and deliver three types of substitution/AoA trainings: Substitution Thinking Training			
Enhance capacity and early thinking on substitution planning among any/all corporate and government decision-makers, SMEs and downstream users. • Introduces the basic ideas and tools of substitution/AoA • Brief 1 hr to ½ day training • "Train the trainer" programme	Adapts available training materials developed by Subsport and US entities.	Inherent challenges involved in (a) finding the right organisation to develop the curriculum and lead the trainings and propagate the training programme via "train-the-trainer" approaches	Consultant needed to adapt existing curriculum and to deliver training objectives in a range of venues; train the trainer programme needs support needed from ECHA or relevant EC directorate or MS Authority *Near and Mid-term strategy*

Objective/Strategy Elements	Benefits	Challenges	Resource Needs and Timing
Capacity 2b. Develop and deliver three types of substitution/AoA trainings: <u>AoA Best Practice Training</u>			
Enhance AoA capacity among ECHA Committees, industry (supply chains) and their authorisation application consultants; REACH Competent authority staff • Reviews best practices in AoA • Provides examples of "poor" "high" quality AoA • Reviews overarching standards of practice (e.g., data sources, being explicit about uncertainties) • Provides resources for additional support	Utilises materials developed by AoA best practice committee above (C1); Envisioned as modules per AoA component	Inherent challenges involved in (a) finding the right organisation to develop the curriculum and lead the trainings and propagate the training me via "train-the-trainer" approaches	Consultant needed to adapt existing curriculum and to deliver training objectives in a range of venues; train the trainer programme needs support from ECHA or relevant EC directorate or MS Authority; Continued training could be offered by ECHA staff on an as needed basis *Near and Mid-term strategy*
Capacity 2c. Develop and deliver three types of substitution/AoA trainings: <u>Specialised Topics for AOA Practitioners: Advancing an AoA Community of Practice</u>			
Provide professional development opportunities to AoA practitioners to keep them abreast of methodological developments. • Envisioned as a peer-to-peer education programme primary webinar-based. • Quarterly series	Supports a growing AoA Community of Practice; convenes practitioners to improve expertise in the field of AoA, provides input to authorities and industry to improve substitution activities	Identifying topics to sustain a programme	Grows out of a professional meeting on AoA topics (e.g., through SETAC or Symposium described in C4; ECHA could engage a research institute or academic institution to sponsor/organise and on-going AoA COP webinar series *Near to mid-term strategy*
Capacity 3. Investigate options for and the feasibility of an AoA certification programme			
Improve the quality and consistency of AoAs for authorisation, restriction or market requirements	Advances a required training programme to improve the quality and consistency of AoAs and grow the field of practitioners based on a continued education on best practices	Establishing and maintaining a certification system; push-back from industry/consultants	ECHA tender for consultant contract *Near to mid-term strategy*

1. *Engagement:* Strategy options for increasing networking and collaboration on substitution

Considerations/Context

The LCSP evaluation conducted in 2016 revealed strong interest by authorities and other stakeholders to develop substitution networks that expand opportunities to learn from the expertise and actions of others in order to advance substitution efforts on common challenges. There is a range of on-going activities on substitution across the EU, yet limited coordination on these initiatives among MS, ECHA, and the Commission. A similar situation happens among stakeholders from industry and the NGO sector. Furthermore, these activities are poorly tied to other EU environmental and sustainability priorities for which they could contribute greatly (e.g., circular economy, non-toxic environment, worker safety). Stakeholders interviewed in the development of these strategy options agreed that establishing networks to support substitution efforts is a fundamental need.

In general, there is no "one size fits all" network that could meet the needs of the range of stakeholders involved in accelerating substitution and AoA capacity in the EU. There are reasons for stakeholder-specific networks and forums (e.g., internal industry dialogs or internal government authority dialogs) as well as multi-stakeholder collaborations. Our experience indicates that there is an important need for authority-to-authority collaboration (without other stakeholders) as well as multi-stakeholder collaboration. Utilising existing networks may be useful in terms of reducing resource needs (i.e., not creating another network or committee), but it is important that the existing networks are amply broad and led in a way that will engage new topics (such as AoA) and perspectives.

Networks are a tool to achieve a number of goals critical to advancing substitution, including: (1) Improving coordination of multiple programmes across the Commission, Member States and industry (e.g., not reinventing the wheel and having an understanding of what others are doing); (2) increasing mutual learning, improving practice, and embedding substitution in the culture of organisations through sharing of challenges and experiences; (3) connecting often disconnected knowledge, expertise, programmes, and other resources; and (4) developing and implementing new understandings and initiatives to overcome barriers and improve substitution practice.

Key considerations for the success of networks based on the structure of other sustainable and productive network models: (a) clear mandate and purpose, (b) strong secretariat/leadership and coordination (c) continuity and trust among participants, and (d) long-term sustainability.

Proposed Actions

OVERVIEW OF PROPOSED ENGAGEMENT ACTIONS
E1. Develop a queriable inventory of EU substitution programmatic activities, models and contacts
E2. Expand the focus of NeRSAP to serve as a multi-stakeholder network for strengthening expertise in the conduct of AoA and related substitution challenges
E3. Establish a new EU-level AoA and Substitution Stakeholder Forum as an expansion to NeRSAP.
E4. Establish an Inter-authority forum on AoA and substitution
E5. Host a 2018 Substitution and Chemical Innovation Symposium

E1. Develop a queriable inventory of EU substitution programmatic activities, models and contacts

- ***Main Strategy Objective:*** To create a resource that clearly outlines the current state of EU substitution projects, programmes, and contacts in government, industry, academia and NGOs to assist with network and associated substitution/AoAs capacity development efforts.
- ***Benefits***: Important background to build necessary programme contacts and materials; clear project scope and makes for a "quick and easy" project tender; can implement in the near-term. Goal is to understand current landscape of programs, initiatives, and projects at the EU and MS level as the starting point for building networks of expertise.
- ***Challenges:*** Maintenance and on-going updating; determining scope of projects, initiatives, and programmes to include/not include.
- ***Resource Needs and Timing:*** Small tender issued by ECHA or another relevant authority to support the work by a consultant; Near–term strategy.

Enhancing engagement and network building on substitution efforts in the EU requires ***first compiling an inventory of existing substitution programme activities and associated contacts***. This "state of play" inventory on substitution could also incorporate relevant policies that have been inventoried elsewhere and evaluated in recent years. Many organisations have pieces of such an inventory, yet not in a useable format or framework to support network building specific to advancing substitution. A key first step to building such an inventory would be to determine the scope of programmes (government, industry, academia) that would be included (for example just those that mention substitution or those that are focused on sustainable chemistry). Further, it would be critical that the inventory not duplicate efforts by other organisations, such as the OECD substitution and alternatives assessment toolkit.

The ***final product of this inventory process should be a queriable database that could be used by stakeholders*** seeking to identify potential collaborators or convene forums, including conferences, webinars, trainings, etc., on substitution. The product of this inventory should be electronic and options should be explored for ***ensuring that the inventory can be easily maintained***, such as using a wiki interface. A secondary part of developing the inventory would be to develop a short analysis of gaps in the network of organisations necessary to support capacity in substitution and how those could be engaged.

It is unlikely that a current organisation would be willing to construct such an inventory without external support. Thus, a small tender issued through ECHA or another authority could support the work of a consultant to complete this effort.

E2. Expand the focus of NeRSAP to serve as a multi-stakeholder network for strengthening expertise in AoA and related substitution challenges

- ***Main Strategy Objective:*** To increase the quality of alternatives assessment and substitution activities while increasing coordination and collaboration on substitution efforts and needs across the EU.
- ***Benefits***: Existing network and structure; a charge that conforms with a focus on AoA/substitution topics; some relevant experts and the range stakeholders are currently engaged; can implement in the near-term.
- ***Challenges:*** Currently meets annually – difficult to maintain momentum and unlikely to support deep collaborative initiatives among participants; Does not currently reach many practitioners involved in substitution (e.g. companies); unclear mandate; no binding/formal decisions.
- ***Resources and Timing:*** Envisioned as a consultant contract with tender issued by DG Environment or another EC authority; Near Term Strategy.

The Network of Reach SEA and Analysis of Alternatives Practitioners (NeRSAP) was established by ECHA as a multi-stakeholder forum to advance dialog and review of concepts, methods and experiences of the Socio-economic Analysis (SEA) and AoA components and on EU-wide or national chemicals management implementation. The goal is to improve the quality of practice in SEA and AoA. It is set up in collaboration between ECHA, Member States and stakeholders from industry and some NGOs. To date, NeRSAP has focused primarily on the SEA components of authorisation more than AoA and broader substitution-related topics, and has not involved practitioners and topics in other aspects of substitution other than those impacted by authorisation or restriction – but it could.

One strategy option to ***expand multi-stakeholder dialog on improving AoA and substitution adoption among EU stakeholders is to amplify the focus of these topics within NeRSAP***. This strategy could be put into effect immediately by leveraging an existing network structure. However, it requires participants to be open to an expanded focus, which has implications for reducing the time spent on the range of important SEA issues given that NeRSAP typically convenes just once a year. It would require a deliberate effort aimed at expanding membership of the committee to include expertise in AoA and substitution from a range of stakeholders. Furthermore, although NeRSAP is open, it does not currently have strong representation from downstream users, SMEs, or non-industry stakeholders.

An AoA/substitution sub-group in NeRSAP could be established to advise on priority issues and topics to guide the development of future meeting agendas. A separate working group of NeRSAP could be formed that focuses exclusively on AoA-related issues and thus not detract from the current NeRSAP focus on SEA. This sub-group could focus on issues such as: understanding challenges in AoAs for which additional training and guidance would be useful, developing potential demonstration projects on substitution, and developing strategies to build capacity for substitution. The sub-group could have separate calls between annual meetings as well as organise a half to one-day symposium each year as part of the annual NeRSAP meeting. This would make it possible for different NeRSAP members with focused on SEA and substitution to be present for different agenda items, but also runs a risk of splitting NeRSAP into two groups.

It is critical ***to ensure that AoA and related substitution topics addressed by NeRSAP are done so in coordination with other existing networks in Europe and beyond***, such as the OECD Ad Hoc Group on

Substitution of Harmful Chemicals. This should not be difficult given that many participants of NeRSAP are also active participants in this OECD forum.

E3. Establish a stand-alone EU AoA and Substitution Stakeholder Forum

- ***Main Strategy Objective:*** Integrate substitution in government and industry decision-making, more effectively connect substitution needs to innovation research and development, increase the quality of AoA, and increase coordination and collaboration on substitution on substitution efforts and needs across the EU among stakeholders.
- ***Benefits***: Modelled after the UK Chemical Stakeholder Forum, an effective multi-stakeholder forum in the UK that has connected substitution initiatives within the context of risk management policy and programmatic discussions. Being a stand-alone forum, increases attention to and momentum for substitution and provides recommendations for policies and collaborations.
- ***Challenges:*** Resource intensive; requires Commission-level support; unclear whether an MS model of the UK forum will work EU-wide; requires regular meetings and calls.
- ***Resource Needs and Timing:*** More time/resources by ECHA staff and NeRSAP participants; Near-term strategy.

The expansion of NeRSAP to focus more on AoA issues is necessary but likely insufficient as an effective multi-stakeholder model to significantly advance dialog and action on substitution. ***A longer-term strategy (beginning 2019/2020) is the formation of a free-standing multi-stakeholder network modelled after the UK Chemical Stakeholder Forum (UKCSF).*** It would include the participation of MS authorities, ECHA, relevant EC officials, industry representatives, academics and NGOs. It would be more strategic in its focus aimed at improving the effectiveness of programmatic substitution efforts, rather than technical discussion of methods and practices that are absent a strategic underpinning (though it could have subgroups that discuss technical issues (see Capacity). ***Establishing such a forum requires developing a clear mandate to provide strategic advice to decision-making bodies within the Commission and MS authorities to take up the recommendations offered by forum***. Other elements of the mandate would focus on the promotion of best practices and connections to sustainable chemistry innovation, and enhancing cooperation among stakeholders to advance voluntary initiatives that engage the supply chain in a transition to safer chemicals, materials and technologies.

Our interviews identified a number of best practices for establishing such a body. It requires strong secretariat that is proficient at facilitation and multi-stakeholder diplomacy. The clarity of the mandate, and the expectation that decision-making bodies will hear the forum's input, is critical to a shared belief in the forum's work. Regular meetings (the UKCSF meets in person four times a year) provide continuity and keep topics in mind, but would be difficult to arrange on an EU-wide scale. Finally, trust in the other participants was identified as a key aspect, but can only be won by regular attendance (rather than attendance by different delegates each meeting).

Establishing such a forum first requires demonstration of need and commitment by the Commission to support its formation. Scoping out the need and structure for such a forum could be taken-up by a sub-group at NeRSAP as a first step.

E4. Establish an Inter-authority forum on AoA and substitution

- ***Main Strategy Objective:*** To enhance inter-authority collaboration and coordination on substitution needs and challenges in order to better leverage resources and reduce redundancies; share lessons-learned, and enhance capacity in general on AoAs and implementation of substitution.
- ***Benefits***: Informality lessens resource burdens on authorities; authority-only dialogue facilitates learning, open discussion, improved communication and identification of opportunities that leverage shared chemical substitution needs across agencies; priority topics/issues taken-up are driven by agencies' needs.
- ***Challenges:*** Need to Identify interest by an agency to provide the necessary leadership and infrastructure to support this inter-authority working group; substitution is not necessarily part of the workload of many authorities currently and limited recognition from superiors can create a barrier to involvement.
- ***Resource Needs and timing:*** NeRSAP participants to scope on the need; Near-term strategy.

Greater engagement across government authorities within the Commission and across Member States is a critical element in promoting the transition to safer alternatives as substitutes to SVHCs. Effective inter-government authority collaborations can help to avoid redundancies in efforts when targeting similar SVHCs and their substitution needs and challenges. Activities in one Member State can inform another's and also inform model EU-wide initiatives. Moreover, on-going work by one authority, such as authority-sponsored efforts to convene supply chain dialogues among national enterprises, sometimes create models and drivers for others and the opportunity to share lessons-learned. Greater inter-authority collaboration on substitution needs and challenges is an important vehicle to enhance the capacity of MSs that are less active on substitution and less resourced and also to enhance the capacity of officials at lower-levels of governmental offices that are more directly in contact with companies, including those responsible for enforcement and facility inspections. US experience from a similar inter-authority dialogue has shown that having a "safe" place for inter-agency discussions opens up new opportunities for sharing concerns, open dialogue and information sharing and identifies opportunities for substitution that may not have been obvious by a single agency.

ECHA should ***establish an Inter-authority AoAs and chemical substitution working group,*** similar to existing groups on enforcement, restrictions and risk assessment, that meets on a regular basis to discuss challenges to substitution, share lessons, open doors to collaboration, and identify concrete collaborative initiatives that could be undertaken across Member States to improve substitution.

A first step would be to identify a range of interested parties from the different Commission authorities and a range of Member States to establish a steering committee that would initiate discussions over a 6-8-month period via teleconference to develop an understanding of collaborative needs. This would lead to a background options paper to lay out collaborative opportunities that would stimulate discussion at 1 to 1.5 day in person meeting, possibly convened as a "pre-meeting" in conjunction with other meetings/conferences (for example, see E4 below) at the location of one Member State authority. The initial meeting would be facilitated by members of the initial steering committee. Meeting participation would be closed to non-authority representatives with the exception of invited experts. The planning committee could consider inviting US or Canadian agency

representatives (e.g., US EPA, and state agencies such as Massachusetts) that could share interagency collaborative efforts.
Prior to the meeting, the advisory group could survey MS participants and collect an inventory of their current substitution efforts/capacities and relevant staff contacts. A MS and EU resource substitution directory could be created and shared as part of the meeting materials for the meeting.

Desired outcomes could include:

- To discuss cross-cutting capacity, technical, and regulatory challenges where enhanced inter-authority collaboration would be useful in adopting innovative substitutes for SVHCs.
- To identify training topics and industry case studies to use in a curriculum and to identify specific/specialised training needs of MS authorities (from help desks to enforcement).
- To exchange information on national substitution initiatives of shared interest.
- To identify effective mechanisms for continued collaboration and information sharing on safer alternatives to chemicals of priority concern.
- To identify a shared goal and concrete collaborative activities to move the transition to safer chemicals forward in the next five to ten years.

Subsequent to this first meeting, ECHA could work with authorities to identify a secretariat among them, willing to take leadership for the first 2 years of the working group. A rotating MS authority leadership model is envisioned, however, other leadership options are possible. In the US, LCSP (an academic institution) has coordinated a working group on behalf of agencies. In order to share this secretariat responsibility, leadership could rotate every 2-3 years among the Member States.

Additional actions by this working group after the first meeting could include:

- Convening a planning committee to identify priority topics to engage the inter-authority working group in quarterly calls. The agendas for these calls could be:
  - *Discussion-focused,* e.g., working through specific practice or regulatory implementation challenges, including authorisation enforcement. Professional networks among MS authorities could be tapped to help identify technical experts to assist with such challenges, especially with respect to the R&D of safer solutions.
  - *Strategically focused,* e.g., opportunities to link substitution efforts more closely with national and EU circular economy discussions; or
  - *Education-focused*, e.g., webinar platforms to share recent AoA methodological advances or new national substitution initiatives.
- Hosting quarterly calls based on the identified topics and discussion priorities.

E5. Host a 2018 Substitution and Chemical Innovation Symposium

- ***Main Strategy Objective:*** To convene government regulatory and funding authorities, industry, NGOs and academic stakeholders to build understanding on a broad range of substitution topics, develop strategies and organise new collaborations to support substitution.
- ***Benefits***: Useful engagement mechanism to engage a number of networking strategies – multi-stakeholder, inter-authority and supply-chain professional exchange. Supports multi-stakeholder engagement in building strategy, projects, and new collaborations; reframe substitution as an innovation activity and not simply regulatory.
- ***Challenges:*** Needs to be strategically focused and planning is intensive; ensuring broad attendance; strong leadership/coordination/facilitation to include the perspectives of the broad range of sponsors and balancing the overarching needs/aims of the symposium; cost.
- ***Resource Needs and Timing:*** ECHA/EC/MS authority time and commitment; additional resources by authority to takes on the Secretariat role; Mid-term strategy.

While there have been workshops in Europe focused on substitution (including AoAs) or innovation, there has not been an effort to convene expertise and insights from the two groups that can serve to build new networks and projects.

Such a workshop could potentially support all three priority thematic strategy areas. Our interviews and experience have demonstrated a disconnect between AoAs and substitution and innovation research and support. Yet, in many cases, companies are hesitant to substitute because there cost-effective, performing alternatives are not available (see Innovation, below). We have found that strategic, well-planned and organised "kick-off" meetings can serve to build networks, identify collaborative opportunities and lead to improved understanding of barriers, needs, and opportunities. Both the Green Chemistry and Commerce Council, a business to business network focused on accelerating green chemistry through the value chain, and the US-based Alternatives Assessment Community of Practice,[3] began with a smaller group multi-stakeholder discussion over a year-long period, followed by an initial meeting with short presentations, dialogue, and strategic discussions. In each case, the meetings led to facilitated follow up and new networks with differing sources of funding. In each case, it was initial strong facilitation and stakeholder engagement in building the desired outcomes and agenda that led to success. For a European meeting, the proposed Substitution Stakeholder Forum or a sub-group of it could take the lead on meeting organising (or if not yet established, a subgroup of the NeRSAP).

The aim of the symposium is to position substitution as a key risk management and innovation strategy in the EU; to build an understanding of key challenges in conducting AoAs as well as the research, development and adoption of substitutes; to connect key people and organisations working on and interested in advancing substitution and chemical innovation efforts in the EU; to outline strategic next steps to advance safer chemistry in Europe; and to achieve input and buy-in among authorities and stakeholders on key next steps to ensure momentum and actions to advance dialogue and engagement on substitution.

This symposium (maximum 200 people to ensure ability for dialogue) would require investment by a range of organisations, including ECHA, DG Environment, DG Grow, MS authorities, trade

[3] See www.greenchemistryandcommerce.org and www.saferalternatives.org

organisations and individual companies, academics and NGOs. The agenda would consist of three themes: improving AoA capacity (see Capacity, below); advancing substitution in the supply chain: challenges and opportunities; and driving innovation in sustainable chemistry. Case examples (successful and less successful that provide instructive lessons), foundational research, and specific experience would drive the agenda development. These three thematic areas would address capacity; research and adoption challenges. A goal of the meeting would be to identify concrete next steps/activities that could advance substitution activities in Europe (including training, case examples, model supply chain collaborations, etc.,) and establish a plan for on-going multi-stakeholder engagement.

2. *Innovation:* Developing structures to promote innovation and infrastructure to support research and development and adoption of sustainable chemistry substitutes

Considerations/Context

The 2016 LCSP report found substantial gaps around support for substitution, both adoption of alternatives and innovation in sustainable chemistry solutions. In particular, LCSP pointed out a lack of public and public/private investment for this type of R&D. The report concluded that "Innovation research on safer alternative is not routinely aligned with regulatory priorities," citing a "a disconnect between industry's needs to identify alternatives to SVHCs and the research base and research agendas in academia and other research institutes". This disconnect continued to be mentioned in our recent interviews, despite significant market and regulatory drivers for chemical substitution. In addition, interviewees repeatedly described a second disconnect, one between upstream producers/manufacturers and the needs of downstream users.

These disconnects exacerbate a significant challenge: the timeframes and costs of research, adoption (including redesign, certifications, etc.), and scale of substitutes. Adopting an already existing, often "drop-in" alternative or one nearly to market may take 3-5 years depending on certifications needed. However, development of a totally new substitute or process redesign may take 8-10 years for research, development, testing, and scale. A smaller, niche market use of a substitute may take less time to adopt versus a substitute needed in millions of units of a formulated product (which may take clear demand signals for capital investment to take place to reach scale). At the same time, if firms are making a significant investment in a substitute (perhaps costing tens of millions of Euros) they want assurances that the substitute will meet safety and performance requirements.

Hence there are there particular needs: increasing research and development in innovative substitutes tied to market and regulatory priorities; technical institutes supporting adoption of substitutes; and connecting supply chains to drive innovations.

RESEARCH INVESTMENT

Innovation funding is widely available in the EU and in Member States from various programmes. A range of public and private research and innovation funds was identified in the 2016 report. A number of early stage venture capital funds focused on green and bio-based chemistry exist at the EU level (such as Capricorn Ventures) and several Member States, such as Denmark and the Sweden have environmental innovation funds that have invested in substitutes. The Dutch Government is currently developing a sustainable chemistry research agenda to focus and prioritise research on safer, more sustainable chemistry. Large EU research programmes, such as the LIFE and Horizon 2020 and in particular the SME Instrument provide significant funding for basic, breakthrough and applied research, development, and collaborative innovation between firms. As immediate action that ECHA, DG Environment and DG Grow could be undertaking with stakeholders is to influence the development of the 9th Framework Research Programme (FP),[4] which is currently under discussions. In particular, these authorities could make sure that sustainable chemistry research targeted towards SVHC chemicals is embedded in FP9, specifically connected to pillars on the circular economy, the bio-economy and climate reduction. In other words, it is important to position substitution as core to the objectives of pillars of FP9 moving forward. This can help advance a mind-set change and cultural shift

[4] See: http://sciencebusiness.net/news/79966/EU-Commission-sketches-possible-directions-for-FP9

among government decision-makers that positions substitution as an innovation activity that creates economic, environmental and public health benefits. Additionally, if an European Innovation Council is established as part of FP9 (which is currently a virtual network), authorities involved in chemical substitution could work with the Council to ensure that environmental technology funding includes safer chemistry.

Several interviewees made important distinctions about the types and/or phases of funding required. Academic and green chemistry researchers often rely on funding for basic research, distinct from particular applications. While this is important funding, it is not typically targeted at the substitution needs of industry. However, interviewees also identified a major gap in the next stage of funding: supporting the basic practical needs required for adoption. For example, interviewees cited gaps in funding for performance testing on a practical scale, and/or for basic toxicity testing leading to registration (We note that low-volume exemptions from registration are allowed for this sort of research, but any significant amount of production might easily exceed these volumes).

SUPPLY-CHAIN COMMUNICATION

A second disconnect was echoed by a number of interviewees, who commented that the needs of downstream users (DUs) are poorly represented in substitution decision-making. Many DUs have extremely complex, global supply chains, which makes understanding what chemicals are used in what applications and what alternatives may exist for specific SVHC applications extremely challenging.

Particularly in the case of SMEs and companies without strong technical knowledge, most "substitution" activity is what might be termed "shallow" substitution, driven by primarily regulatory requirements, and resulting in more drop-in substitutes that might be structurally similar. Interviewees suggested that this fact is in part the result of the greater REACH expertise and substance-level technical knowledge of upstream manufacturers.

DUs often have much less technical knowledge about specific substances, and may be limited by the advice given to them by the supplier of a newly-regulated substance. However, it is possible that a less closely-related substitute, or an alternative technology, process or product design (addressing the functional need, if indeed the function is needed), might also be viable from the downstream perspective. A proper consideration of alternatives from a downstream perspective requires that the DU investigate a full range of possible solutions, including those outside the expertise of their current suppliers.

In order to promote a fuller consideration of alternatives, and to improve communication through the supply chain, a number of particular actions were identified, including engaging supply chain dialogues on specific SVHC applications and training DUs in substitution approaches.

A related concern about supply chain communications that was raised by several interviewees involved getting businesses to discuss specific solutions or alternatives that may provide a competitive advantage. In other cases, a business relationship (perhaps protected by an NDA) may preclude frank discussion of all possible solutions. Concerns over competitiveness may inhibit open discussion. However, it is in the interest of an actor in possession of a viable alternative to publicise and promote it and for those investing in solutions to open those solutions to gain market scale (and lower costs) once competitive advantage has been gained. Firms are increasingly willing to collaborate in pre-competitive ways to find sustainable solutions to priority chemicals given the challenges of substitution.

Finally, a number of interviewees stressed the need for technical support and local, on-site, industry- or business-specific conversations as being the most effective in raising awareness or changing business practices. These are likely to require significant engagement and some technical expertise from the advising bodies (e.g., an ECHA or Member State Substitution Support Office).

Proposed Actions

OVERVIEW OF PROPOSED INNOVATION ACTIONS
I1. Conduct an Inventory and Gaps Assessment of Innovation Research Support Infrastructure for Sustainable Chemistry Development
I2. Develop early alert/connections databases
I3. Enhance research partnerships to advance innovative solutions to substitution challenges
I4. Convene Sector-Specific Supply Chain Dialogues
I5. Establish Substitution Support Office and network of Substitution Support Centres

I1. Conduct an Inventory and Gaps Assessment of Innovation Research and Support Infrastructure for Sustainable Chemistry

- ***Main Strategy Objective:*** Build an understanding of available public and private funding opportunities at the EU and MS levels for innovation research, public private partnerships for substitution and innovation support centres to understand gaps and opportunities for supporting substitution.
- ***Benefits***: Develop a baseline understanding of available funding, opportunities for connecting that funding more effectively to substitution needs, and building collaborations between funding institutions. Use this baseline to engage private and public funding institutions and share such information with industry and authorities to advance R&D and application of safer alternatives.
- ***Challenges:*** Funding is not well coordinated and between the EU and MS and there are distinctions between basic funding, technical support for adoption, and private public partnership funding.
- ***Resource Needs and Timing:*** Envisioned as a consultant contract with tender issued by ECHA; Near Term Strategy.

The innovation support field in the EU is splintered and complex, with many different types of support available at different levels. Our discussions echoed the conclusions of the 2016 report: "ECHA could undertake a landscape analysis of research and innovation funding agencies at the European Union and Member State levels that could be engaged in supporting chemical substitution and sustainable chemistry research and innovation." Our 2016 identified a broad range of innovation and eco-innovation funds operating at the Member State-level that are not engaged on the substitution innovation R&D needs. We recommend that ECHA tender a proposal for ***an inventory of support for innovation, at all levels, throughout the EU***.[5] A detailed inventory would help connect users and researchers of all types with specific sources of funding or other expertise.

[5] The strategy for a non-toxic environment of the 7th Environment Action Programme compiles some of this inventory work in Substudy f, An R&D Programme on new, non-toxic substances; however, more detail on specific funding mechanisms, especially at the MS level, as well as technical support institutions, would provide a more complete picture.

Accompanying the inventory, ***a gaps assessment of funding for safer alternatives*** would be very valuable. In addition to a lack of support for developing safer alternatives, there is a lack of funding on the practical second-tier research necessary for adoption: Performance testing, or basic toxicity testing leading to registration. A gaps assessment would allow new public or public/private investments to be targeted to the areas where they would be most necessary, not just to on the R&D needed to discover alternatives, but to test them, register them, and ultimately bring them to market. This information would also be useful to engage existing funders to direct more resources to research and development of safer alternatives.

A goal of this inventory would to identify a targeted list of public and private funding institutions to pursue discussions about supporting innovation research for safer alternatives in their grant and investment programmatic priorities that are linked to substitution priorities. Both ECHA and national authorities, including the Netherlands have proposals to pursue such dialogues. Existing R&D streams that could support substitution/alternatives research could also be incorporated into the Connections Database (see I3).

I2. Develop Early Alert / Innovations Connections databases

As we have discussed, regulation is a significant (and perhaps most important) driver in substitution. Most often, this occurs when a particular substance is added to a REACH list (e.g., Candidate List or Annex XIV); to a non-EU list like Stockholm; to a company's or sector's RSL; or when it is proposed for restriction. For its part, ECHA is very public in identifying upcoming actions, through tools like the CoRaP, the Public Activities Coordination Tool, and the Registry of Intentions.

Although these lists are broadly available, access is not the same as knowledge. A substance manufacturer may come under great pressure to quickly find (and scale up) a substitute when their substance reaches a particular list (e.g., Annex XIV). However, SMEs and downstream users with less specific technical experience – who are unlikely to be actively following regulation of that specific molecule, or in some cases may not even know that their product incorporates it – are far less likely to identify a substance they use when it appears on such a list. Of particular concern are applications where there is a long time frame for certification or approval, such as in the aerospace sector, where significant lead time to find high performing alternatives is necessary. The challenge for many firms may not be their own use of a particular chemical but that the chemical is essential to a specific part or formulation that is integral to their product. Hence, there is a need for users to have early warnings as to when a substance may be substituted to begin to look for safer substitutes.

I2a. The "early alert" database

- ***Main Strategy Objective:*** Provide early notice of possible regulatory changes to relevant actors throughout supply chain.
- ***Benefits***: Disseminates information widely, especially to downstream users who are less likely to be tracking chemical regulation; motivates research and possible action on alternatives at a much earlier timeline and by upstream and downstream users.
- ***Challenges:*** Need to identify interested parties and communicate clearly to them; will require research to establish and to maintain; probably relies on intermediaries (e.g., trade groups).
- ***Resource Needs and Timing:*** Substantial ECHA support or aligned ED directorate; Mid-term strategy.

In order to promote widespread advance knowledge of likely upcoming regulations, we propose an "early alert" system. The most likely the target of the alert will not be the individual downstream users, but an intermediate connector, like a trade organisation. The "early alert" tool would notify relevant recipients when any specific substance or a closely related substance appears on any of the monitored lists or is likely to be subject to regulatory or market restrictions in coming years (many larger firms already keep this type of list). Alerts might be given as well for structurally similar and unrelated substances fulfilling similar functions, since those changes are likely to impact the marketplace even for nonusers.

Populating the "early alert" system would require some effort in order to identify the appropriate connector organisations, to get their buy-in, and to ensure that the correct keywords and substances are identified. (A small tender issued through ECHA or another agency could support the work of a consultant to complete this effort.) This system would rely on the relationship of the connector with their members, such that when an "early alert" is generated, the relevant information is passed on. For example, a trade organisation could publish the alert in their trade newsletter.

It is important to note that the "early alert" itself is not a regulatory signal, but is intended to prompt early research, discussion, and collaboration far in advance of possible regulation. Such an alert system could be seen as exceeding ECHA's authority, if it promotes replacement of substances before they have been identified through the appropriate REACH process. However, given the possible impact of non-EU regulations on EU markets, and the similar global pressure of advocacy campaigns, the alert system should be seen as protecting the competitiveness of EU industry and preparing industry so as to not risk disruption from restricted supplies of necessary chemicals to their processes or products.

I2b. The "connections" database

- ***Main Strategy Objective:*** Provide connections between actors with substitution needs and potential alternatives.
- ***Benefits*****:** Allows for connections to be made between unconnected actors; promotes connections within internal market; increases competitiveness.
- ***Challenges:*** Some development time/cost; requires active buy-in by many users to become viable. Investigate success of EEN database or ChemSec Marketplace as a model.
- ***Resource Needs and Timing:*** ECHA or consultant staff time; mid-term strategy.

There is a broad need to improve connect the R&D and application needs of companies seeking to replace chemicals of concern with partners in industry and funding institutions that can supply the alternatives, R&D funding or technical expertise. While the goal of the "early alert" system is to prompt early research and action on upcoming substitution needs, links to a second “connections” database is needed. This “connections data-base” could be modelled after the Partnership Opportunities Database (POD). This database was developed by the Enterprise Europe Network (a project of the EC to support SME growth an innovation. The POD allows for open submission of functional needs (e.g., flame retardancy, corrosion resistance) and technical solutions (substances or processes), which can then be searched to develop new connections between suppliers, downstream users, trade organisations, researchers, and other experts. This model lends itself to questions of substitution, particularly when its use could be triggered by an “early alert” of upcoming or potential regulation. It seems likely that most of the connections made this way will not be direct (drop-in) substitution solutions; however, the earlier the connections are made, the more likely it is that they can be brought to market when needed. The new ChemSec Marketplace could be a similar tool focused on specific chemical/application substitution, providing links between companies seeking substitutes and providers of them.

Although the POD facilitates connections between those that need solutions with those that can offer those solutions, the funding support for these efforts can be a missing link. Although enterprises often have their own R&D funding streams, SMEs may not. Therefore, it is important that this connections database also include a third-leg: funding and technical support organisations. The results from inventorying and engaging funding streams (I1 above and I3 below) could be incorporated into this connections database.

As with the “early alert” database, the “connections” database would require substantial resources to set up, buy-in from industry, and an on-going commitment to keeping it up to date. However, relying on intermediary connections like trade organisations would help streamline it. In the long run, an office for substitution support at ECHA or within national authorities (see below) could be best suited to provide support to keep these databases updated, and would themselves follow up on early alerts in an attempt to connect needs with solutions.

I3. Enhance research partnerships to advance innovative solutions to substitution challenges

- ***Main Strategy Objective:*** To enhance research and development partnerships among industry, academia, and research and technology organisation on substitution challenges by leveraging existing collaborative models such as the SusChem European Technology Platform, ME310 Global and Member State eco-innovation funding models.
- ***Benefits***: Important mechanism to advance R&D on substitution challenges among enterprises that lack R&D capacity; leverages existing innovation partnership models.
- ***Challenges:*** Requires EU and MS investment to prioritise innovation for substitution challenges; requires expanding models to include chemical innovation/substitution; timeframes and focus of industry and academic research often conflict; time needed to expand model academic-industry research programmes across member states.
- ***Resource needs and timing:*** ECHA and MS authority facilitation support; Near-term strategy.

Academic research institutes and national level Research and Technology Organisations (RTOs)[6] are an under-utilised resource to support the R&D needed for safer alternatives innovations. Large multi-national product manufacturers often have substantial in-house R&D expertise. Yet this R&D capacity is often lacking among smaller and medium-sized firms. ECHA and Member State authorities can play a role in facilitating the growth of research partnerships among academic institutes, RTOs and industry that focus on innovating new design solutions to current substitution challenges.

Models such as Suschem and ME310 Global could be leveraged. Suschem is one of more than 40 European Technology Platforms (ETPs) designed to channel discussion on innovation from industrial sectors to the commission. The ETPs provide input to the Commission to shape research and work programmes. In particular, the Suschem ETP is one of the most active, engaging industry, academia RTPs and some NGOs. Suschem has provided input into FP7 and Horizon 2020 and is the chancel where the Commission can work with industry and other stakeholders to gain input on sustainable chemistry and then shape research calls and convening of experts to solve problems. Suschem provides a platform for creating consortia to develop specific funding proposals. The programme is now mostly financed by the European chemical industry association CEFIC but its programme is strongly driven by its board and 2200 individuals in its network and a network of 14 Suschem national technologies platforms have been created to link to national funding streams. While downstream users have not been widely involved in Suschem to date and substitution has not been a key area of focus (the research agenda has focused more on specific technology applications (such as materials for windmills and electricity storage), Suschem is sufficiently flexible to integrate the entire value chain to develop collaborative research challenges to solve substitution challenges.

ME310 Global is part of the Stanford School of Engineering, yet includes a consortium of university partners throughout Europe, including in Germany, Switzerland, France, Sweden and Finland. ME310 engages a team of mechanical engineering graduate students at Stanford and one other international partner university to work directly with an industry corporate partner on a design challenge need. The programme is structured around the rapid development and deployment of multiple prototypes. Design ideas and assumptions are put to test through iterative prototyping – 10-30 such prototypes for a given project. The Industry partner is the financial sponsor of the research ($60K-$120K) and works in partnership with the team of student researchers and faculty throughout the effort.

ME310 Global offers a ready-made method and structure to engage academic product design expertise to support the re-design needs of industry as they seek to eliminate SVHCs. However, project efforts to date have mainly focused on mechanical engineering solutions. Although many substitution challenges require materials and process-redesign needs that require mechanical engineering expertise, many will require chemical engineering expertise as well. Thus there will be a need to broaden the base of ME310 Global to include chemical engineers in the prototyping work. Chemistry professors at Aalto University in Finland have recently become trained on the ME310 approach and are one of the first to become interested in its application to substitution challenges, such as SVHCs in paints and coatings. Similar student-faculty-industry research and innovation programmes exist around the Globe and could be leveraged to support sustainable chemistry innovation, for example the safer solutions course in green chemistry at the University of California Berkeley.

[6] RTOs throughout Europe are coordinated by the European Association of Research and Technology Organisations – EARTO – www.earto.eu

Additional academic-industry R&D funding models are needed to support smaller enterprises. Not all enterprises requiring innovation substitution R&D can fully sponsor an academic partnership project. Denmark's Environmental Technology Demonstration Project (MUDP) offers one effective national model that could be replicated in other Member States to help subsidise R&D projects. MUDP has co-sponsored 29 substitution R&D innovation projects among Danish companies, 15 of which have succeeded in the identification and adoption of a safer substitute. MUDP requires companies to co-fund 30-50% of the project depending on the size of the company. The projects tap the R&D expertise from technical universities. The focus of the research is on the testing and demonstration of candidate alternatives rather than the R&D of a new compound or material. It focuses on promising alternatives that require testing in real-world settings before the can be adopted and scaled.

Our 2016 report identified several MS innovation funds, some currently focused on eco-innovation, some not. All focus on supporting the national innovation needs that benefit national interests, as is the case of the MUDP model. Once the inventory and gaps assessment in I2 above is connected, there is both a need an opportunity to disseminate the MUDP funding model to other Member States. This could be accomplished by hosting a ½ day forum among national innovation funds to share the MUDP model, including case examples of research conducted to date focusing on substitution challenges in order to stimulate interest in a similar focus and funding strategy.

I4. Convene sector-specific supply chain dialogues

- ***Main Strategy Objective:*** Leverage supply chain engagement to both communicate needs in substitutes and demonstrate demand as well as accelerate development and scale of sustainable chemistry solutions. Demonstrate viability of substitution options.
- ***Benefits:*** Important strategy to gain the interest and engagement of supply chain actors, particularly downstream users/SMEs. Broad range of companies/researchers/expertise involved may surface innovative alternatives not previously identified from within the supply chain. Capacity and partnership building along supply chains to support substitution.
- ***Challenges:*** Often focused on single application/single chemical of concern; difficult to advance broad-scale engagement and change.
- ***Resource Needs and Timing:*** ECHA limited convener/facilitator role; other organisations e.g., trade organisations; travel resources; Near-term strategy.

We have seen that communication through the supply chain is a key limitation of (broader) substitution thinking. However, communications within any given supply chain are often very specific to that sector's needs. Therefore, any attempt to improve supply chain communication will be most beneficial when its challenge or application specific. Research and experience of the Green Chemistry and Commerce Council (GC3), a 100 member business-to-business organisation driving green chemistry innovation has identified value chain collaboration and partnership as a critical lever for green chemistry. For example, the GC3 Collaborative Preservatives Innovation Challenge has convened nearly twenty firms to issue an open innovation challenge with the innovation consultant InnoCentive for safe and effective preservatives for consumer products. In this case, every company in the supply chain gains from access to innovative preservative technologies. Our interviews identified a number of value chain collaborations in the footwear and apparel sector (with regards to perfluorinated water and stain repellants), plating sector (efforts in the US and Europe aimed at identifying and undertaking joint testing of non-hexavalent chromium alternatives, etc.,) and

pharmaceutical sector (undertaking collaborative research on solvent substitutes). A key to success of such initiatives is a joint chemical function challenge where there is no particular competitive advantage in being first to implement solutions as well as an interest in sharing costs and gaining economies of scale relatively quickly.

However, many of the supply chain conversations in the European contact are convened by national-level CAs and emphasise national interests. This has two limitations: (1) they are not available in all nations, especially under-resourced nations, and (2) they are not addressing the EU wide supply chain and the opportunities provided by the internal market.

We propose that ECHA work with a small number of sectors (or academic institutions) to initiate collaborative supply chain dialogues on sustainable chemistry solutions to SVHC chemicals. These could happen at the EU level or at an MS level, in collaboration with MS authorities. These expanded supply chain dialogues should happen much earlier in the process (well before regulation); should include technical institutes and innovation fund representatives to allow discussion of research and development and substitution transition needs; and should involve capacity building among participants on substitution. It is important that the supply chain dialogue be held well in advance of regulation, and probably in advance of commercialisation of likely innovative alternatives. Once commercialisation of alternatives has begun, competitive and confidentiality concerns could increasingly hamper discussion. Furthermore, it is important that well-placed and expert researchers be present as well, to provide wide-ranging expertise on the relevant substances as functions, probably broader than can be openly supplied by upstream manufacturers. Euratex has recently used this model for the textile industry to discuss perfluorinated chemical alternatives.

ECHA should identify one major upcoming sector-wide substitution need well in advance of likely regulation, given the following criteria:

- Dialogue should be centred on a widely-used substance or related substances (e.g. SHVC, or related group of SVHC candidates) and application of concern for which regulation is likely upcoming (or market pressures are increasing), but well in advance of expected prioritisation.
- **Choose a subject that is likely to generate a success and that focuses on a chemical/application that is in the window far before authorisation.** This point emphasised in several calls.
- Defining substitution in **functional need** terms would permit engagement of the whole supply chain and researchers. This is not a drop-in substitution research project. It would identify a range of options to meet the functional use.
- Connect with researchers/experts and innovative start-ups and identify likely solutions that have not been up-scaled, and possible future approaches.
- Identify possible future market drivers that will encourage researchers and new suppliers to jump on the topic.

In partnership with an appropriate sectoral actor, and with the help of organisational facilitators/consultants, ECHA will then convene an EU-wide supply-chain dialogue on the issue, identifying and inviting all players through the supply chain, including suppliers of alternatives and alternative technologies, researchers on both the specific substances and on the appropriate functional categories, and relevant health experts. The supply chain actor (e.g. Euratex) supplies the knowledge of the entire supply chain, while ECHA facilitations the connections and contributes resources to developing a two-day in-person meeting and follow-up communication. One option is to

start with a series of national-level supply chain dialogues on substitution and scale them to the EU level.

The dialogues would include discussions on technical performance needs, criteria for safety evaluation, and opportunities for joint testing. Case examples and best practices would be developed based on these dialogues. Substitution training would form part of the workshops.

In cases where no good alternative is found to exist, this would be an opportunity to issue a technical challenge, similar to the GC3 Collaborative Innovation Challenge. Supply chain discussions could help develop the criteria for safe and effect substitutes.

The funding inventory (noted above) could be used then try to **connect researchers with specific funding sources** to prototype innovations.

I5. EU Substitution Support Office and Network of Substitution Support Centres

- ***Main Strategy Objective:*** Establish technical support infrastructure for SMEs to undertake substitution.
- ***Benefits:*** Assists SMEs to overcome technical barriers to substitution and links them with resources necessary for adoption of sustainable chemistry solutions.
- ***Challenges:*** Funding is needed to support such a network; would have to be distributed around Europe as language will be a challenge for many SMEs.
- ***Resource Needs and Timing:*** Substantial funding and commitment required from EHCA or from MS's to establish centres; long-term strategy.

While there is a need for research and development funding as well as supply chain dialogue to support shorter and longer term innovation in sustainable chemistry solutions, many firms are hindered by the risk of switching out of a chemical that they know functions well and at cost. Evaluating technical feasibility of alternatives as well as modifying production process or product specifications to implement a substitute is a difficult task for many firms. This is of particular concern for high performance uses in the aerospace and auto sectors.

There is a need to support innovation in substitution throughout the EU and through the supply chain. Simply having technical support centres in a small number of MSs may not be enough and misses the strengths of the internal market. As a starting point, ECHA (or another EU agency such as EASME) could establish a Substitution Support Office that could work to connect those with substitution problems with potential experts (solutions providers). The office could identify technical needs of companies across sectors (technical evaluation, case examples, access to suppliers, etc.) and conduct initial research on alternatives. A goal would be to create an interconnected network of substitution support centres across the EU that could provide services ranging from performance testing, to convening supply chain dialogues, to organising demonstration projects, to seeking funding for research. For example, key technical research centres in specific technologies (textiles, plating, solvents, electronics) could be engaged to support sector based efforts, including providing joint testing facilities. A database of support centres that service different applications or sectors (and

support a number of languages) could be created. A central EU-based hub (Substitution Support Centre) could coordinate/facilitate the connection between the various nodes.

3. *Capacity-building:* Enhancing capacity development for authorities and businesses on substitution

Considerations/Context

Enhancing the quality and consistency of AoAs is a key element in the transition to safer chemicals, processes, and products. Our 2016 report found that while clearer guidelines and templates are a pre-requisite for improved quality, foundational knowledge and training for those engaged in substitution planning and those completing AoAs (under REACH and other regulatory and non-regulatory programmes) are also critical. The 2016 report identified varied capacity building needs ranging from:

- professional development for SMEs and downstream users that may not have the capacity to undertake their own analyses of alternatives, but need information on the substitution approach and strategies to engage their chemical suppliers and distributors in information about alternatives to SVHCs and conduct initial research on potential alternatives and their trade-offs;
- trainings to support reviews of AoAs by authorities, ECHA and members of SEAC; and
- professional development for routine AoA practitioners within authorities and the business community on specialised AoA topics in order to state abreast of emerging methods and tools in the field.

Conversations as part of this current effort to inform the development of strategy options revealed that there is not an infrastructure currently in place to support AoA and substitution planning training and guidance despite the need for these. Leadership in firms and authorities often do not understand the value of substitution or its connections to chemicals management or other sustainability priorities.Firms often do not have the knowledge to even do screening level identification and evaluation of alternatives. And enforcement and inspection officials may not know how to look for potential substitutes or to ensure that substitution planning for a firm receiving an authorisation is being pursued. There are only a few examples of consultants/training centres in Member States offering basic substitution training courses, and archived materials for a substitution training programmes that was conducted in years past through the Subsport initiative. However, there are useful relevant training resources and tools to support substitution and AoA that have been archived and organised on the OECD Substitution and Alternatives Assessment (SAA) Tool box website. Strategies to deliver training need to focus not just on developing curriculum that is appropriate for the range of targeted audiences given the very distinct capacity development needs, but also using range of approaches to deliver the information, from the integration of substitution-thinking training objectives into substitution-focused workshops, such as supply chain dialogues (strategy option I4 above) to stand-alone training sessions on AoA specialised topics. In the mid-term, there is a need to develop a robust infrastructure of trainers and a training system (a train-the-trainer network). Such an infrastructure can help build a “community of practice” for AoA and substitution that expands practice in the field.

Proposed Actions

OVERVIEW OF PROPOSED CAPACITY-BUILDING ACTIONS
C1. Align and update as needed ECHA AoA guidances with best practices, developing resources for those conducting AoAs or investigating alternatives
C2. Develop and deliver three types of substitution/AoA trainings C2a. Substitution Thinking Training C2b. AoA Best Practice Training C2c. Specialised Topics for AOA Practitioners: Advancing an AoA Community of Practice
C3. Investigate options for and the feasibility of an AoA certification programme

C1. Align and update as needed ECHA AoA guidance documents with best practices

- ***Main Strategy Objective:*** To improve the quality and consistency of AoAs, including but not limited to those for authorisation and restrictions proposals.
- ***Benefits***: Establishes standards of practice in response to developments in the field of AoA to better align practitioners; improves quality and consistency of AoAs; needed to guide and focus AoA trainings.
- ***Challenges:*** Inherent methodological and consensus challenges regarding establishing best practices.
- ***Resource needs and timing:*** Convened and facilitated by ECHA; expert participation; near-term strategy.

Training programmes will need to focus on the sharing best practices as a means to improve quality in AoAs. AoA specific trainings will need to refer back to ECHA guidance documents on conducting AoAs in the context of both restriction proposals and authorisation applications. However, the field of AoA has dramatically advanced in just the last 5-years. Moreover, the quality of AoAs submitted as part of REACH processes (authorisation and restriction) has been highly variable revealing differences in quality and thus best practices. As such, there is a need to review existing guidance documents with regard to best practices and update them accordingly as a necessary first step before developing training curriculum.

Clear guidance on best practices will:

- fill gaps currently seen in AoAs and better guide both industry, their consultants as well as authorities that prepare AoAs;
- help ECHA and ECHA committees to evaluate the quality and depth submitted AoAs; and
- target training objectives for curriculum development.

Fortunately, a number of new alternatives assessment frameworks have been developed since the publication of the EHCA restriction guidance[7] and authorisation guidance[8] documents (2007 and 2011 respectively). Perhaps the most prominent is *The Framework to Guide Selection of Chemical Alternatives* (2014) published by the US National Research Council.[9] Other recent frameworks are also

[7] See ECHA restriction guidance here: http://echa.europa.eu/documents/10162/13641/restriction_en.pdf
[8] See ECHA authorisation guidance here: https://www.echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf
[9] See: US NRC report here: https://www.nap.edu/catalog/18872/a-framework-to-guide-selection-of-chemical-alternatives

available from the US. These include frameworks developed by the Interstate Chemicals Clearinghouse (2017) (a consortia of state agencies),[10] and another by the Washington Department of Ecology (2015)[11] that focuses on guidance for SMEs and downstream chemical users. The State of California is currently developing guidance for AoAs conducted as part of its Safer Consumer Products Regulations.[12] In addition, DG Employment's *Minimising chemical risk to workers' health and safety through substitution* (2012)[13] is another EU focused framework that offers practical methods tools that is similarly helpful for SMEs and larger enterprises.

We recommend that ECHA ***establish an AoA best practice evaluation group to bring ECHA's guidance materials into alignment with updates in the field***, recognising the obligations and challenges that are unique to the REACH context. This small best practices group (~10-12 persons) would consist of ECHA staff along with experts familiar with (a) the international landscape of AoA methods and practices and (b) with evaluation of AoAs conducted under REACH to date and should include members from the Multi-Stakeholder and Inter-Authority groups identified in E2 and E3 earlier. This group would be tasked with:

- reviewing informative AoA frameworks that reflect recent advances in the field and informative AoA methods and practice research papers published in the literature,
- establishing metrics for best practices,
- identifying AoA case study examples to serve as best practice models, and
- developing best practice guidance for relevant components of the AoA process
- Identifying essential AoA resources (data and databases, tools, additional guidance).

Special attention should be paid to the evaluation of scoping and technical feasibility as this component of the AoA process was identified by both authorities and industry representatives as a priority topic for capacity building in the 2016 evaluation.

Given that the publication of new guidance is a significant undertaking for ECHA, ***the product from this AoA best practice evaluation group's effort should be the development of "AoA Best Practice Briefs***" that ECHA could publish online. There could be 5-7 such briefs in this series, each focused on the various components of an AoA (e.g., AoA essentials/AoA 101, scoping, hazard assessment, exposure characterisation, technical feasibility, economic feasibility, decision analysis, etc.). An additional brief could focus on technical assistance for substitution. This would require investigating and providing links to resources and technical institutes that might form part of an AoA Community of Practice (below - for support in evaluating alternatives) or network of substitution support centres (above) or a that reflects the range of expertise needed to complete an AoA. These briefs could support AoA training modules and shared with industry and authorities during relevant workshops and conferences hosted by ECHA on authorisation and restriction topics.

This effort should be limited to what can be achieved within a 12-month time-period. AoA is a growing science policy field and it is important to recognise that new methods, tools and best practices will continue to emerge. This effort should to focus on the core need in the moment of improving quality

[10] See IC2 framework here: http://www.theic2.org/article/download-pdf/file_name/IC2_AOA_Guide_Version_1.1.pdf
[11] See Washington Department of Ecology's framework for SMEs here: https://fortress.wa.gov/ecy/publications/documents/1504002.pdf
[12] See California Safer Consumer Products Alternatives Analysis Guidance http://www.dtsc.ca.gov/SCP/AlternativesAnalysis.cfm
[13] See framework here: http://bookshop.europa.eu/en/minimising-chemical-risk-to-workers-health-and-safety-through-substitution-pbKE3012758/?CatalogCategoryID=Ke4KABstjN4AOAAEj8pAY4e5L

and consistency of AoAs generated for REACH processes, and what is essential in terms of communicating best practices to serve this need as a way to bound the level of effort required for this undertaking.

C2. Develop and deliver three types of substitution/AoAs trainings

- ***Main Strategy Objective:*** To enhance capacity and early thinking on substitution planning and AoAs across a range of audiences.
- ***Benefits***: Advances a training programme to support substitution efforts and to advance the practice of AoA that are appropriate to information and education needs of different stakeholders. This programme should be adaptable and scalable in order to integrate into a variety of convening models, from discussions with public and private-sector decision-makers to help advance a "mind-set" shift on substitution to supply chain dialog substitution workshops to specialised AoA seminars, to general industry sustainability conference presentations, to technical training workshops.
- ***Challenges:*** Inherent challenges involved in (a) finding the right organisation to develop the curriculum and lead the trainings and propagate the training programme via "train-the-trainer" approaches in C2a and C2b.
- ***Resource needs and timing:*** Consultants needed to adapt/create training for C2a and C2b and to deliver the train the trainer programmes; support needed by ECHA or relevant EC directorate or co-supported by MS authorities; Mid-term strategy.

We propose that three types of substitution trainings be developed and delivered. When viewed as a collection, the overarching goals of this training programme are to:

1. Build a culture of broad substitution thinking among EU-level organisations, Member States, and throughout supply chains;
2. Promote integration of broad substitution thinking with other sustainability and health programmes within the EU (e.g., circular economy, pollution prevention, non-toxic environment, etc.);
3. Advance and ensure the competiveness of EU industry by encouraging early adoption of safer alternatives in advance of regulatory requirements (whether within the EU or elsewhere);
4. Improve the quality and consistency of AoAs to support a transition to safer chemicals and technologies and to improve stakeholder trust in current REACH authorisation processes by promoting best practices; and
5. Build a "community of practice" for substitution that can be engaged on an on-going basis.

Wherever possible, it will be important to leverage existing resources and initiatives that are working to build capacity on substitution and AoA, including connections to the innovation economy. Examples include the on-going work of the OECD Ad hoc committee on the substitution of harmful chemicals that is working to maintain the useful SAA Toolbox and is creating opportunities to convene meetings of stakeholders to support substitution/AoA focused discussions, as well as a range of national initiatives and meeting forums focused on sustainable chemistry and substitution.

C2a. "Substitution Thinking" training

Target audience:

- Any/all SMEs and downstream users who use substances subject to regulation under REACH – including substances that are or could be targeted for inclusion on the Candidate List and those being targeted by Member States or market-initiatives, such as the SIN-List.
- Decision-makers within the private- and public-sectors to advance a cultural shift about the economic, environment, and public health benefits of substitution.
- Authority staff (including ECHA and MS Authorities) that are in risk assessment, management and enforcement roles.

Training Objectives and Content Overview:

This brief (1 hr to ½ day) training operates at a screening/cultural level, not a deep technical, level. It would provide a cookbook approach to thinking about substitution similar to training developed by the U.S. Occupational Safety and Health Administration to assist SMEs in utilising their Transitioning to Safer Chemicals Toolkit and offered through a network of OSHA Training Centres.[14] Core objectives of the training are to:

1. Introduce the ideas of substitution and of the AoA approach and how it serves chemical risk management goals and strategies;
2. Describe case histories and success stories (defined both in terms of risk reduction and of cost savings);
3. Introduce to the most basic tools of substitution (e.g., RSLs);
4. Introduce the basic structure of AoAs and the team of experts typically needed to carry it out;
5. Introduce resources available for conducting screening level assessments and AoA Community of Practice – technical institutes can could possibly provide technical assistance
6. Connect the audience with the "early alert and connections database;
7. For industry-specific audiences: provide examples of how downstream users can engage with their suppliers/distributors (or their competitors) to assist with identifying alternatives and provide critical questions to ask as well as other information sources to use/experts to ask.

Development and Delivery:

This training is envisioned as a "train the trainer" programme. Existing Subsport and U.S.-training materials could be reviewed, updated and adapted as needed for this training. Thus, this particular training is not envisioned as a resource-intensive effort to develop. In the near-term a priority set of the core objectives above could be integrated into presentations and delivered in substitution-oriented workshops and meetings. In the mid-term, ECHA, a relevant EC directorate or a MS authority should consider offering financial support for developing and delivering a "Substitution Thinking" train-the-trainer programme in order to disseminate the model broadly in order to reach the large base of the targeted audience. A training or professional education centre should be targeted for the roll-out of this training – it should not be seen as advocacy campaign nor should it be viewed as a marketing strategy for consulting services. Targets for the "train-the-trainer" trainings could be REACH help desks, national training centres that currently target the relevant REACH business community (e.g., UK-REACH Centre), but that do not offer substitution trainings in their current offerings, occupational safety and health training centres, etc. To increase its efficacy, the train-the-trainer programme should be guided by leveraging current trainings on topics such as sustainability, circular economy, risk management, chemicals management and seeding a substitution module within these topics.

[14] See: https://www.osha.gov/dsg/safer_chemicals/

C2b. AoA Best practice training

Target Audience:

- ECHA Committees
- Industry and their authorisation application consultants
- REACH Competent Authority staff

These audiences would have the basic understanding of what an AoA is as covered in the "Substitution thinking" training. These audiences should be those tasked with the professional responsibility of conducting and/or reviewing AoAs. Those AoA's could be ones required under REACH, other policies or where market drivers are leading to restriction of a particular chemical or class of chemicals. A goal of this training is also to improve the success of substitution (avoiding regrettable substitutions) regardless of the reason to substitute by improving the process of evaluating alternatives.

Although it is beyond the capacity of any ECHA committee or authority to fully understand an industry's processes and requirements, it is possible for authorities to rigorously review AoAs, critique results, and research substitution plans to ensure that due diligence has been done in the preparation.

Training Objectives and Content Overview:

Drawing on C1 above (*Align and update as needed ECHA AoA guidance documents with best practices*), this training will focus on the following:

1. Provide basic overview of AoA
2. Review best practices in AoA
    a. Scoping/functional needs assessment
        i. Basic sources that should be reviewed for the availability of alternatives (e.g., best available technique resources, (e.g., http://eippcb.jrc.ec.europa.eu/reference/)
    b. Technical feasibility
    c. Economic feasibility
    d. Risk evaluation [hazard assessment and exposure characterisation]
3. Review overarching standards of practice, i.e., transparency in data/information used in the assessment; being explicit about data uncertainties, etc.)
4. Provide examples of "poor" and "high" quality AoAs

Development and Delivery:

Development of this training should proceed after the development of AoA best practice briefs per C1 described above. Trainings could be separated into modules per topic (~1 hr per topic) or a ½ day to full day training. The trainings should be delivered by those experienced in the given topic area. Thus, ECHA could consider engaging the expert best practice group (above) or experts in the AoA Community of Practice (below) to assist with delivering trainings on the various AoA topics that are the focus of the best practice briefs. Easy to use check-lists/considerations for quality AoAs should be developed as resources. ECHA staff could take responsibility for continued training on this topic on an as needed basis during: (a) workshops for new authorisation applicants (c) training of new ECHA committee staff, (d) training of ECHA and REACH Competent Authority Staff. A train-the-trainer series for MS entities could also be pursued.

C2c. Specialised Topics for AOA Practitioners: Advancing an AoA Community of Practice

This last type of training is envisioned as high-level technical training for AoA professionals/practitioners.

Target Audience:

- Consultants and authorities engaged in conducting AoAs. This audience is assumed to have a high level of expertise. Given that the field is quickly addressing current methodological challenges, this training strategy is intended to provide a service to AoA professionals to keep them abreast of developments and to support a growing Community of Practice.

Training Objectives and Content Overview:

- Share emerging developments in AoA methods and practice. Possible topic examples:
  - Performance assessment/testing
  - Use of predictive toxicology to fill hazard data gaps
  - New hazard assessment tools
  - Socio-economic assessment methods developments: emerging data sources/tools
  - Relevant advances in sustainable chemistry/materials research
  - Incorporating broader life cycle considerations
  - Alternative product design
  - Case studies from relevant supply chains
- Establish an AoA "community of practice"

Development and Delivery:

These trainings are envisioned along the lines of a peer-to-peer education programme, using primarily a webinar series and discussion board format focused on sharing relevant developments in the field of AoA. This could be a quarterly series hosted and organised by ECHA or an academic institution. Where appropriate, webinars could be held in conjunction with the inter-authority AoA working group (see above: Engagement proposed action E4) in order to target an established group of authority officials whose work includes conducting AoA. The presentations would be given by researchers/experts on the given topic. ECHA staff could solicit ideas for webinar topics from NeSRAP participants, from its network of AoA researchers and experts and from reviews of recently published research articles.

As part of this training, ***ECHA could engage a research institute or academic institution to help coordinate a "community of practice" that builds the field of AoA and substitution, engages expertise in AoA and substitution and provides a support network for AoA and substitution activities*.** The community of practice could be a sub-committee of the Substitution Stakeholder Forum (Strategy Option E3). Such a Community of Practice, could serve as a home for discussion about key elements of an AoA and development of methods, tools, and approaches; convenes practitioners to improve expertise the field of practice, including consistency; and provides input to authorities and industry on improving substitution activities. An initial meeting of the Community of Practice could occur in conjunction with a scientific conference, such as the Society of Ecological Chemistry and Toxicology, as part of the Symposium on Substitution and Innovation (above) or organised as a separate event by an academic institution or centre such as the European Environment Agency.

C3. Investigate options for and feasibility of an AoA certification programme

- ***Main Strategy Objective:*** To improve the quality and consistency of AoAs for authorisation, restriction or market requirements.
- ***Benefits***: Advances a required training programme to improve the quality and consistency of AoAs and grow the field of practitioners based on a continued education on best practices.
- ***Challenges:*** Establishing and maintaining a certification system; push-back from industry/consultants.
- ***Resource Needs and Timing:*** ECHA tender for a consultant; Near- to mid-term strategy.

To build capacity and ensure quality in the conduct of AoAs, one strategy option is to require those that submit AoAs for authorisation to be a "certified AoA practitioner".

Under the Massachusetts Toxics Use Reduction Act,[15] every Toxics Use Reduction Plan (including the evaluation of alternatives) must be completed by a certified Toxics Use Reduction Planner and signed off by a senior official of that company. The majority of planners become certified via 40-hour training course that requires a written examine to pass, and fulfilling continuing education credits every 2 years. Certified planners include those from both industry as well as consultants. TURA officials have observed the benefits of the TURA training course in the evaluation of industry's plans – the quality of plans is improved among those participating in the 40-hour course.

We recommend further investigation into options for and the feasibility of an AoA certification programme that would mandate AoA training and continuing education requirements for industry representatives and/or their consultants completing AoAs for authorisation, for agencies or consultants completing AoAs for restriction proposals and for those AoAs done in response to market-based actions. There is no current certification programme that exists for this purpose and would have to be developed. If this strategy option is of interest, it requires further research and assessment to propose a feasible certification system, and the curriculum framework for the certification programme.

[15] See: http://www.mass.gov/eea/agencies/massdep/toxics/tur/