Improving the Identification, Evaluation, Adoption and Development of Safer Alternatives:

Needs and Opportunities to Enhance Substitution Efforts within the Context of REACH

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List of Acronyms Used

AITEX	Textile Industry Research Association
CAD	Chemical Agents Directive
CBI	Confidential Business Information
CLH	Harmonised classification and labelling
CoRAP	Community rolling action plan
COSME	European Programme for the Competitiveness of Enterprises and Small and Medium-Sized Enterprises
CMD	Carcinogens and Mutagens Directive
CLP	Classification, Labelling and Packaging
CMR	Carcinogen, mutagen or reproductive toxicant
CSR/ESR	Chemical Safety Report/Exposure Scenario Roadmap
CTCR	Footwear Technology Centre of La Rioja
EAP	Environment Action Programme
DG	Directorate General
EC	European Commission
ECHA	European Chemicals Agency
ENES	European Network on Exposure Scenarios
ETV	Environmental Technology Verification
EU	European Union
FTE	Full Time Equivalent
GHS	Globally Harmonized System of Classification and Labelling
IC2	Interstate Chemicals Clearinghouse
MEPs	Manufacturing Extension Partnerships
NEWMOA	Northeast Waste Management Officials' Association
NeRSAP	Network of REACH SEA and Analysis of Alternatives practitioners
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Co-operation and Development
PACT	Public Activities Coordination Tool
R&D	Research and Development
RAC	Risk Analysis Committee
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REEG	REACH Exposure Group
RMOA	Risk Management Options Analysis
RoHS	Restrictions of Hazardous Substances
SEAC	Socio-Economic Analysis Committee
SMEs	Small and Medium Sized Enterprises
SVHC	Substances of Very High Concern
TURA	Toxics Use Reduction Act
TURI	Toxics Use Reduction Institute
UK	United Kingdom
UK CSF	United Kingdom Chemical Stakeholder Forum
US	United States
US EPA	United States Environmental Protection Agency
US NIST	US National Institute for Standards and Technology
WUR FBR	Wageningen University Institute on Food and Biobased Research

Executive Summary

Chemical substitution is commonly defined as "the replacement or reduction of hazardous substances in products or processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organisational measures." It is a long-standing risk management approach in Europe and is a goal of the European Union (EU), Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation. In particular, the authorisation and restriction processes are two important regulatory drivers of substitution within REACH. Substances of very high concern (SVHC) that are made subject to authorisation require an analysis of alternatives to ensure that these highly hazardous substances are progressively replaced by safer alternative substances or technologies where economically and technically feasible. Member State or European Chemical Agency (ECHA) proposals seeking to restrict substances that pose an unacceptable risk to human health and the environment are also required to undergo a Socio Economic Impact evaluation that contains a similar analysis of alternatives process.

In order to improve current working practices in the EU in identifying, evaluating and adopting safer alternatives and to more broadly enhance support for substitution among Member States and the European Commission, ECHA commissioned the Lowell Center for Sustainable Production to undertake a landscape analysis of current capacity and needs. The goal of this project is to identify specific priorities that ECHA and other public authorities could support in the near term in order to advance substitution programs and practices among Member States. A review of select applications for authorisation and restrictions proposals, in addition to surveys and interviews involving industry, Member State and Commission authorities, and NGOs were undertaken to obtain critical insights needed for this research.

Key Findings

European Commission and Member State policies are driving consideration of substitution.

81% (N=79) of industry survey respondents and 59% (N=10) of industry consultant survey respondents stated that they have (or their clients have in the case of consultants) implemented substitutes for hazardous chemicals in that last 10 years. REACH emerged as a particular driver of substitution, but the breadth of product safety regulations, occupational safety and health regulations and market pressures were noted as important drivers of substitution whose influence is often dependent on where an actor is positioned within the supply chain. Nonetheless, regulatory requirements alone may be insufficient to ensure that effective substitution occurs, particularly for smaller firms with limited technical expertise and resources. It is important that government authorities supplement the regulatory drivers with capacity building and the facilitation of resources (technical and financial) to substitute.

The principle of substitution is not strongly connected to the resourcing and implementation of programs and activities that promote substitution among the European Commission, ECHA and Member State authorities.

Despite mandates for substitution, very few staff focus on substitution among Member State authorities, ECHA, and the Commission. Instead, authorities view their role primarily as collecting data on hazards and exposures and determining if risks identified warrant risk management actions. Researching and evaluating alternatives is an important component of substitution initiatives and the majority of Member States expressed limited capacity in this area. Given the limited staff resources dedicated to substitution activities, sharing of resources and coordination between authorities becomes a critical priority. However, chemical substitution initiatives among the European Commission, ECHA and Member States remain largely disconnected.

Technical feasibility assessment is a challenging aspect of conducting an analysis of alternatives and has notable support barriers.

Evaluating technical feasibility in the analysis of alternatives is a shared challenge among authorities and industry. Few authorities have engineering expertise to effectively evaluate the technical feasibility of alternatives and most of them do not see this as their role. Industry noted the need for time to research and adopt alternatives, lack of technical support, and supply chain access to information as important barriers.

The quality and consistency of analyses of alternatives could be significantly improved.

Limits in opportunities were identified to enhance the quality and consistency of analyses of alternatives across several key elements of the analysis: (1) scoping/screening, (2) technical feasibility, (3) economic feasibility, (4) hazard/exposure assessment and (5) decision approach. In addition to the barriers regarding technical feasibility as addressed above, other notable issues identified include lack of consideration of a broad range of alternatives to meet a chemical function, lack of full cost accounting in the economic feasibility assessment, and lack of consistency in hazard endpoints reviewed.

Member State programs to support safer alternative adoption exist but are not commonplace.

While several authorities mentioned examples of successful industry sector/supply chain engagement programs to support substitution, both industry representatives and authorities elevated the importance of increased activity in this arena to enhance substitution efforts. In addition, there was general agreement among stakeholders that REACH has made possible an abundance of data that could be extremely valuable in enhancing support for the initial identification of potential alternatives. However, this information is not readily useable to identify alternatives in its current form. Lastly, while some efforts exist for authorities to coordinate on

shared substitution challenges, additional collaboration was seen as an important vehicle to enhance the capacity among Member States, including those less active on substitution.

Innovation research on safer alternative is not routinely aligned with regulatory priorities.

Interviewees pointed to the need for greater engagement and investment in sustainable chemistry solutions. There is currently a disconnect between industry's needs to identify alternatives to SVHCs and the research base in academia and other research institutes capable of identifying sustainable chemistry alternatives for these chemicals. In addition, there is a lack of public or public/private investment to support this needed R&D. While some Member States have engaged in alternatives research and provide innovation funding to support development and adoption of substitutes, most have not. Public procurement programs were also voiced as another route to link regulatory safer alternatives priorities with authority decisions and programmatic actions.

Recommendations

Our assessment identified a number of recommendations to enhance the capacity of ECHA, EU and Member State authorities to support to the identification, evaluation, and adoption of safer substitutes. Priorities should focus on infrastructure development (including funding mechanisms), increased training and education on analysis of alternatives, and creating sustainable structures for industry and authority collaboration on substitution. These include:

Building infrastructure to support substitution

1. Significantly grow ECHA and Member State authority staff capacity over time to support substitution through training as well as recruitment. As a first step, ECHA could establish a dedicated group of staff with expertise in chemical hazard evaluation, chemistry, technical assessment, and economic analysis that could then provide training and support to other authorities and industry.
2. Coordinate EU and Member state grant-mechanisms and private/public partnership funds to invest in innovation research to support alternatives development and diffusion for priority hazardous chemicals of concern. 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.
3. Build technical assistance structures for companies, in particular small and medium sized enterprises (SMEs), for evaluation and adoption of substitutes. To achieve this, ECHA could undertake an analysis of technical support capacities for SMEs at the EU and Member State level (including trade associations) that could be engaged in supporting chemical substitution activities.
4. Expand government "green" procurement programs to include chemical substitution in addition to addressing other important sustainability issues. Similar to the US Environmental Protection Agency (US EPA) Safer Choice Program, ECHA could explore the development of a "safer chemical ingredient" listing program utilising REACH data and

third party certification to identify safer alternatives for different functional classes of chemicals.

Increasing engagement/collaboration around substitution

1. Create mechanisms for enhanced Commission and Member State collaboration/coordination on substitution, including support for smaller Member State authorities. ECHA could establish an inter-authority analysis of alternatives and chemical substitution committee that meets on a regular basis to discuss challenges to substitution, share lessons, open doors to collaboration, provide support to smaller Member States and identify concrete projects that could be undertaken across Member States.
2. Create or expand mechanisms for greater supply chain collaboration and engagement, including shared performance testing and evaluation, and demonstration sites. ECHA could undertake an evaluation of existing supply chain partnership and collaboration models at the EU and Member State levels and mechanisms to enhance supply chain communication around substitution, including establishing 1-2 model supply chain substitution projects.
3. Develop networks of experts – academics, consultants, and government research institutes – to support authorities and industry in both assessment and adoption of substitutes preferably using already existing networks. ECHA could establish an on-line clearinghouse of experts with training in analysis of alternatives and substitution processes.

Enhancing technical capacity to support analysis of alternatives and substitution

1. Develop more detailed guidance or guidelines, instructions or other suitable material for authorities and industry to complete analyses of alternatives in applications for authorisations and restrictions proposals outlining minimum components and quality criteria.
2. Provide enhanced analysis of alternatives support and training to ECHA, including SEAC and RAC, Member State authorities, and industry/consultants to improve quality and to enhance consistency. In particular, ECHA could develop training curricula and explore the feasibility of establishing of “a certified analysis of alternatives practitioner program.”
3. 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.

Conclusion

There are many challenges but significant opportunities to accelerate the identification, evaluation and adoption of safer substitutes in the EU. REACH and other policies, coupled with market forces, have provided important market drivers for avoidance of SVHCs. Thoughtful analysis of alternatives processes, combined with structures to support supply chain collaboration as well as research, innovation, and technical support can enhance the probability that successful substitution will occur. Our analysis found 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. ECHA can specifically support substitution moving forward in two distinct ways: improving its own capacity as well as that of Member States and industry for conducting analyses of alternatives; and providing mechanisms (including facilitating collaborations and serving as a hub for best practices) to support substitution activities. ECHA can also recognize and support those companies that are leaders in sustainable chemistry in order to help drive further market-based activities. In other words, ECHA can use its regulatory authority to strengthen implementation of the REACH goal of substitution of SVHCs. It can also use its discretionary powers to facilitate and encourage early marketplace actions to identify, develop and adopt safer substitutes (even before regulation).

Context and background

Chemical substitution is commonly defined as "the replacement or reduction of hazardous substances in products or processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organisational measures."[1] The substitution process is one of continuous improvement and consists of three primary steps: identifying alternatives, evaluation, and adoption.

The substitution of hazardous chemicals is a long-standing approach in Europe to more effectively manage and reduce risks from chemicals of high concern to human health and safety, and the health of the environment. For example, the European Commission (EC) has supported the inclusion of substitution requirements in major international agreements and legislative efforts**,** such as the 1987 Montreal Protocol, the 2001 Stockholm Convention, and the United Nation's Strategic Approach to International Chemicals Management. A substitution approach is mandated in a number of European Union (EU) occupational health and safety regulations referring to hazardous agents in the workplace as well as in EU directives and regulations on biocides, cosmetics and toys, which restrict the use of certain chemicals (primarily carcinogens, mutagens, and reproductive toxicants (CMRs)) and in regulations restricting carcinogens in consumer available preparations. The Chemical Agents Directive (CMD) (98/24/EC) specifically states that "substitution shall by preference be undertaken, whereby the employer shall avoid the use of a hazardous chemical agent by replacing it with a chemical agent or process which, under its condition of use, is not hazardous or less hazardous to workers' safety and health, as the case may be."[2]

Classification and Labelling of chemicals has long been an important driver for substitution in the EU. The 2008 European Commission regulation on Classification, Labelling and Packaging of Substances and Mixtures (CLP), updated the European classification and labelling process, including processes for harmonized classifications, in line with the Globally Harmonized System of Classification and Labelling (GHS). While the concept of substitution is not directly addressed in the harmonised classification and labelling process (CLH), hazard classifications are directly linked to chemical restrictions and substitution provisions in EU policy and many Member State regulations and provide a strong incentive to industry to substitute on their own.

At the Member State Level, several countries, including Denmark, France, Germany, Norway and Sweden have instituted substitution provisions in national policies and have developed tools and guidance to support substitution processes. For example, the Swedish government instituted the "substitution principle" as a core principle of environmental policy in the 1970s and in the 1985 Swedish Act on Chemical Products, resulting in a number of initiatives to advance

[1] Lohse J. et al. *Substitution of Hazardous Chemicals in Products and Processes.* A report compiled for the Directorate General Environment, Nuclear Safety and Civil Protection of the Commission of the European Communities. Hamburg, March 2003. Available at: http://s1.downloadmienphi.net/file/downloadfile6/151/1384386.pdf

[2] See: https://osha.europa.eu/en/legislation/directives/75

substitution. The German government has funded the development of a number of substitution frameworks and tools.[3]

Substitution of hazardous chemicals with safer alternatives is also a critical risk management strategy in the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation. The regulation aims to protect human health and the environment from harms posed by hazardous chemicals while ensuring the competiveness of the European chemical manufacturing and industrial users of those chemicals. The authorisation and restriction processes are two important regulatory drivers for substitution in REACH. Substances of very high concern (SVHCs) that are subject to authorisation require an analysis of alternatives to ensure that these highly hazardous substances are progressively replaced by safer alternative substances or technologies where economically and technically feasible. Similarly, Member State proposals seeking to restrict substances that pose an unacceptable risk to human health and the environment are also required to undergo a Socio Economic Impact evaluation that contains a similar analysis of alternatives process.

Analysis of alternatives, also known as alternatives assessment or chemical substitution assessment, is broadly defined in the scientific literature as a process for identifying and comparing potential chemical and non-chemical alternatives that could replace chemicals of concern on the basis of their hazards, performance, and economic viability.[4] A recent review published by the Organisation for Economic Co-operation and Development (OECD) noted that most definitions of alternatives assessment share a common focus on intrinsic hazard reduction and on taking action to replace chemicals of concern with safer alternatives.[5] While required in the authorisation and restriction processes, the substitution or analysis of alternatives approach has been used in regulatory and non-government programs in the United States (US) and some EU Member States for many years and, due to market and policy pressures, is increasingly being used in voluntary corporate sustainable chemicals management programs.

Analysis of alternatives is a step-defined, solutions-oriented process. The analysis focuses on examining alternatives that could replace the specific function provided by the hazardous chemical of concern. The focus is not on replacement with particular chemicals, but rather the functions those chemicals can provide. This replacement could be made possible with chemical, process or technology changes. It may also be determined that the function provided by the chemical is simply not essential or can be achieved by other means. Analysis of alternatives is

[3] See: http://www.subsport.eu/substitution-tools

[4] See: Jacobs et al. Alternatives assessment frameworks: research needs for the informed substitution of hazardous chemicals. *Environ. Health Persp.* 2015. DOI:10.1289/ehp.1409581. Available at: http://ehp.niehs.nih.gov/1409581/; Geiser K., et al. Architecture of alternatives assessment. *Risk Anal.* 2015 Dec;35(12):2152-61; National Research Council. *A Framework to Guide Selection of Chemical Alternatives.* Washington DC: National Academies Press. 2014. Available at: http://www.nap.edu/catalog/18872/a-framework-to-guide-selection-of-chemical-alternatives

[5] Organisation for Economic Co-operation and Development. Current Landscape of Alternatives Assessment Practice: A Meta-Review. Series on Risk Management No. 26. ENV/JM/MONO(2013)24. 2013. Available at: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO%282013%2924&docLanguage=En

action-oriented as the comparative basis of the analysis provides a choice among options that directly informs decisions and changes to business operations.

Adoption – the actual implementation of an identified alternative in an industrial setting – is frequently viewed as a critical element of substitution process, following the analysis of alternatives. If an alternative does not perform well or is not cost-effective or if it creates new risks in its implementation this can undermine informed substitution efforts. Further, analysis of alternatives may be outside of the technical expertise of many small and medium sized enterprises (SMEs), where, as opposed to larger companies, there may be no scientific staff with knowledge of chemical assessment. These same firms may not have the resources or ability to implement necessary process/product design modifications or take the risk of implementing a substitute that may not work effectively in their particular application.

While the substitution of hazardous chemicals occurs primarily at the company level, decisions whether to pursue substitution and if, when, and how it occurs are influenced by many internal and external factors. Corporate sustainability and product stewardship policies often support substitution of hazardous chemicals. Market and government policies (including enforcement) can be important drivers for substitution. Yet, government also plays an important non-regulatory role in supporting investment, capacity building, and facilitation of supply chain collaborations around safer substitutes.

Purpose

In order to improve current government and industry practices in the EU in identifying, evaluating, and adopting safer substitutes in the context of applications for authorisation and restriction processes under REACH, and to more broadly enhance support for substitution among Member States and in industry, the European Chemicals Agency (ECHA) and the European Commission sought to first understand the landscape of current capacity and needs.

The goal of this project is to identify specific priorities that ECHA and other public authorities could support in the near term to advance substitution programs and practices among Member States and the Commission, including specific needs related to analysis of alternatives capacity.[6] In 2015, ECHA commissioned the Lowell Center for Sustainable Production to work with the Agency on this landscape analysis. This evaluation was not designed to be a comprehensive review of substitution programs and practice, but rather to provide a preliminary review of capacity needs (and opportunities) for ECHA and Member State authorities and also to identify future programmatic and policy research and interventions that could address these needs. Information for this assessment was collected via surveys and interviews with Member State authorities, industry representatives, industry consultants, ECHA and Commission representatives, and non-governmental organisations (NGOs). Reflections on the results and recommendations for

[6] ECHA. Improving the Analysis of Alternatives and Practical Ways of Promoting Innovation and Substitution in the EU – project description. Helsinki. January 26, 2016. See: http://echa.europa.eu/documents/10162/13630/substitution_project_en.pdf

capacity development are also based on the over two decades of experience by the Lowell Center for Sustainable Production in researching and implementing chemical substitution programs. Understandably, the findings and recommendations are based on observations from a US-based entity and as such may not fully capture the unique nature of institutions and their functioning at the European level.

Approach

Several qualitative research methods were used to characterize current capacity and challenges to promote and support chemical substitution among the Commission, ECHA and Member States, including surveys, "key informant" interviews and reviews of relevant authorisation applications and restriction proposals. Our review examined the range of activities and associated capacity needs related to supporting and promoting substitution, including identification of alternatives and comparative evaluations (which are included in analysis of alternatives), adoption/substitution of safer alternatives and safer alternatives research and development.

Surveys were developed and administered to Member State Competent Authorities of REACH, industry representatives and industry consultants. Contact lists targeted those organisations and individuals who have been active in the restriction and authorisation processes, including those engaged in stakeholder consultations. A subset of survey questions was used for this project. The remaining survey questions are being used as part of the sub-study on substitution in support of DG Environment's study into "the strategy for a non-toxic environment of the 7th Environment Action Programme (EAP)" being conducted by researchers at Risk & Policy Analysts Ltd.[7]

Survey questions for this project queried information about organisational resources devoted to substitution; specific activities related to substitution (identification, evaluation, and adoption), including challenges and needs associated with analyses of alternatives; drivers and obstacles to substitution; and suggested priorities for enhancing substitution activities by Member States and in support of industry. Both the industry and industry consultant surveys were used to gain insights about capacity needs and challenges so as to provide insights to the design of government programs that can help address those challenges. Frequencies were calculated for survey responses and open-ended responses were analysed for themes.

Interviews with "key informants" were conducted with a sample of REACH Competent Authorities in Member States who responded to the survey in order to delve deeper into issues characterized in survey responses. Interviews were also conducted with innovation research program officials to help characterise opportunities to support alternatives research as well as industry consultants that have significant experience and insight regarding substitution capacity needs and opportunities given their routine involvement in the development of authorisation applications for industry clients. Experts from NGOs engaged in promoting chemical substitution were also

[7] See: European Commission. Environment. Environment Action Programme to 2020. Available at: http://ec.europa.eu/environment/action-programme/

interviewed. For all interviews, semi-structured interview guides were developed and followed in order to analyse and synthesize dominant themes across interviews.

In order to protect the confidentiality of interviewees and survey respondents, specific comments are not ascribed to specific individuals in the following results section or in the supplemental Annexes.

Prior to interviewing Member State Competent Authorities of REACH and industry consultants, relevant restriction proposals and authorisation applications that pertained to those interviews were reviewed in detail. For each authorisation application and restriction proposal reviewed, the analysis of alternatives section was critiqued based on best practices emerging in the growing science policy field of alternatives assessment. Recommendations were supplemented with information and analysis of best practices in the US, utilising the University of Massachusetts Lowell research team's expertise.

Results

14 key informant interviews were conducted including representatives in Member State Competent Authorities (N=7), NGOs (N=3), industry consultants (N=2) and innovation/research centres (N=2).

Survey responses from 16 Member States (Table 1), 105 industry representatives (Table 2) and 18 consultants were received. Multiple responses from two companies were received, and considered separately. The majority of industry respondents represented large companies (86%) (defined as >250 employees and >€50 million in turnover). In addition to individual companies, three industry associations responded to the industry survey and one association responded to the consultant survey. Among consultant survey respondents, the majority have worked with a number of industries on applications for authorisation and other related chemical substitution initiatives.

TABLE 1. MEMBER STATE SURVEY RESPONDENTS

Respondents
Belgium, Federal Public Service – Health
Cyprus, Department of Labour Inspection
Denmark, Danish Environmental Protection Agency
France, Ministry of Environment
Finland, Finnish Safety and Chemicals Agency
Germany, German Environment Agency (UBA)
Germany, German Institute for Occupational Safety and Health (BAuA)
Greece, General Chemicals State Laboratory
Italy*
Lithuania, Lithuanian Environmental Protection Agency
Norway, Norwegian Environment Agency
Netherlands, Centre for Safety of Substances and Products
Romania, Labour Inspectorate
Sweden, Swedish Chemicals Agency
UK, Health and Safety Executive
UK, Environment Agency

**Respondent not a Member State Competent Authority*

The key findings below emerged from a synthesis across interviews and surveys as well as a critique of the analysis of alternatives section in restriction proposals and applications for authorisation.

1. European Commission and Member State policies are driving consideration of substitution.

81% (N=79) of industry survey respondents and 59% (N=10) of industry consultant survey respondents stated that they have (or their clients have in the case of consultants) implemented substitutes for hazardous chemicals in that last 10 years (See Annex B and C, Q3). While this survey was not designed to quantify and characterize the types of substitutions that have taken place, industry responses revealed that substitution of hazardous chemicals is occurring, at least among those surveyed.

TABLE 2. INDUSTRY SURVEY RESPONDENTS

NACE – Description	N
Extraction of crude petroleum and natural gas	1
Mining of metal ores	1
Manufacture of textiles	1
Manufacture of chemicals and chemical products	28
Manufacture of basic pharmaceutical products and pharmaceutical preparations	4
Manufacture of rubber and plastic products	4
Manufacture of other non-metallic mineral products	1
Manufacture of basic metals	2
Manufacture of fabricated metal products, except machinery and equipment	6
Manufacture of computer, electronic and optical products	2
Manufacture of electrical equipment	3
Manufacture of machinery and equipment n.e.c.	4
Manufacture of motor vehicles, trailers and semi-trailers	4
Manufacture of other transport equipment	7
Other manufacturing	1
Electricity, gas, steam and air conditioning supply	1
Construction of buildings	1
Wholesale trade, except of motor vehicles and motorcycles	4
Retail trade, except of motor vehicles and motorcycles	5

**105 representatives responded to the survey although only those noted above (N=80) provided demographic information (industry type based on Nomenclature of Economic Activities (NACE) codes)*

In the opinion of one industry consultant, chemicals that are currently the focus of authorisation are the most challenging cases for substitution:

> *"In most cases it is not because companies were unaware of the hazard; these companies are still using these SVHCs because they could not get rid of them….These are the most difficult cases related to identifying alternatives."*

The REACH regulation clearly emerged as a dominant driver of substitution in the EU among survey respondents, including authorities, industry representatives and industry consultants. Other drivers of substitution noted in interviews included the Restrictions of Hazardous Substances (RoHS) regulation, the End of Life Vehicle Directive (ELVD), chemical restriction policies (e.g., occupational carcinogens, toys), CLP and market pressures (see Q3 in Annex A, and Q1 in Annex B and C). The importance of a given regulatory driver was described by one industry consultant as dependent on where an actor is positioned within the supply chain. Placement of a substance on the Candidate List – SVHCs that could be subject to future authorisation – in particular, was stated as a key step in the regulatory process that initiates the interest in and search for substitutes. This was confirmed during interviews with industry consultants and is supported by prior analyses.[8] The Annex XIV REACH authorisation list was also noted as a key driver. One consultant shared case examples of substitutions that occurred

[8] Centre for Strategy and Evaluation Services. Interim Evaluation: Impact of the REACH Regulation on the Innovativeness of EU Chemical Industry. Sevenoaks: CESS, June 2012. Available at: http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/innovation-final-report_en.pdf

prior to the authorisation applications dates, thus mitigating their client's need to subsequently apply for authorisation.

The most commonly identified benefits of substitution outlined by companies that have implemented substitutes include improved worker safety (72% of responses); improved brand reputation (51%); improved worker satisfaction (40%); decreased regulatory costs (32%); and decreased chemicals management costs (28%) (See Annex B, Q4). However, companies noted a number of common challenges, most notably increased production costs (67%); customer concerns with product/process changes (46%); reduced performance/product quality (41%); supply chain availability of the alternative (40%); and that the substitute turns out to also be a substance of concern and subject to regulatory and non-regulatory actions (37%) (See Annex B, Q5). These identified challenges indicate that more organised support structures for substitution could help maximize benefits while addressing challenges.

2. The principle of substitution is not strongly connected to the resourcing and implementation of programs and activities that promote substitution among the European Commission, ECHA and Member State authorities.

Despite the requirements and strong regulatory signals for substitution provided by REACH and other Commission directives and regulations and Member State policies, very few staff focus on this issue among Member State authorities, ECHA, and the Commission. These regulatory signals create a responsibility on, government authorities to support the informed substitution of chemicals that minimize unintended consequences of policy actions. However, with two exceptions, Member States reported limited full-time equivalent (FTEs) staff dedicated to supporting chemical substitution efforts. These substitution efforts involve for example: developing guidance, tools, information or technical assistance to support industry, researching, evaluating and comparing alternatives for priority chemicals of concern, facilitating interagency or industry sector/supply chain dialogues on substitution, or enforcing substitution requirements. While staff may work some on issues that intersect with substitution, it is not a major focus of their jobs. About 50% (N=8) of Member State survey respondents reported having only one dedicated FTE (See Annex A, Q1). As authority representatives explained in interviews and survey responses:

> *"We have not done much on substitution – our focus is on getting the risk management right in the workplace via exposure control, even though substitution [is at] the top part of the hierarchy of industrial hygiene controls."*
>
> *"Currently our organisation lacks the resources to build the relevant capacity for substitution of hazardous chemicals. Our role is restricted in participating [in] specific ECHA processes and on a helpdesk level." (Note: This was a response to a survey question about analysis of alternatives.)*

As noted above, the limited number of FTEs focused on substitution in ECHA, Commission services and Member State authorities may be a reflection of the traditional regulatory risk assessment/risk management focus of current chemicals management agencies. In other words,

despite the principle of substitution being clearly present in regulations and statements, there is limited coordinated activity that is promoting industry practice of substitution by government authorities as they view their role as primarily collecting data on hazards and exposures and determining if risks warrant risk management actions. Expertise in these agencies reflects this perspective. Several interviewees noted that the role of government has been to provide the risk management measures and then let industry implement the particular action without getting involved in decisions about technology choices.

However, the innovation literature notes that regulatory requirements alone may be insufficient to ensure that effective substitution occurs, particularly for smaller firms with limited technical expertise and resources.[9] The regulatory driver needs to be supplemented by capacity building and the creation of opportunities to substitute.

Researching and evaluating alternatives using analysis of alternatives process is an important component of substitution initiatives and the majority of Member States expressed limited capacity in this area. As stated by one Member State representative:

> *"We do not have and are not expected to have detailed knowledge on alternatives assessment, but the government can provide technical support and funding for substitution initiatives at companies."*

A significant challenge related to the Commission, ECHA and Member State capacity to support substitution is the limited coordination between initiatives. Over the past 20 years, a number of smaller and larger substitution efforts, including analyses of barriers and opportunities, evaluations of alternatives, guidance frameworks, and supply chain dialogues have been funded or undertaken by ECHA, DG Environment, DG Employment, DG Research, and DG Grow (as well as research institutes under these Directorate Generals) and a number of European Member states including Norway, Germany, Denmark, France, Sweden, and the United Kingdom. For example, ECHA's effort to enhance capacity for substitution, DG Environment's Nontoxic Environment effort, DG Employment's recent research initiative on chemical substitution, and a new tender from DG Grow on chemical substitution[10] have been largely disconnected and even more disconnected from efforts in the Member States. There has been little collaboration or coordination to build connections between these various, often overlapping efforts. There is no "repository" of all studies or initiatives taken in the past two decades and thus, there is risk of duplicating efforts when new studies or initiatives are taken. Given the limited staff resources dedicated to substitution activities in the Commission, ECHA and Member State authorities, sharing of information and coordination is particularly important.

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[9] Ashford, Nicholas. An Innovation-Based Strategy for a Sustainable Environment. In *Innovation-Oriented Environmental Regulation: Theoretical Approach and Empirical Analysis.* Potsdam, Germany: European Commission Joint Research Centre. 1999.

[10] See: https://etendering.ted.europa.eu/cft/cft-display.html?cftId=1469

3. Technical feasibility assessment is a challenging aspect of conducting an analysis of alternatives and has notable support barriers.

Evaluating technical feasibility in the analysis of alternatives was ranked as the top challenge among authorities and industry where capacity-building support and assistance is needed (Table 3). Yet technical feasibility assessment was a challenge for industry and authorities for different reasons.

TABLE 3. MOST CHALLENGING ELEMENT OF AN ANALYSIS OF ALTERNATIVES WHERE CAPACITY BUILDING IS MOST NEEDED

Analysis of Alternatives Component	Competent Authorities (N=10)	(Industry Representatives N=70)	(Industry Consultants N=11)
Identifying/screening alternatives	20%	17%	27%
Technical feasibility assessments	60%	44%	45%
Economic feasibility assessment	10%	9%	9%
Hazard/risk assessment	10%	12%	0%
Decision analysis/ decision support	0%	4%	18%

Industry representatives noted the significant resources needed to test the performance of potential alternatives and validation needs related to customer specifications as important barriers. Substitution is not an easy process and may require significant product or manufacturing process changes that can affect product quality. A chemical composition change in a formulated product or material can directly affect the performance or appearance of the product requiring time to make necessary formulation adjustments to maintain or improve performance characteristics. Further, while a specific alternative may work in some applications, it may not in others, given unique manufacturing process or performance criteria. As illuminated in a few examples from the survey comments:

> *"We don't have existing alternatives for all relevant substances at present. To be able to find a satisfactory substitute, we invest substantial resources both internally in R&D and externally as consultancy services."*
>
> *"Performance requirements are so high that there are very little options for substitution."*
>
> *"None of the substituted processes give identical performance profiles to the original processes. Thus there are problems with customer and market acceptance."*
>
> *"It takes years and significant financial and human resources to research, develop, manufacture, test and assess, support applications and uses development and to distribute new chemical products (this statement is from the perspective of production of high volume commodity chemicals; for low and medium volume chemicals these statements will apply to a lesser degree). The low success rate in the development of new products, because they do not meet market expectations in terms of safety, performance and affordability, is an obstacle not only to substitution, which should not be a goal in itself, but also to the marketing of innovative chemical products."*

Industry representative survey comments and interviews with industry consultants also noted supply chain complexity as a key barrier when evaluating technical feasibility and performance, specifically for analyses of alternatives conducted by contract manufacturers (those that manufacture components or products under contract for a brand or brands). While the analysis of technical feasibility requires clarity of specific technical parameters and a clear description of how the Annex XIV chemical is being used and the function it performs, contract manufacturers often lack such information. Brands create the specifications and only provide limited information to their contract manufacturers to protect sensitive intellectual property/confidential business information (CBI). While this barrier was described as a specific problem related to contract manufacturing, it illuminates how technical performance and product and process design information that is dependent on the position of a given company within the supply chain is a key analysis of alternatives challenge confronting industry. A secondary problem noted by industry consultants are the costs involved in modifying the design of a long life, complex product (recertification, etc.) and the risk that a product or process chemical change will result in unexpected performance or longevity impacts.

With regard to barriers and capacity needs identified by Member State authorities, staffing expertise necessary for effectively evaluating the technical feasibility of alternatives is a significant capacity need. However, the shared perspective among authorities is that determining the technical feasibility of alternatives is not the role of government. As one Member State authority stated:

> *"Technical feasibility assessment requires very specific expertise on process technology that might often only be available within industry itself…. It is clear to us that this knowledge to understand the actual functionality of the substance and potential alternatives and the exact technical requirements for specific applications and uses is crucial to evaluate the technical feasibility of alternatives and to be able to make well informed choices regarding regulatory steps."*

Nonetheless, several Member State authorities noted the need to have a basic understanding of what to look for and resources to consult in evaluating technical feasibility assessments. Having access to industry and engineering experts with expertise in substitution was seen as an important need.

> *"We see a need for access to independent external experts who have deep knowledge of a certain sector when substitution of substances in that sector is discussed. A number of years ago with the help of a consultant that knew that part of industry very well [we] convinced a number of companies using mercury in articles that in fact it was possible to substitute this use."*

Because technical feasibility information is needed for an analysis of alternatives in restriction proposals produced by public authorities, these authorities are limited by publicly available data and whatever information industry is willing to share. Authorities described working with consultants to collect information on the relevant components of an analysis of alternatives for restriction proposals, including performance information. This process was seen as a necessity

not only because of the staffing limitations, but also because of difficultly regulatory authorities experience in trying themselves to collect the necessary performance information on alternatives from industry, supply chain actors and trade sector organisations. Yet those authorities that had used survey data administered by industry associations in restriction proposals noted that information on technical/performance characteristics of alternatives was often limited. These surveys were not developed for the specific purpose of collecting data necessary for restriction proposals – authorities simply used data wherever they could find it. Thus the desired information relevant to performance/technical feasibility was often missing. Based on this experience, authorities voiced the importance of developing adaptable survey templates that could improve the utility of technical/performance data collected by third parties. These parties often use surveys to collect supply chain information about the performance of alternatives for their clients and association members. While performance information is often very application-specific, there remain a core set of questions and issues related to technical feasibility of alternatives that need to be addressed to inform broad policy proposals in restriction applications. These could form the basis of template survey questions and joint performance evaluation guidelines that address the range of performance criteria needed for a chemical, function, and application and adapted as needed.

While applicants for authorisation need to justify a lack of alternatives that can technically achieve the necessary function and performance of the SVHC, our review of submitted applications identified a consistent issue of overly prescriptive or overly broad functional requirements. This is not unexpected given the purpose of the application for authorisation. Several interviewees noted that performance requirements might be over-specified (requiring a specific performance – for example a level of corrosion resistance or water repellancy – that may not be required for an application) by those submitting applications for authorisation in some cases. This can result in the range of options considered for substituting an SVHC being unnecessarily narrow. As such, some firms noted that no available alternative could achieve the exact performance of the existing SVHC option in their particular application, despite evidence from the sector of available alternatives (either noted in comments on the application or in the application itself). In some applications, firms noted that no one alternative could meet all of the functions of the SVHC chemical and hence there was a need for continued use.

Several interviewees across stakeholder groups noted that evaluating the validity of the technical feasibility assessment of alternatives in authorisation applications is particularly problematic for the Social Economic Analysis Committee (SEAC) members. As with Member State authorities, SEAC members do not have the technical expertise and background in engineering and product/process design/redesign to more thoroughly evaluate the validity of statements made in authorisation applications regarding the technical feasibility of alternatives.

Evaluating technical feasibility is complicated. In some cases, the performance (and use of the SVHC chemical) may be required by government or industrial specification (for performance or historical reasons), in which case that specification may need to be changed. In other cases, an SVHC chemical may perform well in multiple applications and a range of alternatives may be needed to achieve that performance. These challenges point to a need for greater attention to

performance considerations, including the range of alternatives (chemical and non-chemical) and performance requirements in the analysis of alternatives process.

Surveys, interviews, and our review of applications for authorisation and restrictions proposals indicate a need for greater guidance and training on technical feasibility assessment. This includes the need to have a broad scope in identifying potential alternatives that can replace not simply the chemical, but the chemical function through a chemical, process, or design modification. In addition, guidance and training is needed to narrow-in on the essential performance requirements for a specific chemical application and whether a specific level of performance is necessary.

4. The quality and consistency of analyses of alternatives could be significantly improved.

There are five primary components of an analysis of alternatives, broadly speaking: (1) scoping and screening of alternatives for the assessment, (2) technical feasibility, (3) economic feasibility, (4) hazard/exposure assessment and (5) decision approach/analysis. In addition to capacity needs related to assessing the technical feasibility of alternatives as described in detail above, our review of analysis of alternatives sections in a select number of applications for authorisation[11] and restriction proposals, comments from interviewees, as well as reviews of best practices identified in a range of alternatives assessment frameworks and tools[12] identified additional needs for improvements in the practice of analysis of alternatives (see Table 4).

As previously noted, limitations in the depth and quality of analyses of alternatives, particularly in applications for authorisation, are to be expected as the purpose of such an analysis is to demonstrate the need for continued use of an SVHC.

Scoping

The scope of the analysis of alternatives outlines the chemical use/function and applications, the range of alternatives (chemical, process, and design changes) to be considered as well as hazard endpoints and potential exposures of highest concern. The scoping stage is critical for identifying other relevant and important life cycle stages that should be considered in the analysis. The scoping stage also outlines goals and decision-rules for the analysis (such as ensure rapid degradation for a substance that might be released to water or avoidance of CMRs). The scope, like the methods section in a research study, provides a transparent means

[11] See: http://echa.europa.eu/support/socio-economic-analysis-in-reach/examples-of-sea-and-analyses-of-alternatives

[12] See: Jacobs et al. Alternatives assessment frameworks: research needs for the informed substitution of hazardous chemicals. *Environ. Health Persp*. 2015. DOI:10.1289/ehp.1409581. Available at: http://ehp.niehs.nih.gov/1409581/; Geiser K., et al. Architecture of alternatives assessment. *Risk Anal.* 2015 Dec;35(12):2152-61; National Research Council *A Framework to Guide Selection of Chemical Alternatives.* Washington DC: National Academies Press. 2014. Available at: http://www.nap.edu/catalog/18872/a-framework-to-guide-selection-of-chemical-alternatives.

to identify the approach taken in the analysis and allows for critique. Scoping becomes more complicated the broader the description of "use" and applications to be considered.

Few of the analyses of alternatives evaluated contained a thorough scoping section that provided background on the function of the substance and focus of the analysis. The majority simply provided the preliminary screened list of alternatives that were the subject of the assessment.

Technical feasibility

As noted in the previous section, primary challenges in conducting technical feasibility assessments include: achieving adequate performance of alternatives, R&D resource challenges for industry, infrastructure and staffing challenges among Member State authorities, and technical performance data availability for alternatives accessible across the supply chain and among Member State authorities. Clearly and broadly defining functional and performance needs for the substance upfront in the scoping process of the analysis of alternatives can create an opportunity to identify a broader range of options that might meet that function (including whether the function is needed or could be eliminated through redesign). A narrow framing of function and performance needs can either lead to the conclusion that there are no available feasible or safer alternatives, lead to regrettable substitutions by moving towards similar but possibly more (or only slightly less) toxic

TABLE 4. ANALYSIS OF ALTERNATIVES (AoA) – CAPACITY NEEDS REVIEW

AoA Component	Challenges and Problems Identified*
Scoping of Alternatives	– Limited range of alternatives identified based on function – Limited initial screening of unacceptable alternatives (or many excluded due to overly specific performance requirements) – Limited transparency regarding approach and decision-rules
Technical Feasibility Assessment	– R&D resources (industry challenge) – Staffing and infrastructure resources (MS authority challenge) – Technical performance information availability – The need for comparative standards and metrics – Overly prescribed technical performance requirements
Economic Feasibility Assessment**	– Lack of "total cost accounting" – cost measures typically address, capital costs, operation costs, retooling/R&D costs. Other direct and indirect costs (i.e., regulatory compliance, insurance, liabilities, etc.), should be examined – Limited cost data for alternatives available in restriction proposals
Hazard/ Exposure Assessment	– Lack of consistency in hazard endpoints addressed – Consideration of hazards for non-chemical alternatives – Need to supplement the use of GHS classifications with health effects literature reviews
Decision Approach	– No clear description of process (general approach, i.e., use of weighting) to integrate results from components of the analysis (i.e. performance, cost and risk) to make a final decision

*Identified in at least one of the AoA reviewed in restriction proposal and/or authorisation application – select number of AoAs reviewed.
**This review examined the initial economic feasibility assessment within an AoA. It did not address the subsequent socioeconomic analysis for authorisation applications.

alternatives.[13] When technical feasibility assessments are transparently provided, it also allows for those commenting on an application or proposal to provide insights on a broader range of alternatives. Some applications for authorisation and restrictions proposals, however, did identify innovative longer- term options for which targeted investment could speed time to market and adoption. Exploring a broader range of chemical and non-chemical options (including a variety of alternatives for different applications of an SVHC and those that might could serve as replacements for multiple uses) in restriction proposals and applications for authorisation – even those that may not be feasible for some time – could help prioritise research and development investments.

Economic feasibility

Economic feasibility assessments in the analyses of alternatives evaluated were limited in scope, mostly focusing on capital costs, operational costs (including the unit price of the existing chemical and alternatives) and cost impacts associated with lapses in production due to retooling/re-engineering for alternatives.

Among authorisation applications, few took into account the full costs associated with the continued use of the SVHC chemical, including permitting and handling costs, insurance and liability costs or considered the potential lower cost of alternatives as they grow in use. As noted, this is expected given the purpose of the application for authorisations. While the analysis of alternatives process does not require long-term economic benefits from investment in alternatives to be considered (which should be considered subsequently in the socio-economic analysis) a more holistic economic analysis of alternatives in the form of total cost accounting may be able to identify alternatives where support in terms of incentives, technical or research assistance, or market connections may help overcome cost barriers to adoption. Similarly, among restriction proposals reviewed, the direct short-term cost of switching to an alternative tends to be the focus of the economic assessment.

The main capacity need identified in economic assessments completed in support of restrictions proposals was also a limited inclusion of cost data. This issue was explored in interviews with Member State authorities. Interviewees described a similar information collection barrier as noted above in the earlier section on technical feasibility – economic feasibility assessments by authorities are limited to market information that is publicly available, collected by consultants or collected in prior research projects conducted by trade associations. Access to survey templates that better outline the desired cost information to collect was a recommended remedy.

Hazard/exposure evaluation

Analyses of alternatives and restriction proposals varied significantly in the evaluation of hazards. In the authorisation applications and restriction proposals reviewed, there was no consistent list

[13] Tickner J, et al. Advancing safer alternatives through functional substitution. *Environ. Sci. Technol.* 2015; 49 (2): 742–749.

of endpoints that were assessed. For example, some applications for authorisation provided only basic acute and chronic/systemic toxicity information, while others reviewed a large number of hazard endpoints recommended by a number of hazard assessment screening tools. Restrictions proposals varied similarly in the breadth of hazard end points considered and depth of data analysis. Of priority need are clearer standards and expectations on the hazard endpoints that should be evaluated in an analysis of alternatives.

The current authorisation application guidance[14] and restriction proposal guidance[15] offer broad discretion to those conducting an analysis of alternatives. Concerning applications for authorisation, the main evaluation metric offered is simply ensuring that the hazard profile of the alternative under review is not worse than the Annex XIV chemical at least for the endpoint of concern. Such a limited review is consistent with legal requirements and justified further as it may not be an effective use of resources for authorisation applicants to conduct a more comprehensive hazard and exposure assessment review on alternatives judged to be economically and technically infeasible. In addition, it is assumed that the analysis also ensures that no other hazards would similarly qualify the alternatives as SVHCs are introduced. However, a more thorough evaluation of the hazards of alternatives would be of assistance to applicants and others reviewing the merit of such applications for alternatives that will become feasible in the future due to economies of scale and advances in technological R&D.

The practice of assessing hazards in an analysis of alternatives could be improved by more clearly articulating a required set of endpoints (i.e., evidence of carcinogenicity, neurotoxicity, sensitization, endocrine disruption, aquatic toxicity, etc.) that should to be considered, documenting sources of the information that should be used to evaluate specific endpoints, and hazard assessment criteria to support comparisons among alternatives. At a minimum, thorough evaluation of hazards that could result in a chemical being designated as SVHC should be considered. Several hazard assessment frameworks and tools outline these minimum set of endpoints. This may promote a broader comparative assessment than simply the comparison of GHS hazard classifications, which may not include important endpoints of concern. Although data gaps may not permit a thorough analysis of all endpoints, one of the benefits of conducting an analysis of alternatives is making explicit what is known and not known about hazard. By highlighting data gaps, analysis of alternatives can help prevent unintended consequences associated with the adoption of product designs or the substitution of specific chemicals, materials or technological processes about which there is little information.

Nonetheless, given the lack of technical/scientific expertise in many SMEs, there is a need for actionable data to support the hazard evaluation process. In other words, such companies need accessible data and tools to be able to efficiently classify a range of hazards. While ECHA and others, such as the OECD and the US Environmental Protection Agency (US EPA) have created

[14] European Chemicals Agency. Guidance on the Preparation of an Application for Authorisation, Version 1. January2011. Available at: https://www.echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf
[15] European Chemicals Agency. Guidance for the Preparation of an Annex XV Dossier for Restrictions. June 2007. Available at: http://echa.europa.eu/documents/10162/13641/restriction_en.pdf

tools to more effectively provide chemical hazard information, it is necessary to examine their effectiveness and how these tools can be adapted to support alternatives analysis within SMEs.

Decision Approach

A final step in the analysis of alternatives is making a transparent decision about alternatives: what alternative was selected or not selected, and why. In the case of restriction proposals, authorities are not recommending one alternative over another, yet decisions are being made as a result of the analysis of alternatives, which demonstrates whether safer, feasible alternatives are available. In both restriction proposals and authorisation applications, comparative tables showing how alternatives perform against each other were often used, i.e., 1-, 2-, 3- point scales. These tables provide a useful overview of all alternatives and whether they are better, equivalent or worse than the SVHC of concern as it relates to performance, cost and hazards. Such tables can provide a transparent means to outline the decision-making process. Clarity regarding decision rules and general approaches used to generate the final decision, considering technical feasibility, economic feasibility and risk is important to convey, but was often missing.

5. Member State programs that support substitution exist but are not commonplace.

When asked, "What could ECHA do to most effectively support Member State activities to promote substitution?" the vast majority of survey respondents stated: (1) engaging with industry sectors and associated supply chains on substitution-related challenges, and (2) developing databases on alternatives and data mining tools to support using data and information submitted under REACH for identifying potential alternatives. A third theme emerged prominently in the interviews, included: (3) helping to convene and enhance greater Member State collaboration on substitution.

Enhanced supply chain engagement

The need for enhanced industry/supply chain engagement on both technical and non-technical aspects of substitution was a common theme among Member State authority survey responses and also emphasized in subsequent interviews. As one interviewee stated,

> *"Substitution needs to be seen as stakeholder collaboration rather than something that Member States push onto industry."*

Survey responses and input during interviews noted the need for more activities that convene supply chain and sector dialogues on priority substances as an important mechanism for enhancing the identification, evaluation and market adoption and growth of safer substitutes. At least three Member State authorities interviewed identified specific industrial, sector, stakeholder forums where substitution of SVHC chemicals are discussed. For example, the United Kingdom Chemical Stakeholder Forum (UK CSF) is a national forum where industry, trade unions, NGOs,

regulators and the scientific community can discuss matters relating to the use and risk management of industrial chemicals. The CSF has published a guide to substitution.[16]

Interviewees noted that these forums have been useful in enhancing dialogue and providing a good incentive for starting research on safer alternatives – particularly at the early stages when chemicals are included on candidate list or even before when they have been identified as having SVHC characteristics. Similarly, there are a number of sector-based technical research centres and initiatives that have been active in chemical substitution in a number of Member States, including footwear and textiles and the building sector. Given the technical expertise and application knowledge of these organisations, they could be more effectively engaged in substitution processes. While CBI concerns were raised as a possible barrier to such collaborations, the number of examples provided indicates that such barriers can be overcome.

Databases of information on alternatives

All Member State authority survey respondents who conduct analyses of alternatives stated that access to databases of alternatives organised by use/function would enhance their authorities' ability to identify/screen substitution options. A number of Member States have developed reports and case examples of alternatives for particular uses and sectors. However, these do not tend to be widely disseminated and are often in the Member State language only. Interviews with industry consultants noted that while having case examples of successful alternatives for similar functions/applications, such as those maintained in resources like Subsport[17] are helpful, applications/uses of SVHC chemicals that are subject to authorisation are often so specific, that no inventory of current substitution case examples can capture all uses. The Danish Environmental Protection Agency is currently funding a consultant to compile alternatives to substances on candidate/signal lists. The Swedish NGO ChemSec is currently working to establish a "marketplace" of for those seeking alternatives to identify potential providers. And private companies, like SpecialChem[18] have open source and closed access information on alternatives. The OECD Alternatives Assessment Toolkit[19] contains a compilation of many of these tools, databases, and case studies on substitution and could serve as a central repository for case examples and reports of substitution. Some authorities cautioned that developing a single substitutes database that has real utility in helping to identify alternatives will be difficult given the variety of industry processes and needs for substitutes. Databases may need to be supplemented with collaborative tools that link those that have chemical challenges with potential solutions providers.

There was general agreement among industry and Member State authority respondents that REACH has made possible an abundance of data on chemical hazards and uses. These data, particularly information on functional use and application as well as physical chemical characteristics, could be extremely valuable in for the initial identification of potential alternatives.

[16] See: https://www.gov.uk/government/groups/uk-chemicals-stakeholder-forum
[17] See: http://www.subsport.eu/
[18] See http://www.specialchem.com/
[19] See: http://www.oecdsaatoolbox.org/

Enhanced Member State collaboration

As previously noted, Member State substitution efforts and development of analyses of alternatives could be improved with enhanced inter-authority collaboration. Authorities voiced interest in the development of an informal substitution network to expand opportunities for staff to learn from and to engage with each other on common substitution problems. Such collaboration could help identify expertise in particular sectors and expertise on specific chemicals and their substitutes within Member State authorities and public and private sector institutions. This could help to avoid the need for each authority to develop such expertise. An informal substitution network could also identify and support training and education needs as well as provide an opportunity to support Member State authorities with less technical expertise (and where staff regularly transition out of agencies). Several Member State authorities interviewed indicated that informal consultations across Member States in analysis of alternatives do occur but it is not commonplace. Some models were noted as examples to learn from, such as the ECHA-coordinated Task Force on the efficiency of restrictions and the Reach Exposure Group (REEG), a network of Member State authorities and ECHA experts that discuss challenges in exposure assessment in REACH substance evaluations. Such collaboration was seen as an important vehicle to enhance the capacity of Member States that are less active on substitution 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 facility inspections.

6. Innovation research and support on safer alternatives is not routinely aligned with regulatory priorities.

When asked "who else needs to be involved" to help promote and adopt safer alternatives, survey respondents and interviewees often pointed to the need for greater research engagement and investment in safer substitutes and sustainable chemistry (also referred to as green chemistry) solutions. As noted by one industry representative respondent:

> "*As ECHA add substances to the Authorisation list, they should also coordinate and fund research activities across the EU. This is necessary, as companies need information on alternative substances to those being phased out through Annex XIV in order to continue operating in Europe. The consequences of ECHA/Commission not supporting R&D would be for companies (particularly smaller companies which cannot afford R&D departments) to move production outside of Europe and continue using substances of very high concern. This would harm the European economy without reducing the risk to people or the environment on a global level."*

There is broad agreement among those that participated in this project that substitution is challenging, innovation takes time, and the regulatory signal of authorisation is often too late for

impacted companies to undertake innovation research.[20] The Candidate list elevates those chemicals that are of priority concern and could be subject to authorisation in the future. Although some Member States have engaged in alternatives research and have provided support for innovation funding to promote development and adoption of substitutes, most have not due to the traditional risk management focus of the authorities.

Interviewees in general noted minimal connection between regulatory priorities (Candidate List, Authorisation List) and targeted, coordinated research and development, demonstration and investment activity. Nonetheless, interviewees identified a number of European Commission and Member State funding sources that could be leveraged to enhance research on safer substitutes, including analysis of alternatives methods. At the EU level these sources include the COSME and Life Programme grants and those under the Horizon 2020 program as well as funding through the European Investment Bank. Additionally, many Member States have innovation programs and funds that support new technology development (public-private funding streams), some directly connected to environment ministries. At the European Commission level, while there is some alignment between the Horizon 2020 research program and programs of other Directorate Generals, such as the 7th Environmental Action Programme, this does not seem to have happened in the area of sustainable chemistry. Authorities such as DG Research and the European Investment Bank have dedicated significant research, development, and application resources into projects that support the Circular Economy. These specifically focus on biomass feedstock extraction (with climate change being a key driver) and bio-based replacements for petroleum-based chemistries. However, there appears to be less coordinated and funded research activity on sustainable chemistry, despite the opportunity for some bio-based chemicals to be used as substitutes for SVHCs in some applications. It is important that existing European wide research and engagement programs on sustainable chemistry, such as SusChem,[21] be engaged in supporting efforts on substitution, even if they have not specifically focused on substitution to date.

At the Member State level, several Member States have innovation research funds that have supported substitution research on priority chemicals in specific uses. For example, the Danish EPA supports *Kemi Kredsløb*[22] a partnership that funds Danish enterprise development activities aimed at reducing chemicals that are hazardous to humans and the environment. DKK 5.75 million is available (2015-2018) to finance enterprise projects. Danish EPA also has an Eco-innovation funding programme,[23] which has been leveraged to support substitution research by

[20] It should be noted that ECHA is working on increasing transparency and predictability of actions on substances of potential concern by gathering all information on these substances in one place (e.g. PACT, RMOA, CoRAP). See https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern.
[21] See: http://www.suschem.org/
[22] See: *http://eng.kemiikredsloeb.com/til-virksomheder/*
[23] See: http://eng.ecoinnovation.dk/the-danish-eco-innovation-program/ecoinnovation-subsidy-scheme/
Environmental technologies are defined as: "Any technology, that either directly or indirectly improves the environment. It includes technologies for limiting pollution with the held of cleaning, more environmentally friendly products and production processes, more efficient energy and resource management as well as technological systems that reduce the environmental impact."

private and public companies and institutions in the context of the development of environmental technologies. However, the research developed has suffered from limited dissemination and demonstration of alternatives. In Germany, several Ministries are involved in an Environmental Innovation Programme, which provides investment grants or grants to cover interest on loans to support the development of technologies that can be replicated to reduce and prevent harm to the environment.[24] In addition to government-initiated institutes, there are also a number of university and non-profit based research institutes funded by government agencies and industry. For example, the Wageningen University Institute on Food and Biobased Research (WUR FBR) has undertaken research on process technology that supports a better understanding of the functionality, application, and performance needs for substances of concern and alternatives. Survey respondents noted that networks of private and public sector institutions with similar capacities would be very valuable too for substitution efforts.

Additionally, some Member States noted that procurement programs are an important route to link regulatory safer alternatives priorities and authority decisions with programmatic actions. These Member States have engaged in discussion with public procurement agencies to accelerate substitution through purchasing policies though such a link between regulatory priorities and purchasing as a vehicle to drive innovation and adoption of safer substitutes is not commonplace. Often times, purchasers rely on ecolabels to make sustainable purchasing decisions. At the European Union level, the EU Eco-label criteria include avoidance of specific chemicals (and classes of chemicals) of concern for specific product categories.[25] However, it appears that there is little focus on how alternatives to these restricted substances are evaluated.

Recommendations – opportunities for enhancing substitution practice

Below, we present a number of recommendations to enhance ECHA, EU and Member State capacity to support to the identification, evaluation, and adoption of safer substitutes. These recommendations – technical, policy, and administrative – are categorized by infrastructure needs, collaboration/engagement needs, and technical needs. In general, recommendations span more than one of these three areas of needs for capacity. In other words, stakeholder and supply chain engagement requires infrastructure in authorities as does augmenting technical skills. Many of these recommendations refer to actions to be carried out by industry but initiated and facilitated by government authorities. In some cases, it will be important to develop pilots and case examples to demonstrate how these recommendations could be carried out at a larger scale.

These recommendations are focused primarily on implementation of REACH. However, ECHA's evaluation of alternatives/substitution is also part of the Biocidal Products Regulation (for which ECHA plays an assessment role), and many other directives, for example on Toys, Cosmetics, and occupational exposures to hazardous agents, contain substitution provisions. Many of the processes envisioned in these recommendations could clearly support substitution activities under legislation implemented by other agencies, strengthening collaboration and coordination.

[24] See: http://www.umweltinnovationsprogramm.de/englisch
[25] See: http://ec.europa.eu/environment/ecolabel/products-groups-and-criteria.html

Further, these recommendations would strengthen the role of authorities in supporting the marketplace for sustainable chemistry. Where relevant, lessons learned from the US related to specific recommendations are included to help illuminate case-examples of successful programmes, policies and practices that are encouraging a transition to safer chemicals.

Building infrastructure to support substitution

1. ***Significantly grow ECHA and Member State authority staff capacity over time to support substitution through training as well as recruitment.***

The survey and interviews conducted indicated only a limited number of staff at the Commission or Member State levels involved in substitution activities and of those, few with specific industry experience. There are two fundamental capacity concerns that need to be addressed: (1) the lack of staff whose jobs involve supporting the evaluation and adoption of safer substitutes; and (2) the lack of staff with some technical expertise or training to be able to conduct or critically evaluate analyses of alternatives.

It may be possible to engage risk assessment staff (which agencies tend to have) in analysis of alternatives/substitution activities. However, a first step could be for ECHA (currently with limited staff resources dedicated to substitution) and other Member States undertaking initiatives in chemical substitution to hire new staff, or at least reassign existing staff, with experience in industrial manufacturing, engineering, and product design to deepen expertise around technical feasibility. Staff resources could be supplemented with consultants and other experts who can support authority activities. For example, a significant portion of the toxicological evaluations conducted under the US EPA alternatives assessment and Safer Choice programs are conducted by external "direct support contractors" with expertise in such evaluations.[26] While the current economic climate in the EU may not support such options in the near term – a theme that was strongly expressed in survey responses among Member State authorities – it may be possible for Member State authorities as well as ECHA to shift staff to support substitution specific activities. Within ECHA, such shifts would assist the agency in developing restriction proposals as well as supporting the Committees in evaluating authorisation applications and restriction proposals. It could also support the facilitation of inter-authority and supply chain collaboration.

2. ***Coordinate EU and Member state grant-mechanisms and private/public partnership funds to invest in innovation research to support alternatives development and diffusion for priority hazardous chemicals of concern.***

[26] For example, SRC Inc., has conducted numerous alternatives assessments for EPA's Safer Choice program (formerly EPA's Design for the Environment program) under direct contract with the Agency; see: http://www.srcinc.com/about/

Government can play an important role in supporting innovation. Time is needed for innovation development, adoption, and diffusion to support a transition to safer chemicals. It is important that early signals be provided to the marketplace on substances of potential concern to initiate innovation activities. The Candidate List - and even earlier warnings on substances of potential concern - provides a prioritisation signal to target R&D on the development of safer alternative chemicals and technologies for SVHCs. Developing alternatives once a chemical is on the authorisation list however is often too late for enterprises to start innovation research without being provided an authorisation.

One way for ECHA (and the European Commission) and Member State authorities to enhance substitution of priority hazardous chemicals is to directly support innovation research via grant programs, and/or to collaborate with or coordinate other institutions that provide funding for research and development as well as innovation in Member States and the EU.

TABLE 5: EXAMPLES OF EXISTING R&D INNOVATION FUNDING SOURCES*

EU-Level
- COSME - DG Environment (via 7th Environmental Action - Programme) - DG Research (via Circular Economy R&D) - European Institute on Innovation and Technology - European Investment Bank, "InnovFin – EU Finance for Innovators" and Circular Economy funding support - Horizon 2020 program - Life Programme grants
Member State Level
- Bertelsmann Stiftung (Germany) - Eco-Innovation (Sweden) - Environmental Innovation Programme (Germany) - Kemi Kredsløb (Sweden) - Mistra (Sweden) - Nesta (UK) - Sitra (Finland) - Tekes (Finland) - Vinnova (Sweden)

*Not comprehensive. Provided as examples that could be possibly leveraged to support R&D on safer alternatives as tied to SVHC/regulatory priorities.

In addition to innovation research funds described by interviewees that could be broadened to include research on sustainable chemistry and green engineering, there are numerous additional funding agencies that support innovation research at both the EU and Member State level (Table 5). For example, the European Institute on Innovation and Technology is one of several EU innovation funds.[27] The European Investment Bank's "InnovFin – EU Finance for Innovators" is another.[28] Sitra and Tekes in Finland, Mistra and Vinnova in Sweden, Nesta in the UK and Bertelsmann Stiftung in Germany are examples of innovation funding institutes in Member States that support national technology research efforts as well as innovation networks, including "challenge events" that bring together innovators around a specific technology challenge/need. In 2016, ECHA initiated contact with two innovation funding organisations (Sitra and Tekes) and trade associations to develop a pilot related to alternatives to hexavalent chromium in plating operations. It is important that such pilot projects: (a) involve the convening supply chain actors (particularly SMEs) and other companies providing alternatives to facilitate opportunities for private enterprises to connect and discuss problems (e.g., specific uses/applications still dependent on SVHCs) and possible solutions; and (b) support networking and innovation funding opportunities for enterprises that are committed to a transition to alternative (safer) technologies.

[27] See: https://eit.europa.eu/
[28] See: http://www.eib.org/products/blending/innovfin/

Existing EC programmes could be further leveraged to help sustainble chemicals and technological innovations reach the market place. For example, the Environmental Technology Verification (ETV) is one such programme and tool that provides critical third party verifications regarding claims about performance for new innovative environmental technologies.[29] Additional capacity could be sought within ETV to enhance peformance testing verification for safer alternatives that are emerging for specific applications/uses of SVHCs.

In the US, the Massachusetts Toxics Use Reduction Institute (TURI) has supported several programmes that can serve as models of targeted research funding and convening of researchers and industry to support substitution efforts (See box 1). Technology innovation events such as Slush can further serve as an inspiration and model for the stimulating exchanges and innovations that can be made possible.[30] The value of and need for ECHA and Member State authorities to facilitate these types of research and innovation collaborations around safer substitutes cannot be overstated. Such efforts need to be supplemented with facilitated supply chain partnerships to enhance the adoption of substitutes through demonstration and joint performance evaluation.

BOX 1. Applicable Models from the United States: Sustainable Chemistry and Green Engineering Innovation Research Programmes

The Massachusetts Toxics Use Reduction Institute's industry research programme provides an example of how small research grants to academic researchers with built-in company partnerships has significant return on investment. The research programme hosts technical forums to better connect the research needs of industry associated with problematic hazardous chemicals with the research capacity in academia and other research institutions. For example, the Institute has funded research on alternatives to nonylphenol ethoxylates, bisphenol-A, methylene chloride and numerous other solvents, and brominated flame retardants. It hosts a bi-annual "greener materials research symposium" where academic researchers and industry partners discuss development options for safer alternatives to toxic chemicals of priority concern. The Institute provides small grants to help manufacturers implement processes changes that facilitate the minimization or elimination of priority toxic chemicals. Lastly, the Institute provides grants for small business, including dry cleaning operations, to transition from solvent based processes to water based processes. Results of these research initiatives are widely distributed and networking between firms is encouraged.

Source: see http://www.turi.org/research

3. Build technical assistance structures for companies, in particular small and medium sized enterprises (SMEs), for evaluation and adoption of substitutes.

While all companies have specific substitution adoption challenges, small and medium sized enterprises (defined as ≤250 employees and ≤€50 million in turnover) frequently lack the technical expertise to evaluate or adopt safer substitutes. In such firms, individuals often have multiple positions and may not have specific expertise to evaluate substitutes, potentially leading to regrettable substitutions. Enhancing capacity to support chemical substitution practice, particularly among SMEs, requires building technical support mechanisms. It also requires education and often cultural change within an organisation or supply chain. ECHA and Member

[29] See: http://ec.europa.eu/environment/etv/
[30] See: http://www.slush.org

State authorities can play important role in helping to facilitate structures for technical support and non-technical awareness raising in firms regarding substitution.

Several countries have specific "innovation centres" that work with SMEs and the European Commission has established the European Enterprise Network Partnership Opportunities Database to connect and coordinate resources that could support SMEs. Trade associations and associated research institutes can also be engaged to provide technical support to SMEs. For example in Spain, CTCR (the Footwear Technology Centre of La Rioja) and AITEX (Textile Industry Research Association) provide research and development services that directly support the environmental and occupational health needs of the footwear and textile industries respectively.[31] While these organisations have received EU support for various projects, future priorities could be guided and supported by ECHA, other EU authorities and national efforts to enhance substitution research efforts within specific industry sectors. In the US, there are two noteworthy technical assistance models including Manufacturing Extension Partnerships (MEPs) coordinated by the federal National Institute for Standards and Technology (US NIST), as well as the Massachusetts Office of Technical Assistance and other pollution prevention technical assistance agencies at the state level (see Box 2).

BOX 2. Applicable Models from the United States: Supporting SME technical chemical substitution needs

In the United States, two specific models for technical support to SME's exist. Manufacturing Extension Partnerships (MEPs), coordinated by the National Institute for Standards and Technology (part of the Department of Commerce), provide services, training, networking assistance and technical support to SMEs at the state level.[i] Under the Massachusetts Toxics Use Reduction Program, the state Office of Technology and Technical Assistance offers free, voluntary and confidential technical assistance to firms examining options for toxics reduction, including the implementation of safer substitutes. The Massachusetts Toxics Use Reduction Institute provides technical evaluation for the efficacy and toxicity of safer solvents and surface cleaners, reducing the technological risk associated with transitioning to safer alternatives.[ii] These technical support mechanisms have played a critical role in building capacity in firms but also in decisions to substitute.

Sources:
[i] See: http://nist.gov/mep/
[il] See: http://www.turi.org/Our_Work/Research/Alternatives_Assessment

4. *Expand government "green" procurement programs to include chemical substitution in addition to addressing other important sustainability issues*.

As large purchasers, governments can lead by example and drive the marketplace for safer chemistries. Education of institutional purchasers in public and private sector organisations was identified as an important strategy to encourage substitution by interviewees and survey respondents. Significant efforts have been undertaken in both the EU (and Member States) and US to strengthen procurement policies, ecolabels and other sustainability standards (for example,

[31] See AITEX - http://www.aitex.es/en/; CTCR - http://www.ctcr.es/en/

for electronic products) to better address toxicity considerations in purchasing decisions.[32] These efforts include clear obligations to substitute SVHC chemicals and to evaluate safer alternatives could support market actors to develop and assess alternatives.

Purchasers often rely on ecolabels to make sustainable purchasing decisions, given their lack of expertise in evaluating products. However, the main focus of many ecolabels is on resource efficiency and greenhouse gas reduction, not on toxicity. Nonetheless, as noted previously, many formulated consumer product ecolabels contain some restriction on chemicals of concern. One ecolabel specifically focused on safer chemistry is the US EPA's Safer Choice program, which recognizes formulated products with safer chemicals for specific functional uses products based on stringent human health and environmental health criteria (see Box 3).

BOX 3. Applicable Models from the United States: Integrating Toxicity into Purchasing Decisions in the US EPA's Safer Choice Program

The US EPA Safer Choice program provides a model for integrating consideration of toxicity into purchasing decisions. EPA has developed a set of toxicological criteria for functional classes of ingredients used in different formulated product categories. Those that are third party verified to meet the criteria for safer ingredients are placed on the EPA's Safer Chemical Ingredient List from which formulators can choose ingredients based on functional information. Products that contain the safest chemistries for their function can obtain an EPA Safer Choice label.

Source: See https://www.epa.gov/saferchoice

Potential Next Steps

Immediate next steps to advance these structural capacity building recommendations could include:

- Establish a dedicated group or team of staff members to support chemical substitution within ECHA with capacity in chemical hazard evaluation, chemistry, technical assessment, and economic analysis to coordinate, facilitate, and support the activities identified in these recommendations.
- Undertake a landscape analysis of research and innovation funding agencies at the EU and Member State levels that could be engaged in supporting chemical substitution and sustainable chemistry research and innovation. Based on that analysis, host a meeting of representatives of these institutions and Member State authorities to discuss opportunities to collaborate in supporting substitution activities.
- Establish 1-2 pilot projects that engage authorities with funding agencies in spearheading supply chain collaboration to identify, develop and evaluate alternatives to specific SVHC chemicals in targeted applications.

[32] See for example: https://www.epa.gov/sites/production/files/2015-09/documents/uml-rpt_greenpurchasing_7_15_14-2_0.pdf

- Undertake an analysis of technical support capacities for SMEs at the EU and Member State level (including trade associations) that be engaged in supporting chemical substitution activities.
- In conjunction with institutional purchasers, explore development of a "safer chemical ingredient" listing program utilising REACH data (below) and third party certification to identify safer alternatives for different functional classes of chemicals.

Increase engagement/collaboration around substitution

1. ***Create mechanisms for enhanced Commission and Member State collaboration/coordination on substitution, including support for smaller Member State authorities.***

Collaboration among government agencies is a critical element in achieving the goal of promoting the transition to safer alternatives. Effective collaborations can help: avoid redundancies in efforts and appropriately share responsibility when targeting the same issues and chemicals of concern; provide knowledge growth opportunities on substitution-related issue among Member States with minimal staffing capacity; and reduce the potential for regrettable substitution by addressing broader impacts that are often outside a single authority's area of focus. The creation of an inter-authority substitution network is an important first step. Such a network could be modeled after existing committees established under REACH.

One model to explore is the US Interstate Chemicals Clearinghouse (IC2), which fosters coordination and capacity development among government agencies regarding chemicals policy and substitution practice (see Box 4). While IC2 focuses on supporting agencies' work on alternatives assessment, much of the work to date has focused primarily on guidance on how to conduct assessments and hazard evaluation, not particularly on technical feasibility or economic assessment issues.

ECHA and other Member State authorities should continue to support and participate in the work of the OECD Ad Hoc Group on Substitution of Harmful Chemicals. Although this working group is not limited to government agency participation it is an important network that is enhancing the development of tools and resources to support substitution practice.[33]

[33] See: http://www.oecd.org/env/ehs/risk-management/substitution-of-hazardous-chemicals.htm

BOX 4. Applicable Models from the United States: ***Enhancing interagency collaborations - the Interstate Chemicals Clearinghouse and the Interagency Alternatives Assessment Working Group***

The Interstate Chemicals Clearinghouse (IC2) is an association of state, local, and tribal governments that promotes the development and use of safer chemicals and products. The group functions to support and build capacity among health and environmental government agencies in the development of analysis of alternatives methods through guidance development and trainings, and developing platforms for data sharing on hazard and exposure information of alternatives, among other functions. The IC2 is staffed and coordinated through the Northeast Waste Management Officials' Association (NEWMOA).

Source: See http://www.theic2.org/

2. Create or expand mechanisms for greater supply chain collaboration and engagement, including shared performance testing and evaluation, and demonstration sites.

There is an opportunity to advance substitution efforts by greatly expanding direct work with individual companies, industry sectoral organisations and other public and private research institutions to engage supply chain dialogue with regards to substitutes for chemicals that are subject to restrictions or authorisation requirements. Supply chain engagement provides an opportunity to leverage market forces to accelerate substitution activities and can recognize leaders in specific sectors.

For example, when a chemical is placed on the candidate list, ECHA and other Member State authorities could identify priority functions/uses and convene supply chain actors to initiate dialogue aimed at identifying or developing safer substitutes. Several Member State authorities offered useful examples of successful industry collaborations and engagement efforts that have advanced sector-wide discussions about safer alternatives, such as Norway's work with the building and textile sectors.

In addition, there are two important mechanisms used by TURI to engage supply chains in supporting the evaluation and adoption of safer substitutes: demonstration projects and supply chain research consortia. Demonstration sites provide an opportunity for leaders to share experiences and challenges with other firms, outlining how they have implemented substitutes for a particular chemical of concern. TURI has successfully undertaken a number of such demonstration projects in the plating, printing, and electronics industries.[34] TURI has also coordinated two supply chain research consortia on alternatives to hexavalent chromium coatings in the aerospace industry and lead alternatives in the electronic industry. Based on their experiences with these collaborations, the Institute compiled a list of factors that enhance the likelihood of effective supply chain collaboration and engagement (Table 6).[35] The key to effective

[34] See: http://www.turi.org/Our_Work/Business/Industry_Sectors

[35] The workshops that Eurometaux and Cefic organised, in collaboration with ECHA, on the application for authorisation of chromium compounds in 2012-14 can be seen as the beginning of such activities. See http://www.reach-metals.eu/index.php?option=com_content&task=view&id=202&Itemid=308

collaborations is a clear market or regulatory driver, as well as pre-competitive engagement of partners that share the same need and problem regarding a chemical of concern and have a willingness to share resources whether it be in-kind staff time or testing facilities. For example, the lead in electronics collaborative successfully identified safer alternatives the met required performance specifications developed by the collaborative.

TABLE 6. SUCCESS FACTORS FROM COLLABORATIVE SUPPLY CHAIN PROJECTS – THE MASSACHUSETTS TOXICS USE REDUCTION INSTITUTE EXPERIENCE
1. Use of a toxic chemical(s) of concern is pervasive in an industry sector
2. Toxic chemical is not used for competitive advantage (in other words, no particular companies gains individually by employing a safer substitute)
3. Strong market and/or regulatory drivers to reduce the use of the toxic chemical
4. Significant research required to switch to the use of safer alternatives
5. Time and cost intensive for companies to individually conduct research
6. Independent third party available to manage and coordinate the effort
7. Voluntary participation by government, academic, and industry collaborators
8. Participants provide either in-kind contributions (production equipment, technical expertise, materials, supplies, testing, etc.) or direct funding
9. Intent of participants is to adopt the safer alternative solutions identified
10. All results made public so that other companies can adopt solutions identified
Source: http://www.turi.org/content/download/8335/140853/file/TURI%20Aerospace%20Defense%20Supply%20Chain-%20Morose.pdf

Innovation institutions, identified earlier, could also play a critical role in supporting supply chain networking and engagement to support safer alternatives development and evaluation. These funding institutions provide a critical financial incentive for supply chains to connect and collaborate on research needs and opportunities. Other models for convening supply chain actors to identify safer substitutes include ECHA's partner's service for applicants for authorisation,[36] ChemSec's proposed "marketplace" for safer alternatives where solutions providers can link with companies that have technical challenges related to substitutes, and the substitution partnering network through the European Enterprise Network to be established through DG Grow's current tender. In these cases, solutions providers may be academics, small start-ups or larger established firms (including those manufacturing the SVHC). Such collaborations need to be focused on a particular sector/chemical function to be successful.

It is important to explore how existing REACH mechanisms to support information exchange within supply chains could be leveraged to enhance substitution actions. The Exchange Network on Exposure Scenarios (ENES) and the Chemical Safety Report/Exposure Scenario Roadmap (CSR/ES Roadmap) are two such mechanisms. ENES, an established supply chain collaborative network and the CSR/ES Roadmap, a multi-sectorial initiative, are both focused on the use of exposure scenario information submitted by importers and manufacturers to enhance best communication practices throughout the supply chain regarding the conditions of safe use and associated risk management practices. While actions to enhance substitution practices have not

[36] See: http://echa.europa.eu/web/guest/applying-for-authorisation/partners-service-for-applicants

been addressed in the current Roadmap and are not a focus of discussion within the ENES, these existing structures could be leveraged in the future to support such actions.[37]

3. ***Develop networks of experts – academics, consultants, and government research institutes – to support authorities and industry in both assessment and adoption of substitutes preferably using already existing networks.***

Analysis of alternatives and substitution are relatively new fields. While there is extensive technical knowledge available in industry on chemical processes, there may be less (particularly in SMEs) on technical options for substitution, including expertise for conducting analyses of alternatives. To build a stronger community of practitioners and reliable expertise available to ECHA, Member States, and industry in analysis of alternatives and substitution, it would be useful to create a network of experts. Similar professional and practice networks exist, for example in the field of risk assessment and high throughput toxicological testing. One potential existing network that could be used for this purpose is the Network of Reach SEA and Analysis of Alternatives Practitioners (NeRSAP), a multi-stakeholder group working on improving socioeconomic impact assessment.[38] Another model is the European network for clean process technologies.[39] In the US, a group of academic, industry, government, and non-profit experts have been engaged in efforts to establish a "community of practice" for alternatives assessment, to create a more coordinated field of alternatives assessment.[40] While the group has been successful in raising awareness of alternatives assessment, identifying research and practice needs, and convening a growing, multidisciplinary group of experts, its impact has been limited by a lack of more formal structures and sufficient, sustained funding. There have been several meetings and/or dedicated alternatives assessment sessions in professional meetings (e.g., the Society of Environmental Toxicology and Chemistry (SETAC)) where the community has gathered to discuss methodological issues and advances, case studies, and research needs. As with any growing field, the current challenge to supporting this work is resources to support the necessary coordination and growing infrastructure needs.

Potential Next Steps

Immediate next steps to advance these engagement capacity development recommendations include:

- Establish an Inter-authority analysis of alternatives and chemical substitution committee that meets on a regular basis to discuss challenges to substitution, share lessons, open doors to collaboration, and identify concrete projects that could be undertaken across Member States.

[37] See: https://echa.europa.eu/regulations/reach/registration/information-requirements/chemical-safety-report/csr-es-roadmap
[38] See: https://echa.europa.eu/support/socio-economic-analysis-in-reach/network-of-reach-sea-and-analysis-of-alternatives-practitioners
[39] See: http://ec.europa.eu/environment/etv/
[40] See: www.saferalternatives.org

- Undertake an evaluation of existing supply chain partnership and collaboration models at the EU and Member State levels (both public and private sector) and mechanisms to enhance supply chain communication around substitution. Based on this, undertake 1-2 model supply chain partnerships or demonstration projects at the EU level or in conjunction with a Member State authority to demonstrate the viability of such partnerships in accelerating safer chemistry.
- Create an on-line network of experts in analysis of alternatives and chemical substitution that outlines specific expertise and interests so that authorities, industry, and others can connect needs with expertise.

Enhance technical capacity to support analysis of alternatives and substitution

1. ***Develop more detailed guidance or guidelines, instructions or other suitable material for authorities and industry to complete analyses of alternatives in applications for authorisations and restrictions proposals outlining minimum components and quality criteria.***

There is a need to develop minimum standards to aid the development of more consistent, high quality restrictions proposals, applications for authorisation, and review procedures. While a core principle of the field of alternatives assessment is the need for flexibility in the analysis given differing contexts,[41] minimum standards incorporated into practical guides and reporting formats (such as the joint reporting format for Socio-Economic Assessments and Analyses of Alternatives)[42] would enhance the quality, utility and comparability of the analyses. While ECHA has developed specific guidance for completing a restrictions proposal and application for authorisation, it is not clear if the existing guidance is too complex, not sufficiently specific or written in a style that does not facilitate its use. A discussion with users of the guidance is warranted to understand how more detailed educational and instructions could enhance the quality of assessments.

The areas where specific enhancements in analyses of alternative would be most helpful are in scoping, including alternatives identification and hazard assessment. In the context of scoping, more particular steps for identifying a range of chemical, process and design alternatives to meet a specific function (including consideration of the need for and performance needs for the function) would expand the range of alternatives to be considered and create additional opportunities for external reviewers and stakeholders to provide meaningful comments on possible alternatives. In the context of restrictions proposals, ECHA or Member States, in addition to convening supply chain groups, could develop alternatives identification survey templates to gather background information from industry on possible alternatives for specific functions. These surveys would collect necessary and relevant information from industry to inform the analysis of alternatives process.

[41] Geiser K., et al. Architecture of alternatives assessment. Risk Anal. 2015 Dec;35(12):2152-61.
[42] See: https://echa.europa.eu/applying-for-authorisation/preparing-applications-for-authorisation

With regards to hazard assessment, several entities in the US have adopted more rigorous hazard assessment approaches that could inform minimum standards for an analysis of alternatives that could be folded into future reporting formats, practical guides and training opportunities for industry, Member State Authorities and RAC members (see Box 5). A recent review of alternatives assessment frameworks provides a starting-point for examining the current state of practice of the hazard assessment element of an analysis of alternatives to help guide standards development. [43]

BOX 5. Applicable Models from the United States: *Hazard Assessment Approaches*

Several rigorous and comprehensive hazard assessment models have been development by US agencies and NGOs. The US Environmental Protection Program's Safer Choice Program (previously the Design for Environment Program) alternatives assessment guidance outlines ~13 human health and environmental hazard endpoints and criteria to support a relative ranking scheme that supports comparisons.[i] The GreenScreen for Safer Chemicals similarly outlines 19 hazard endpoints in its approach.[ii] The Washington State Department of Ecology offers a more streamlined approach in its Quick Chemical Assessment Tool that outlines 9 endpoints that should be reviewed in comparing alternatives.[iii] GreenScreen is now widely used by industry across sectors and is integrated into numerous sustainability standards to guide the selection of safer chemicals.

Sources:
[i] See: https://www.epa.gov/sites/production/files/2014-01/documents/aa_criteria_v2.pdf
[ii] See: http://www.greenscreenchemicals.org/
[iii] See: http://www.ecy.wa.gov/greenchemistry/QCAT.html

2. *Provide enhanced analysis of alternatives support and capacity building to ECHA, including SEAC and RAC, Member State authorities, and industry/consultants to improve quality and enhance consistency.*

As noted above, enhancing the quality and consistency of analyses of alternatives plays an important role in the development, evaluation, and adoption of safer substitutes. However, while clearer guidelines and templates are a pre-requisite for improved quality, foundational knowledge and training for those completing analyses of alternatives are also critical, particularly where internal capacity and resources in an agency are insufficient to conduct detailed review of every analysis. Capacity building and continued professional development are needed for those conducting analyses of alternatives as well as for those who are reviewing such analyses, undertaking research on alternatives or supporting industry efforts, and implementing or enforcing substitution policies. To build capacity and ensure quality in the conduct of analyses of alternatives, under the Massachusetts Toxics Use Reduction Act,[44] 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 (see Box 6).[45]

[43] See: Jacobs et al. Alternatives assessment frameworks: research needs for the informed substitution of hazardous chemicals. *Environ. Health Persp*. 2015. DOI:10.1289/ehp.1409581. Available at: http://ehp.niehs.nih.gov/1409581/
[44] See: http://www.mass.gov/eea/agencies/massdep/toxics/tur/
[45] See: http://www.mass.gov/eea/agencies/massdep/toxics/tur/toxics-use-reduction-tur-planners.html; and http://www.turi.org/Our_Work/Education_and_Training/Continuing_Education

While those completing analyses of alternatives need more extensive training, those reviewing such analyses or chosen options, such as, members of RAC and SEAC, most ECHA staff, Member State REACH Competent Authorities, or enforcement staff in Member States need at least a basic understanding of the processes of analysis and adoption alternatives, including what critical evaluation questions to ask. Beyond training opportunities, capacity building for government authorities also requires the development of educational materials and establishment of inter-authority support networks, as previously noted.

Similarly, many companies, particularly SME's and those that do not have their own manufacturing operations, such as brands and retailers, may not have the capacity to undertake their own analyses of alternatives but need information on the substitution approach. Trade associations that support members may not need extensive analysis of alternatives expertise but rather know how to identify resources. Such knowledge needs could be achieved through short training courses or webinars, in addition to accessible databases and expert networks. To achieve the greatest impact in reaching the most people, train-the-trainer type curricula could be developed.

Member States could effectively engage institutions of higher education to develop both university and professional education courses that train chemists, engineers, and health scientists in the fields of analysis of alternatives, substitution and sustainable chemistry. Most chemists and engineers are not educated about chemical hazards, how to evaluate them, or how to think about the connection between function, chemical design and selection and toxicity. Specific training programs in substitution/analysis of alternatives, combined with broader education in sustainable chemistry, could significantly enhance industry and authority capacity to support substitution.

BOX 6. Applicable Models from the United States: *Certified Assessors under the Massachusetts Toxics Use Reduction Act Program*

Toxics Use Reduction Planners in Massachusetts must undergo a 40-hour training course, pass a written exam and undertake continuing education credits. About half of those planners are from reporting companies and half are consultants. The "certified planner" requirement has significantly enhanced the quality of plans submitted and increased creativity in looking for solutions, reduced the necessity for authority review of every plan, and has led to the creation of a network of practitioners who can share knowledge and support each other's goals. In Europe, such a course could be provided by an existing government-sponsored training institute or third party standards organisation. In addition to the Toxics Use Reduction Planners Course, the Massachusetts Toxics Use Reduction Institute hosts twice yearly Continuing Education Conferences, where planners, authorities and others can learn about current toxics use reduction challenges, policy updates, and learn from case examples.

Source:
See: http://www.mass.gov/eea/agencies/massdep/toxics/tur/toxics-use-reduction-tur-planners.html

3. 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 documents relating to substitution.

Substitution processes have been hindered to date by lack of data on chemical hazards and uses. The Registration process of REACH (including Chemical Safety Reports) will generate significant knowledge on chemical uses, functions, and toxicity that could be used to support identification, evaluation, and development of safer chemistries for particular functional uses. If compiled into a database of actionable information for alternatives assessment and identification of safer substitutes (by chemical function, class, sector, etc., this information could prove very useful to downstream users and designers in selecting chemicals for various applications. Significant resources have been invested in making REACH data for chemicals accessible;[46] however, a review of how this data can be more effectively used to identify and evaluate alternatives will be useful. Use of approaches such as the EPA Safer Chemical Ingredient List process may provide important information to the marketplace on safer alternatives for specific chemical functions. Such a "positive listing" process could help downstream users identify a range of possible existing options for substitution given chemical function, properties, etc.

While it does not make sense to create a new database of chemical substitution case studies, as several exist already, ECHA could help facilitate transfer results of analyses of alternatives and examples of successful substitution from Member States to either the OECD or Subsport databases to support more centralized information availability.

Potential Next Steps

Immediate next steps to advance these technical capacity development recommendations include:

- Evaluate the feasibility of establishing a certified analysis of alternatives practitioner program.
- Develop "train-the-trainer" and on-line curricula on analysis of alternatives and substitution.
- Develop detailed analysis of alternatives practical guides, reporting formats, and survey templates to enhance detail and quality of analyses of alternatives.
- Explore development of a database to compile REACH Registration information by chemical function, properties, including a summary of hazard and exposure data for different endpoints to facilitate analysis of alternatives.

Conclusion

There are many challenges but significant opportunities to accelerate the identification, evaluation and adoption of safer substitutes in the EU. REACH and other policies, coupled with market forces have provided important market drivers for avoidance of SVHCs. Thoughtful analysis of alternatives processes, combined with structures to support supply chain collaboration as well as research, innovation, and technical support can enhance the probability that successful

[46] See: http://echa.europa.eu/information-on-chemicals

substitution will occur. Our analysis found 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. ECHA can specifically support substitution moving forward in two distinct ways: improving its own capacity as well as that of Member States and industry for conducting analyses of alternatives; and providing mechanisms (including facilitating connections and serving as a hub for best practices) to support substitution activities. In other words, ECHA can use its regulatory powers to strengthen implementation of the REACH goal of substitution of SVHCs. It can also use its discretionary powers to facilitate and encourage early marketplace actions to identify, develop, and adopt safer substitutes (even before regulation).

ANNEX A: Member State Competent Authority Survey Results

The survey results displayed below reflect those questions informing this report. Additional survey questions developed to support DG Environment's sub-study on substitution associated with "the strategy for a non-toxic environment of the 7th Environment Action Programme (EAP)," will be published at a later time. Comments for some questions have been abbreviated in order to protect the confidentiality of respondents and to streamline the display of results. Frequencies were not calculated for specific open-ended comments but were categorized into high-level themes where appropriate.

Q1. How many Full Time Equivalent(s) (FTEs) in your organisation work on chemical substitution initiatives (legislative and/or non-legislative)?	
	Response (N=16)
0-1	50%
1-2	13%
3-5	25%
6-8	0%
9-12	0%
More than 12	13%

Q2. Considering these staff (response directly above), what are their areas of expertise in support of hazardous chemical substitution efforts (check all that apply)?	
	Response (N=15)
Agronomy	13%
Biology*	47%
Chemistry	80%
Economics	40%
Engineering	33%
Environmental Science	47%
Legal	40%
Life-cycle Assessment	40%
Toxicology*	60%
** Including: ecotoxicology and exposure assessment*	

Q3. In your organisation's opinion, what are the main drivers of the substitution of hazardous chemicals (check all that apply)?	
	Response (N=16)
REACH regulations	94%
Health and safety regulations[1]	63%
Product safety regulations[2]	50%
Supply chain request	56%
Consumer's concerns	50%
Worker's concerns	50%
NGO black-listing (e.g. substance included in SIN list)	44%
Economic considerations	38%
Corporate social responsibility policy	25%
Other regulations[3]	38%
Other drivers[4]	38%
[1]*Specific health and safety regulations noted in comments include: OSH directives (CMD - 2004/37/CE and CAD 98/24/EC) and binding OELs, Stockholm convention, national legislation including: article R. 4114-66 of the French Labour code, Internal Control regulations*	
[2]*Specific product safety regulations noted in comments include: RoHS, Toys Directive, Cosmetics, PPP, BPR, WEEE, and national legislation (French prohibition of BPA in food contact materials and the Norwegian Product Control Act))*	
[3]*Other regulatory requirements noted in comments include: phytopharmaceutical regulation, biocides regulation, circular economy package requirements and national legislation including emission permits*	
[4]*Other drivers noted include: dialogues to achieve voluntary agreements, green public procurement (criteria), non-binding REACH elements (e.g., candidate list, CLP process), innovation, the 2020 goal, articulated in paragraph 23 of the Johannesburg Plan of Implementation*	

Q4. In your organisation's opinion, what are the main obstacles to the substitution of hazardous chemicals (check all that apply)?	
	Response (N=15)
Availability of information on alternatives	93%
Availability of alternatives	67%
Lack of relevant expertise in companies	80%
Lack of suitable consultants	40%
Lack of guidelines	13%
Lack of Member State Competent Authorities support	20%
Lack of industry association support	53%
Competition with companies from extra-EU countries with less stringent legislation	67%
Lack of resources/funding at the company-level	73%
Lack of resources/funding at the organisation-level	40%
Regulatory uncertainty	53%
Other[1]	40%
[1]*Other obstacles noted include: availability and sharing of case studies/impact assessment (financial), communication and trust barriers among industry and MS authorities, lack of technical expertise and understanding about the specific function of a chemical and production procedures, insight regarding substitution practice (e.g., time and costs needed for transition), lack of public/private sector R&D funding for innovation projects supporting substitution, and information gaps*	

Q5. What are your organisation's legislative and non-legislative activities to advance substitution of hazardous chemicals (check all that apply)?	
	Response (N=15)
Conduct analyses of alternatives or similar assessments in support of substitution proposals, programs, or risk management decisions	67%
Provide information on alternative substances or technologies during the consultation phase of the authorisation or restriction process	33%
Provide technical assistance, education or guidance to companies to support legislative or non-legislative substitution efforts	40%
Provide funding for substitution initiatives	20%
Establish guidelines on the substitution of hazardous chemicals	27%
Support industry sector partnerships and consortia to identify and/or implement safer alternatives	20%
Publish undesired substances list(s)	33%
Other[1]	47%
[1]Other activities noted include: communication to the public, information dissemination (via websites), hosting educational workshops, participation in relevant substitution OECD working groups, participation in national stakeholder forums on the use and risk management of industrial chemicals (e.g., UK Chemical Stakeholder Forum), dialogues to achieve voluntary agreements, enforcement and associated actions, international training of non-EU authorities, helpdesk system	

Q6. For what purpose(s) does your organisation conduct analyses of alternatives or similar assessments in support of substitution proposals, programs or risk management decisions (check all that apply)?	
	Response (N=11)
Risk Management Options Analysis	100%
Substance of Very High Concern dossiers	73%
Restriction proposals	73%
Implement national/regional chemical substitution programs	18%
Comparative assessment(s) under the Biocidal Products Regulation	55%
Other(s)[1]	55%
[1]Other purposes noted in comments include: substitution obligations required under national legislation, comparative assessments regarding: (a) safety and sustainability issues for the whole life cycle of products (b) production of alternatives for hazardous substances (c) assessments under the phytopharmaceutical products regulation, governmental assignments and self-initiated investigations regarding screening and substance evaluations	

Q7. Which of the following analysis of alternatives elements are particularly challenging for your organisation and where capacity-building support and assistance is a priority need (select one)?	
	Response (N=10)
Identifying/screening potential alternatives for further assessment	20%
Technical feasibility/performance assessments	60%
Economic feasibility assessment	10%
Hazard/risk assessment	10%
Decision analysis/decision support	0%

Q8. Which of the following would enhance your organisation's ability to identify/screen substitution options for further feasibility and safety assessment (select all that apply)?	
	Response (N=10)
Access to useful databases on alternatives for a specific use or technical function	100%
Access to information from trade sector organisations, suppliers or downstream users	80%
In-house expertise to identify alternatives	60%
Access to useful alternatives screening tools	40%

Q9. Please explain your responses above and include other priority needs impacting your organisation's capacity to identify/screen substitution options for further feasibility and safety assessments:
THEMES *(Response to question: N=8)*
INFRASTRUCTURE
Not expected /not cost-effective to have detailed staff knowledge on alternatives assessment; capacity should be on the provision of technical support and funding for substitution initiatives within companies; not cost-effective to develop capacity to routinely provide support to companies; in-house expertise to identify alternatives is difficult to establish and maintain; enhance investment fund engagement in substitution
ENGAGEMENT
Greater contact with industry organisations to enhance in-house expertise; develop and facilitate business/sector networks specialized in tracking and disseminating information on alternatives; enhance access to independent external expertise with knowledge of sector-specific substances under discussion; enhance dialogue with industry focused on alternatives (or lack thereof) for CMRs
TECHNICAL
Development of and access to databases with relevant information from other member states and agencies outside the EU; access to sound data maintained elsewhere where knowledge is available about alternatives

Q10. Which of the following would enhance your organisation's ability to analyse the technical feasibility of alternatives (select all that apply)?	
	Response (N=10)
Detailed guidance for evaluating technical feasibility assessments	10%
Working knowledge of approaches for assessing the technical feasibility of substitution options	60%
Availability of performance data on alternatives	80%
Mechanisms for information sharing and collaboration among academia, industry and NGO experts	60%
Access to training and technical assistance	20%

Q11. Please explain your responses above and include other priority needs impacting your organisation's capacity to assess the technical feasibility of alternatives:
INFRASTRUCTURE
Lack in-house expertise; lack resources; substitution is of low priority given limited authority resources; unlikely to be cost-effective for Competent Authorities to develop such expertise in house; requires very specific expertise on process technology that might often only be available within industry itself; doubt it is possible to establish and maintain this expertise in house – often case specific and differs per substance and application – yet this knowledge is crucial to evaluate technical feasibility and to make well informed choices regarding regulatory steps; a need to work with industry sectors given their knowledge and technical facilities available to identify and pilot test alternatives – consider supplementing technical support from government funded facilities
ENGAGEMENT
Information is often commercially sensitive; need greater access to experts within relevant sectors; need mechanisms to share information about alternatives (or statements about the absence of)
TECHNICAL
Accessible and user-friendly databases with information about alternative chemicals, technologies and other methods very desirable and useful

Q12. Which of the following would enhance your organisation's ability assess the economic feasibility of alternatives (select all that apply)?	
	Response (N=9)
Detailed guidance for evaluating economic feasibility assessments	11%
Working knowledge of approaches and tools for assessing the economic feasibility of substitution options	56%
Utility of available economic assessment methods for substitution considerations	11%
Availability of cost/market data on alternatives	89%
Mechanisms for information sharing and collaboration among academia, industry and NGO experts	78%
Access to training and technical assistance	22%

Q13. Please explain your responses above and include other priority needs impacting your organisation's capacity to assess the economic feasibility of alternatives:
THEMES *(Response to question: N=9)*
INFRASTRUCTURE
Lack of resources; lack of in-house expertise to support substitution work – short- and long-term benefits for health and environment; not cost-effective for authorities – industry knows best if substitution is economically feasible
ENGAGEMENT
Information sharing on cost/market data of alternatives; access to independent external experts with competence in relevant sectors
TECHNICAL
Valid market/cost data availability; development of database for cost/market data of alternatives; development of a broadly accepted methodology for assessing economic feasibility given the likelihood for rapid economic cost/availability changes and the need to challenge/validate information in restriction dossiers and authorisation applications – methods need to provide informative data, but not be laborious

Q14. Which of the following would enhance your organisation's ability to assess the risks of alternatives (select all that apply)?	
	Response (N=10)
Guidance for assessing hazards and exposure potential	20%
Working knowledge of available hazard assessment and exposure assessment approaches and tools for evaluating the safety of substitution options	30%
Utility of available hazard and exposure assessment methods for substitution considerations	30%
Availability of hazard and/or exposure data on alternatives	90%
Mechanisms for information sharing and collaboration among academia, industry and NGO experts	60%
Access to training and technical assistance	10%

Q15. Please explain your responses above and include other priority needs impacting your organisation's capacity to assess the risks of alternatives:
THEMES *(Response to question: N=9)*
INFRASTUCTURE
More trained resources; time and resources to find and evaluate information also about alternative technologies; have sufficient expertise to assess the hazards and potential risks of alternative substances providing hazard characterisation data are available; we have a lot of competence in this area; our organisation lacks the resources to build the relevant capacity for substitution of hazardous chemicals
ENGAGEMENT
the actual exposure situation and the level of exposure is difficult – this is the part of chemicals risk assessment often challenges risk assessors with the largest uncertainties and support at the level of information sharing with other actors can be valuable and could help improve the assessment
TECHNICAL
lack data; comparative risk assessment should not be difficult when the relevant data on toxicology and exposure are available – difficult when e.g. an alternative for a high-tonnage volume chemical is discussed on a dataset according to the annexes VII and VIII of the REACH and while data gaps might be filled in a substance evaluation, this is a time consuming procedure; a challenge to get sufficient hazard data for alternative substances as this information appears to be often lacking or of lower quality than the substance of concern; the priority need is to get the information – risk assessment data on alternatives are less documented and are subject to more uncertainties.

Q16. Are there any other notable needs that if addressed would enhance your organisation's ability to evaluate alternatives in support of both legislative and non-legislative substitution efforts?
THEMES (Response to question: N=6)
INFRASTRUCTURE
Enhancing staff capacity and expertise via training and new staff additions – *enhancing expertise in engineering, product design, process technology and economics*; an understanding that developing dedicated in-house expertise to support substitution is not cost-effective for authorities; developing best practices to enhance private-public partnerships for innovation development and substitution; clearer legislative requirements
ENGAGEMENT
Enhancing industry sector dialogue, including information exchange; enhancing data sharing for substitution assessments; developing best practice analysis of alternatives case studies and examples
TECHNICAL
Enhancing data availability (relevant to multiple geographic scales (e.g., EU-level and individual Member States); training on analysis of alternatives best practices

Q17. Type of assistance my organisation provides in support of companies' substitution efforts?	
	Responses (N=7), % based on total respondents, (N=16)
Technical assistance in the context of companies'; legislative substitution activities (e.g., REACH authorisation, restriction or comparative assessments under the Biocidal Product Regulation)	38%
Technical assistance in the context of companies'; non-legislative substitution activities	19%
Host educational and/or training events (e.g., webinars, workshops, conferences, or other industry-sector/supply chain meetings)	44%
Disseminate information about the availability of safer substitutes for hazardous chemicals of concern	38%

Q18. From your organisation's perspective, what is the most important need to improve how companies evaluate and implement substitutes for hazardous chemicals and how can governmental or publicly funded organisations better support them?
THEMES (Response to question: N=11)
INFRASTRUCTURE
Promoting/financing alternatives innovation research and evaluation support; establishing public procurement policies with health and environment requirement to drive economies of scale for the alternatives; raising the pressure towards substitution through further implementation and enforcement of the Art. 33 obligations; improving the public consultation process to enhance engagement among parties with information about alternatives
ENGAGEMENT
Enhancing supply chain dialogue and engagement to enhance information exchange; enhancing mechanisms to support knowledge sharing between government authorities and industry in support of alternatives identification, assessment and adoption; developing a common understanding “substitution,”; sharing best practices; sharing substitution success stories; sharing information on future substitution needs/problems identified and regulatory changes foreseen as early as possible, providing subsequent legislative process updates
TECHNICAL
Enhancing the availability of user-friendly databases with possible alternative substances, technologies, processes, etc.; Enhancing technical support to companies through industry association support and Competent Authorities; better scoping (uses/applications, types of alternatives included, etc.,) in authorisation applications

Q19. How can ECHA most effectively support national/regional organisations and industry in their substitution activities (check all that apply)?	
	Response (N=16)
Develop enhanced analysis of alternatives guidance materials	50%
Provide more trainings on substitution	31%
Undertake more educational webinars	19%
Coordinate research activities on substitutes	38%
Convene supply chain and sector dialogues to identify, evaluate, and adopt substitutes	69%
Enhanced web-based materials on substitution	50%
Creation of an EU substitution network with periodic meetings and communications	38%
Develop a database of potential alternatives to hazardous substances for specific uses and technical functions	69%
Other recommendations include: enhancing regulatory and public pressure; providing case studies on chemical categories; making data gathered by ECHA in the production of other work available to Member States (e.g., SEA data gathered for one restriction proposal being made available); coordinating with OECD and other international bodies (e.g., UNEP) to enhance (make more user friendly) rather than duplicate efforts related to substitution; providing good substitution support examples on website; financing an independent EU based institute for substitution, considering how the circular economy package can be used to foster substitution activities at company-level	

Q20. Are there institutions (private, academic, other public institutions, e.g., technical assistance or innovation centres) that are not currently engaged in legislative or non-legislative chemical substitution efforts, but that have the capacity to enhance such substitution efforts?	
	Response (N=15)
No	33%
Yes - please describe:	67%
Comments include: research institutes, including academia – requires building relationships with industry sectors; employer organisations; EU Commission, NGOs	

ANNEX B: Industry Representatives Survey Results

The survey results displayed below reflect those questions informing this report. Additional survey questions developed to support DG Environment's sub-study on substitution associated with "the strategy for a non-toxic environment of the 7th Environment Action Programme (EAP)," will be published at a later time. Comments for some questions have been abbreviated in order to protect the confidentiality of respondents and to streamline the display of results. Frequencies were not calculated for specific open-ended comments but were categorized into high-level themes where appropriate.

Q1. In your opinion, how important are the following factors as drivers to substitute hazardous chemicals?

	Not important	2	Important	4	Very important	No opinion
REACH regulation (N=102)[1]	1%	4%	6%	16%	72%	2%
Health and safety regulatory requirements (N=98) [2]	3%	6%	20%	21%	40%	9%
Product safety regulatory requirements (N=96)[3]	5%	7%	21%	26%	25%	16%
Biocidal products regulation (N=96)	10%	10%	19%	13%	15%	33%
Plant protection products regulation (N=96)	18%	4%	11%	7%	7%	52%
Supply chain requests (N=97)	7%	11%	30%	19%	27%	6%
Consumers' concerns (N=101)	10%	6%	22%	23%	31%	9%
Workers' concerns (N=99)	7%	11%	18%	20%	40%	3%
NGO black-listing (e.g. substance included in SIN list) (N=101)	16%	22%	28%	13%	15%	7%
Economic considerations (N=99)	6%	7%	17%	31%	33%	5%
Corporate social responsibility /sustainability policies (N=99)	5%	10%	25%	25%	31%	3%
Internal chemical management policies/procedures (N=97)	3%	13%	22%	19%	40%	3%
Other regulatory requirements (N=85)[4]	11%	8%	5%	7%	16%	53%
Other drivers (N=61)[5]	3%	2%	3%	2%	13%	74%

[1]Specific REACH regulation mechanisms as noted in comments: candidate list, authorisation list, restriction list, public activities coordination tool (PACT), community rolling action plan (CoRAP)

[2]Specific Health and safety regulatory requirements as noted in comments: OSH directives (e.g., CMD - 2004/37/CE, CAD 98/24/EC and binding OELs; Directive 2000/39/EC; Directive 89/391/EEC; Directive 2009/161/UE; Seveso Directive; specific OEM regulations (automotive); national worker health and safety legislation; IPPC, process safety

[3]Specific product safety regulatory requirements as noted in comments: RoHS; food contact; cosmetics; drinking water; medical device; food and feed; national regulation for fire textiles; handling; firing and disposal documentation; battery directive 2006/66/EC; End of Life Vehicles

[4]Other regulatory requirements as noted in comments: CLP, industrial emission directive; water framework directive; waste water; potential future legislation on endocrine disruptors, nanomaterials and nanotechnology; national legislation (e.g., German hazardous substances ordinance; German act on the prohibition of chemicals; Annex 40 of the German act on sewage; German law on electronic devices; Norwegian National Chemical regulations regarding textile products, indoor air emission requirements; EASA or BImSchVO); Stockholm convention; Rotterdam convention; ODS; VOC; Regulation EU 1005/2009; Regulation EU 517/2014

[5] Other substitution drivers as noted in comments: NGO campaigns; Circular Economy; availability of alternatives; price of alternatives; voluntary standards; substance restrictions in other territories (e.g., CA)

Q2. In your opinion, how important are the following factors as obstacles to the substitution of hazardous chemicals?

	Not important	2	Important	4	Very important	No opinion
Availability of information about hazard/risk of alternatives (N=98)	6%	8%	21%	22%	39%	3%
Availability of information about the technical feasibility of alternatives (N=96)	2%	7%	16%	21%	5%	1%
Uncertainty regarding the market potential of alternatives (N=96)	5%	4%	28%	27%	29%	6%
Lack of relevant expertise in companies (N=95)	9%	21%	27%	17%	23%	2%
Lack of suitable external expertise (e.g. consultants) (N=95)	20%	19%	24%	12%	16%	9%
Customer performance specifications (N=95)	4%	5%	26%	15%	39%	11%
Ineffective communication with suppliers about alternative options (N=94)	10%	16%	33%	18%	18%	5%
Lack of technical guidance on analysis of alternatives and/or substitution (N=94)	14%	24%	22%	19%	14%	6%
Lack of support from Member State Competent Authorities (N=95)	24%	13%	18%	12%	23%	11%
Lack of support from industry association (N=94)	23%	19%	21%	19%	10%	7%
Competition with companies from extra-EU countries with less stringent legislation (N=95)	4%	12%	6%	13%	54%	12%
Lack of resources/funding at the company-level (N=96)	6%	9%	44%	23%	13%	5%
Regulatory uncertainty regarding substitutes (N=93)	2%	12%	20%	27%	37%	2%
Other obstacles (N=49)[1]	2%	4%	0%	0%	16%	78%

[1]*Other obstacles noted (not captured above): market expectations in terms of safety; performance and affordability; availability of alternatives; price of alternatives; performance (specifically safety); potential restriction of alternatives; other life cycle considerations (e.g., impact on waste water); competition from competitors using banned chemicals*

Q3. In the last ten years, did your company implement any substitution of hazardous chemicals?

	Response (N=98)
Yes, we did	81%
No, we did not. A search for alternatives was conducted but did not result in the adoption of a substitute	10%
No, we did not consider any substitution of hazardous chemicals	9%

Q4. Considering the substitution of hazardous chemicals that you implemented in the last 10 years, what benefits (if any) did your company and clients experience? (Check all that apply) (N=75)

	Your company	Your clients
Improved performance/product quality	24%	20%
Decreased production costs	13%	5%
Decreased chemicals management costs	28%	17%
Decreased regulatory costs	32%	12%
Improved brand/market reputation	51%	32%
Improved worker safety	72%	35%
Improved worker satisfaction	40%	13%
No benefits	15%	13%

Other benefits noted in comments: Benefits to customers and users of our products; contribution to better indoor environment and air quality; increased knowledge and thereby safety of our products (of benefit to supply chain and environment); increased market share; products that display a higher level of performance and cost effectiveness but that have a much better safety profile and contribute to achieving sustainability and public health objectives; contractual compliance; legal compliance; same performance and properties; benefits for suppliers (sub-contractors) which are requested to use an hazardous substance due to their customer requirements; product quality does not come from the fact that the substitution solution provides a better performance, but from the fact that when implementing a new solution, you have to explore it in detail (with tooling up to date compared to what was available 10 years ago or more) – therefore have a new process on which you have a better control and which is more robust on the production line; where technically feasible – there is no/low impact to product quality; improved risk management measures

**Note respondents included comments about challenges when answering this question, which are captured in Q5.*

Q5. Considering the substitution of hazardous chemicals that you implemented in the last 10 years, what challenges (if any) did your company and clients experience? (Check all that apply) (N=70)

	Your company	Your clients
Reduced performance/product quality	41%	33%
Increased production costs	67%	21%
Increased chemicals management costs	29%	6%
Customer concerns with product/process changes	46%	46%
Worker concerns with product/process changes	31%	11%
The substitute has been found to also be a substance of concern in terms of its hazardous properties and is now also subject to regulatory and non-regulatory pressures (e.g. inclusion in the REACH authorisation candidate list, NGOs black-listing)	37%	19%
Supply chain availability of the alternative(s) or their precursors	40%	11%

Other challenges noted in comments: Support from existing regulations to identify test & validate alternatives; comprehensive and applicable EU legal framework to avoid duplication of national initiatives; long transition [scale-up] time; constant regulatory pressure through REACH and CLP processes on the alternatives developed; difficulty finding drop-in replacements (i.e., formulated chemical products complexities); increased production complexities and associated cost; increased chemical storage requirements and costs; alternatives not available in sufficient quantities; other life cycle impacts or hazards; increased waste production; competition from competitors and customers using restricted substance

Q8. Which of the following components of analysis of alternatives or substitution assessment were particularly challenging for your company and where capacity-building support and technical assistance is therefore a priority need (select one)?	
	Response (N=82)
Identifying/screening potential alternatives for further assessment	17%
Technical feasibility/performance assessments	44%
Economic feasibility assessment	9%
Hazard/risk assessment	12%
Decision analysis/decision support	4%

Q9. For the different components of the substitution process, did your company use internal staff, consultants, external research and development centres or other external expertise? (If you did not use internal staff for any of the components, please skip Q10 and go to Q11) (N=79)				
	Internal staff	**Consultants**	**External R&D centres**	**Other external expertise[1]**
Identifying/screening potential alternatives for further assessment	90%	19%	26%	18%
Technical feasibility/ performance assessments	86%	14%	25%	23%
Economic feasibility assessment	93%	19%	7%	7%
Hazard/risk assessment	86%	26%	18%	15%
Decision analysis/decision support	93%	11%	14%	7%
[1]*Other expertise described in comments: suppliers; academic experts; interdisciplinary teams and task forces; clients/customers; subcontractors (e.g., toxicology test facilities, performance test facilities)*				

Q10. What guidance documents or other resources did your company use to guide the analysis of alternatives (select all that apply)?	
	Response (N=79)
REACH Guidance on the Preparation of an Application for Authorisation	51%
German Federal Environment Agency's Guide on Sustainable Chemicals	11%
BAuA's Technical Rules for Hazardous Substances, Substitution -TRGS 600	13%
OECD Substitution and Alternatives Assessment Toolbox	11%
None	27%
Other[1]	33%
[1]*Other noted in comments: collaborative research and development; internal/consultant expertise; external consultants; suppliers; performance specifications; hazard assessment tools (e.g., GreenScreen); lists*	

Q11. What actions would you like to see from regulators or publicly funded organisations to better support and encourage substitution efforts? (Check all that apply)	
	Response (N=90)
Develop enhanced technical guidance materials on analysis of alternatives	44%
Provide more educational training or webinars on substitution	21%
Develop web-based materials, resources and/or tools on substitution (please describe priority needs in the text box below)	31%
Create an EU substitution network with periodic meetings and communications	38%
Coordinate research activities on substitutes	43%
Convene supply chain and sector dialogues to identify, evaluate, and adopt substitutes	43%
Provide funds for the research and development of safer alternatives	60%
Other[1,2,3]	12%
[1]INFRASTRUCTURE needs noted in comments: EU Commission/ECHA financial support for the research and development of alternatives; incentives for the development of alternative process chemicals; awareness of global markets and competition that are hindering constructive supply-chain information flows and negate beliefs that regulation drives innovation; greater support by authorities and regulators for market driven substitution; the need for alternatives to be scrutinized to the same level of testing and regulatory review [as existing chemicals] to avoid unintended consequences for the sake of a "substitution ideology"; additional/reasonable transition time before sunset date; legal certainty (e.g., SVHC list); more globally harmonized regulations; stricter regulations for % thresholds required to be included on MSDSs; additional regulations focused on the development of new chemicals and requirements for pre-market risk assessments; greater awareness among regulators regarding the difficulties, issues, impact, resource requirements, scientific knowledge, engineering and time scale to develop and implement substitutes; stricter legislation for chemical manufacturers regarding the provision of the full content of chemical products	
[2] ENGAGEMENT needs noted in comments: clearer communications from authorities regarding hazard and risk as well as evaluation, authorisation and restriction	
[3]TECHNICAL needs noted in comments: web-based chemicals encyclopaedia (use/application, legislation status, substitution chemicals, etc.); development of hazard assessment tools; improved guidance on analysis of alternatives for upstream suppliers; need for other capacity-building actions that are more relevant to alternatives that are highly technical and proprietary; inclusion of additional tools such as life cycle assessment (LCA) to avoid regrettable substitutes based on other life cycle impacts	

ANNEX C: Industry Consultants Survey Results

The survey results displayed below reflect those questions informing this report. Additional survey questions developed to support DG Environment's sub-study on substitution associated with "the strategy for a non-toxic environment of the 7th Environment Action Programme (EAP)," will be published at a later time. Comments for some questions have been abbreviated in order to protect the confidentiality of respondents and to streamline the display of results. Frequencies were not calculated for specific open-ended comments but were categorized into high-level themes where appropriate.

Q1. In your opinion, how important are the following factors as drivers to substitute hazardous chemicals?

Answer Options	Not important	2	Important	4	Very important	No opinion
REACH Regulation[1] (N=18)	0%	0%	17%	22%	61%	0%
Health and safety regulatory requirements[2] (N=18)	0%	6%	28%	11%	33%	22%
Product safety regulatory requirements[3] (N=18)	0%	11%	33%	6%	33%	17%
Other regulatory requirements[4] (N=18)	0%	0%	33%	11%	6%	33%
Biocidal Products Regulation (N=18)	6%	11%	28%	11%	22%	22%
Plant Protection Products Regulation (N=18)	6%	11%	17%	17%	22%	28%
Supply chain requests (N=18)	6%	0%	39%	28%	33%	0%
Consumers' concerns (N=18)	6%	17%	22%	28%	28%	6%
Workers' concerns (N=18)	11%	17%	44%	17%	6%	11%
NGO black-listing (e.g. substance included in SIN list) (N=18)	6%	22%	50%	17%	0%	11%
Economic considerations (N=18)	6%	17%	22%	22%	39%	0%
Corporate social responsibility/sustainability policies (N=18)	0%	39%	44%	17%	6%	0%
Internal chemical management policies/procedures (N=18)	6%	22%	1%	17%	6%	0%
Other[5] (N=9)	0%	0%	11%	0%	11%	78%

[1]Specific REACH regulation mechanisms as noted in comments: REACH as a whole; candidate list; authorisation list; restriction; registration and as follows more information of chemicals; when a substance is listed in whatever REACH's list this substance is suspected – not only SVHC list; companies not been affected by other regulations (e.g., smaller companies or DUs) have been mobilized by REACH

[2]Specific Health and safety regulatory requirements as noted in comments: CMD and CAD directives [put economic burden on companies like some REACH elements]; national legislation (e.g., German regulations (MAK-Werte, Berufsgenossenschaft)) workplace requirements; and consequently very limited substitution activities; OS&H regulations -- if the accurate hazard data gets used

[3]Specific product safety regulatory requirements as noted in comments: RoHs, Toys, FCM, EEE; norm and certificates, e.g., for exhaustion equipment; general awareness; product safety regulatory requirements works through the bottom-up way, which could be equalled to the supply chain requests

[4]Other regulatory requirements as noted in comments: CLP; regulations on hazardous waste; national regulations e.g., Germany and France on VOC and door air quality; raw materials initiative; circular economy package; GADSL

[5] Other substitution drivers noted in comments: company values (e.g., environmental footprint), public expectations, market and customers demand, economic and cost factors (e.g., price volatility), risk of supply disruption, competitive edge, research and innovation, and technical factors, etc., – the importance of various drivers is case-specific; all types of regulation are driving substitution yet their importance to parties along the supply chain are different and influence companies via different mechanisms; if risk cannot be controlled, reduced or eliminated, the strongest driver is technical performance and compatibility of the alternative; the problem with chemical policy laws is their enactment – the manufacturer controls the hazard outcome; CMD and CAD requirements experience sufficient implementation [and very limited substitution activities] due to weak enforcement and low prevention level in enterprises; a substance listed as SVHC and intended to be authorised can survive

Q2. In your opinion, how important are the following factors as obstacles to the substitution of hazardous chemicals?						
Answer Options	**Not important**	**2**	**Important**	**4**	**Very important**	**No opinion**
Availability of information about hazard/risk of alternatives (N=18)	6%	17%	28%	17%	33%	0%
Availability of information about the technical feasibility of alternatives (N=18)	6%	6%	17%	28%	44%	0%
Uncertainty regarding the market potential of the alternatives (N=18)	0%	17%	33%	11%	39%	0%
Lack of relevant expertise in companies (N=18)	0%	22%	33%	17%	28%	0%
Lack of suitable external expertise (e.g. consultants) (N=18)	0%	33%	22%	22%	22%	0%
Customer performance specifications (N=18)	0%	0%	33%	22%	39%	0%
Ineffective communication with suppliers about alternative options (N=18)	11%	28%	28%	28%	0%	6%
Lack of technical guidance on analysis of alternatives and/or substitution (N=18)	22%	44%	22%	6%	6%	0%
Lack of support from Member State Competent Authorities (N=18)	17%	39%	28%	0%	0%	17%
Lack of support from industry association (N=18)	6%	39%	28%	11%	0%	17%
Competition with companies from extra-EU countries with less stringent legislation (N=18)	0%	17%	22%	22%	39%	0%
Lack of resources/funding at the company-level (N=18)	0%	11%	11%	17%	50%	6%
Regulatory uncertainty regarding substitutes (N=18)	6%	6%	44%	22%	22%	0%
Other[1] (N=9)	0%	0%	0%	0%	22%	78%

[1]Other obstacles noted (not captured above (N=5)): chemical function; continuity/risk of supply and general availability (in the required quality and sufficient quantities); general legislative stability; internal/external expertise (which if not available can discourage moving forward or can postpone implementation); communication about alternatives and AoA support for more isolated supply chain actors and SMEs; depending on the case, different types of support (e.g., information, training, funds, etc.,) from regulators may be more influential; competition and competitiveness are key drivers towards substitution, but related to reputation and economic factors; industry association support in form of guidance or collective projects (although initiatives can be launched independent of industry associations); import of articles should be limited to those produced with processes in compliance with European standards of health and safety of man and environment protection; substitution transition time/resource as both (or even more) technologies used in parallel – but there is not the additional personal, space (industrial facilities) and market; customer will not accept higher costs for the same service; unavailable skilled workforce necessary for new technology; job loss and collision with job protection legislation; many substances are used for very particular reasons and specific to the process of the individual company – general information about potential substitutes is not useful; lack of awareness among alternatives suppliers about the process characteristics of (potential) downstream users; barriers to supply chain information sharing for genuine strategic, competition and economic reasons

Q3. In the last ten years, did your company implement any substitution of hazardous chemicals?	
Answer Options	**Response (N=17)**
Yes, we did	59%
Yes we did, although the search for alternatives did not result in the adoption of a substitute	18%
No, we did not support any substitution of hazardous chemicals	24%

Q4. Considering the substitution initiatives that you supported in the last 10 years, what benefits (if any) did your clients, and as far as you are aware, their clients, experience? (Check all that apply) (N=9)		
	Your clients	**Their clients**
Improved performance/product quality	11%	22%
Decreased production costs	0%	0%
Decreased chemicals management costs	11%	11%
Decreased regulatory costs	22%	0%
Improved brand/market reputation	33%	11%
Improved worker safety	56%	11%
Improved worker satisfaction	33%	0%
No benefits	33%	11%
Other benefits noted in comments not mentioned above: increased productivity; avoiding regulatory enforcement		

Q5. Considering the substitution of hazardous chemicals that you supported in the last 10 years, what challenges (if any) did your clients and, as far as you are aware, their clients, experience? (Check all that apply) (N=9)		
	Your clients	**Their clients**
Reduced performance/product quality	56%	67%
Increased production costs	89%	22%
Increased chemicals management costs	44%	0%
Customer concerns with product/process changes	56%	33%
Worker concerns with product/process changes	44%	11%
Supply chain availability of the alternative(s) or their precursors	56%	22%
The substitute has been found to also be a substance of concern in terms of its hazardous properties and is now also subject to regulatory and non-regulatory pressures (e.g. inclusion in the REACH authorisation candidate list, NGOs black-listing).	33%	22%
Other obstacles noted in comments: increased costs not able to be passed on to resulting market costs		

Q8. In your opinion, which of the following components of the analysis of alternatives or substitution assessment are particularly challenging and where capacity-building support and technical assistance is therefore a priority need (select one)?	
	Response (N=11)
Identifying/screening potential alternatives for further assessment	27%
Technical feasibility/performance assessments	45%
Economic feasibility assessment	9%
Hazard/risk assessment	0%
Decision analysis/decision support	18%

Q9. For the different components of the substitution process, did your company use internal staff, consultants, external research and development centres or other external expertise? (If you did not use internal staff for any of the components, please skip Q10 and go to Q11) (N=10)

	Internal staff	Consultants	External R&D centres	Other external expertise[1]
Identifying/screening potential alternatives for further assessment	40%	30%	20%	30%
Technical feasibility/ performance assessments	50%	40%	20%	20%
Economic feasibility assessment	60%	20%	10%	10%
Hazard/risk assessment	40%	50%	0%	20%
Decision analysis/decision support	50%	20%	0%	20%

[1]*Other expertise described in comments: literature, industrial associations, Berufsgenossenschaften (health and safety insurance)*

Q10. What guidance documents or other resources did your organisation use to guide the analysis of alternatives (select all that apply)?

Answer Options	Response (N=11)
REACH Guidance on the Preparation of an Application for Authorisation	73%
German Federal Environment Agency's Guide on Sustainable Chemicals	27%
BAuA's Technical Rules for Hazardous Substances, Substitution -TRGS 600	27%
OECD Substitution and Alternatives Assessment Toolbox	18%
None	0%
Other[1]	27%

[1]*Other as described in comments: GreenScreen; A Guide to Substitution: An Information Note from the UK Chemicals Stakeholder Forum" (August 2010); best practice guidance*

Q11. What actions would you like to see from regulators or publicly funded organisations to better support and encourage substitution efforts? (Check all that apply)

Answer Options	Response (N=14)
Develop enhanced technical guidance materials on analysis of alternatives	50%
Provide more educational training or webinars on substitution	21%
Develop web-based materials, resources and/or tools on substitution (please describe priority needs in the text box below)	14. %
Create an EU substitution network with periodic meetings and communications	36%
Coordinate research activities on substitutes	43%
Convene supply chain and sector dialogues to identify, evaluate, and adopt substitutes	50 %
Provide funds for the research and development of safer alternatives	57%
Other[1,2,3]	64%

[1]*INFRASTRUCTURE: prioritize funds for SMEs using chemicals; enhance publicly funded research organisation information, knowledge and test facility sharing with enterprises involved in substitution efforts; support for R&D with sensitivity regarding proprietary needs of industry; contractual obligations through public purchasing*

[2]*ENGAGEMENT: enhance messaging around the analysis of alternatives rather than substitution; information about the absolute need of substitution of dangerous substances; enhancing supply chain communication re: screening available alternatives*

[3]*TECHNICAL: guidance needs specifically on hazard/risk characterization; data base on best practice examples; screening*