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Cross Country Analysis: Approaches to Support Alternatives Assessment and Substitution of Chemicals of Concern – 2nd edition

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Cross Country Analysis: Approaches to Support Alternatives Assessment and Substitution of Chemicals of Concern – 2nd edition

IOMC
INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS
A cooperative agreement among FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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Foreword

This report was developed as background to the OECD Workshop on Government Approaches to Incentivise Substitution that took place in Paris on 20-21 September 2022 under the auspices of the OECD Working Party on Risk Management (WPRM). The drafting of this report as well as the organisation of the workshop was made possible thanks to a voluntary contribution from Australia.

The report provides an overview of cross-country approaches used to support substitution and is the second edition of the report.

The report was prepared by the OECD Secretariat based on a survey conducted of countries and the workshop discussions. It also benefited from input from the workshop participants, as well as members of the WPRM. It is published under the responsibility of the OECD Chemicals and Biotechnology Committee.

Executive Summary

Countries continue to advance approaches to support alternatives assessment and substitution of chemicals of concern. Substitution can occur as a response to regulatory activity or in anticipation of regulations or even in non-regulatory scenarios where a company may wish to switch to an alternative substance or technical solution.

This document summarises approaches used to support alternatives assessments and substitution by countries and lessons learned. It is the second edition of the report and is based on responses received to a questionnaire as well as discussion from the 2022 OECD Workshop on Government Approaches to Incentivise Substitution. In addition, the document summarises third-party approaches to substitution and economic approaches to incentivise substitution, which are further elaborated in other documents also discussed at the workshop. Links to the topics of innovation and safe and sustainable by design are also drawn.

A combination of regulatory and voluntary approaches is used by public authorities to support substitution…

As in the first cross country analysis that was published in 2019, there is still today a combination of voluntary and regulatory approaches that is used across countries to support substitution of chemicals of concern. In many cases, voluntary approaches come to complement regulatory approaches, in particular to provide support and guidance to the implementation of legislative frameworks.

Regulations are still seen as a key means to incentivise substitution with the possibility to encourage substitution from different angles such as restriction of the use of certain chemicals, exclusion provisions combined with criteria for substitution candidates, labelling of consumer products, and occupational safety. Voluntary approaches principally aim to encourage and organise a dialogue amongst stakeholders to respond to the challenges of sustainable substitution with exchange of information, experience, and good practices. Indeed, one of the main issues that was raised at the workshop in 2022 is the need for continuous efforts to keep a dialogue going amongst public authorities, industry, NGOs, and trade unions. Voluntary approaches also aim at informing consumers and sharing information on the chemical composition of products, thus pushing for more transparency along the value chain.

Clear benefits arise from existing regulatory and voluntary approaches but challenges remain…

Information provided as part of the questionnaire shows clear benefits from both regulatory and voluntary approaches that have been implemented to improve the safety of consumer products, in particular vis-a-vis the use of substances of very high concern. Important progress is being made but efforts need to continue, in particular, as the workshop raised, to avoid regrettable substitution and encourage lifecycle thinking to develop more sustainable products. Challenges that remain include: balancing environmental, health and economic incentives;

the complexity of substitution, sharing of information and data; and enforcement and non-compliance to regulations.

Third party approaches have developed to incentise substitution, and they are key to advance the field…

Third-party organisations (organisations that are not involving governments or the regulated industry) such as academic institutions, non-profit organisations and retailers have developed approaches to actively support substitution. Collectively, these approaches cover many different aspects of managing and reducing chemical risk such as providing technical resources and assistance, as well as training, the development of labels, advocacy campaigns, and capacity building. They are targeted toward a variety of audiences and have proved their usefulness within the community.

Economic instruments, coupled with regulations and voluntary approaches, should be explored further as an opportunity to incentivise substitution…

By changing the relative price between chemicals of concern and their less hazardous alternatives, economic instruments can provide continuous incentives for industry to innovate and substitute with safer alternatives. One of the main reasons why price-based instruments are still relatively rare in chemicals regulation is that a primary focus has been on very hazardous substances, where other regulatory measures such as bans and restrictions are more appropriate. There are, however, cases where taxes and other market-based instruments can provide important complements to other types of regulatory measures.

Incentivising substitution of chemicals of concern is an important component of the Safe and Sustainable by Design concept…

Regulations and voluntary approaches supporting substitution present an opportunity for industry to engage in designing products that are inherently safer and more sustainable. It can be seen as a motor to innovation, an incentive to create more transparency amongst stakeholders and a common driving force to developing products that are safer and more sustainable along their life cycle while keeping the economic and social aspects in mind from early on.

However, the integration of safety and sustainability considerations into a product's pre-market design phase can be complex and requires the involvement of a great variety of stakeholders and clear criteria for what constitutes safe and sustainable.

There are opportunities for public authorities to support the field further and help address remaining hurdles…

- ***Fostering communication and collaboration***

Both the workshop and questionnaire have highlighted the progress that has been made in the past years to improve communication amongst stakeholders on substitution challenges, in particular with the development of networks of experts and stakeholders. This has helped in the success of several substitution cases and the development of safer products.

However, efforts should be sustained. Governments are in a unique position to maintain and strengthen dialogue amongst industry along the supply chain, trade unions, and NGOs, also involving the variety of public agencies with different priorities and regulators. Communication was pointed out as one of the best

means to help address the complexity of substitution practices (in particular trade-offs) and the "fear of the unknown" when industry engages in substitution.

- ***Supporting filling of data gaps***

  The workshop emphasised the role governments can play to support the filling of important remaining data gaps. The workshop raised the opportunity to leverage the data already available in public agencies and to find ways to share this data effectively while considering the different information needs from industry, consumers, and manufacturers.

- ***Promoting transparency along the supply chain***

  The need for greater transparency along the supply is still a bottleneck for the field to progress. Efforts that aim to foster transparency should be incentivised and further discussions are needed on concrete means to do so. Enhanced transparency required by regulatory measures could create strong incentives to eliminate hazardous substances.

- ***Governance for substitution: creating regulatory stability and predictability***

  The workshop raised the need to create a governance framework that is science-based, with regulatory consistency and predictability for industry to be able to prepare and respond appropriately. Alignment of regulations globally was also raised as an important component of such a framework. Governance should also include more clarity on the terms used, in particular with the development of definitions or criteria for concepts such as regrettable substitution.

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List of Abbreviations and Acronyms

ANSES	French Agency for Food, Environmental and Occupational Health and Safety
AoA	Analysis of Alternatives
BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (German Federal Institute for Occupational Safety and Health)
BPR	EU Biocidal Products Regulation
CBC	Chemicals and Biotechnology Committee
CMR	Carcinogenic, Mutagenic or Reprotoxic
CSS	EU Chemicals Strategy for Sustainability
EC	European Commission
ECHA	European Chemicals Agency
EPEA	Environmental Protection Encouragement Agency
EPEAT	Electronic Product Environmental Assessment
EU	European Union
GEC	Global Electronics Council
HARN	High Aspect Ratio Nanomaterials
LCA	Life Cycle Analysis
LMW	Lower Molecular Weight
MCNM	Multicomponent Nanomaterial
NAM	New Approach Methodologies
NIOSH	U.S. National Institute for Occupational Safety and Health
NGO	Non-Governmental Organisation
NWA	Nationale Wetenschapsagenda (Dutch National Research Agenda)

OECD	Organisation for Economic Co-operation and Development
OSHA	European Occupational Safety and Health Administration
PARC	European Partnership for the Assessment of Risks from Chemicals
PBT	Persistent, Bioaccumulative, Toxic
PVC	Polyvinyl chloride
R&D	Research and Development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No 1907/2006)
SAICM	Strategic Approach to International Chemicals Management
SCIA	Safe Chemicals Innovation Agenda
SEA	Socio-Economic Analysis
SIN List	Substitute It Now! List
SbD	Safe by Design
SIA	Safe(r) Innovation Approach
SSIA	Safer and Sustainable Innovation Approach
SSbD	Safe and Sustainable by Design
SVHC	Substance of Very High Concern
TSCA	Toxic Substances Control Act
TURA	Toxics Use Reduction Act
UBA	German Environment Agency
U.S. EPA	United States Environmental Protection Agency
USGBC	U.S. Green Building Council
vPvB	very Persistent and very Bioaccumulative

WPMN	OECD Working Party on Manufactured Nanomaterials
WPRM	OECD Working Party on Risk Management

1. Background

This document is the second edition of the report "Cross Country Analysis: Approaches to Support Alternatives Assessment and Substitution of Chemicals of Concern" (OECD, 2019[1]) that was published in February 2019 following an OECD Expert Workshop organised by the OECD Ad Hoc Group on Substitution of Harmful Chemicals. The Ad Hoc Group on Substitution of Harmful Chemicals has been integrated into the OECD Working Party on Risk Management, which was formally established under the Chemicals and Biotechnology Committee (CBC) in September 2020. The Working Party has a mandate to, among others, develop tools and methods to support substitution of harmful chemicals and advance the alternatives and socioeconomic assessment to support chemicals management.

A questionnaire was circulated among the members of the Working Party on Risk Management in spring 2022. Responses were received from Australia, Canada, Denmark, France, Germany, Luxemburg, the Netherlands, the United States, and the European Agency for Safety and Health at Work (OSHA) and the European Chemicals Agency (ECHA). Input from the Vinyl Council of Australia was also received and incorporated into the section on Australia, as the Annex will not outline non-government responses in this edition.

In addition to gathering information on approaches used to support alternatives assessments and substitution within countries, the questionnaire also asked respondents to identify benefits of said approaches as well as challenges to their implementation.

This report presents an analysis of the responses received to the questionnaire, as well as discussions from the 2022 OECD Workshop on government approaches to incentivise substitution, held on 20 – 21 September 2022. It describes the types of approaches in place (regulatory, non-regulatory/voluntary approaches), the chemicals and life-cycle stages they target, as well as challenges to their implementation and identified benefits of the approaches. Moreover, it provides introductions to the topics of economic instruments and third-party approaches to incentivise substitution, the link between Safe and Sustainable by Design (SSbD) and substitution, as well as lessons learned. An overview of the government approaches is available in Annex A of this document.

2. Programmes and Initiatives to Support Alternatives Assessment and Substitution of Chemicals of Concern

2.1. Regulatory and voluntary approaches to support substitution

Voluntary approaches to support substitution continue to outweigh regulatory approaches, with 12 of the 38 approaches detailed in response to the questionnaire being of regulatory nature. This reaffirms the finding of the first questionnaire that a combination of voluntary and regulatory measures appears to be the approach that is the most used across countries. In many cases, regulatory and voluntary approaches are used in a complementary fashion, such as in the case of the U.S. EPA which bases many of its activities under the Toxic Substances Control Act (TSCA) on frameworks, databases, methodologies, expertise and contacts generated under Safer Choice, a voluntary partnership programme to help consumers and businesses find safer products.

Moreover, regulatory measures are not only drivers of substitution itself, but also of voluntary approaches that support substitution. In France, for example, REACH regulation has driven the establishment of an online portal[1], which shares information on chemicals substitution that was provided by companies, as well as methodological guidance. The choice of chemicals addressed on the portal is based on REACH regulation, albeit with a wider scope. Similarly, the German Environment Agency (UBA) has launched the Sustainable Control of Harmful Organisms in the 21st Century (SCOTTY)[2] initiative in response to the EU Biocidal Product Regulation. The initiative seeks to support a broad portfolio of different efficacious options to control pests.

2.1.1. Regulatory approaches

In the European Union, REACH remains the cornerstone of the regulatory framework addressing substitution of chemicals. Its different approaches, such as the EU REACH Application for Authorisation Process[3] or the EU REACH Restriction Process[4], described in detail in the first edition of this report (OECD, 2019[1]) remain highly relevant today and are believed to have led to measurable progress in the area of substitution (see Chapter 3).

Worker health protection remains an issue addressed by regulatory approaches in several countries (AU, DK). In Australia, the Model Work Health and Safety

[1] INERIS. (n.d.) *Chemical substitution portal*. https://substitution.ineris.fr/en

[2] Umweltbundesamt. (n.d.) *Sustainable Control of Harmful Organisms in the 21st Century (SCOTTY)*, https://www.umweltbundesamt.de/en/topics/chemicals/biocides/sustainable-control-of-harmful-organisms-in-the

[3] European Chemicals Agency. (n.d.) *Authorisation*. https://echa.europa.eu/regulations/reach/authorisation/applications-for-authorisation

[4] European Chemicals Agency. (n.d.) *Restriction process.* https://echa.europa.eu/restriction-process

Regulations[5], which provides harmonised work health and safety laws across states and territories, contains provisions for risk management. This relies on the hierarchy of control, a system for controlling risks in the workplace that includes substitution.

In March 2022, the Canadian government launched national consultations with interested stakeholders on mandatory labelling for chemicals in consumer products, including cosmetics, cleaning products, and flame retardants in upholstered furniture. The consultations will help identify ways to address both the growing public demand for readily accessible information on chemicals in consumer products and the need for better ingredient disclosure to enable the informed substitution of toxic chemicals with safer alternatives. Views on the type of information needed by consumers have varied, for example, on whether ingredient lists or risk communications would be most appropriate. Participants have highlighted the importance of applying a scientific approach to define the scope of any labelling requirements, taking existing labelling regimes into account, and considering data standardization and interoperability in addition to alignment with other jurisdictions. There is general agreement that labelling approaches should include digital considerations, for example in how information is reported, stored, or provided to consumers.

Biocidal products are a further focus area of regulatory approaches, and in Europe, the core lies with the EU Biocidal Products Regulation (BPR). In addition to exclusion provisions for active substances of very high concern, the BPR also provides for substitution criteria with the concept of candidates for substitution for certain active substances presenting a concern. Products containing active substances that are candidates for substitution are subject to a comparative assessment before they are considered for authorisation. Individual countries have initiated complementary regulatory measures such as the efficacy testing of rodent traps as alternatives to rodenticides under the German Infection Protection Act, which results in a comprehensive public list[6] of approved products which drives substitution.

2.1.2. Voluntary approaches

Regulatory measures are frequently important driving forces for complementary, voluntary approaches supporting substitution.

Platforms for dialogue and exchange of information

In many cases, voluntary approaches are multi-stakeholder approaches, seeking to engage a variety of stakeholders and establishing dialogue and cooperation. One such example is Australia's PVC Stewardship Program (PSP)[7], a voluntary

[5] Safe Work Australia. (n.d.) *Model WHS Regulations.* https://www.safeworkaustralia.gov.au/doc/model-whs-regulations

[6] Umweltbundesamt. (n.d.) *Liste der geprüften Mittel und Verfahren zur Bekämpfung von Gesundheitsschädlingen, Krätzmilben und Kopfläusen gemäß § 18 Infektionsschutzgesetz.* https://www.umweltbundesamt.de/sites/default/files/medien/362/dokumente/ss_18_liste_infektionsschutzgesetz.pdf (German only)

[7] Vinyl Council Australia. (n.d.) *PVC Stewardship*. https://www.vinyl.org.au/sustainability/stewardship

initiative launched in 2002 that brings together raw material suppliers, product manufacturers and distributors to share in the management of health, safety and environmental aspects of PVC products throughout their entire life cycle. Today there are more than 50 signatories to the PVC Stewardship Program and the Program's commitments range from production and storage to waste management, research and reporting and include substitution of hazardous substances such as lead and cadmium.

In Germany, the German Environment Agency (UBA) organised a stakeholder dialogue concerning the substitution of creosote-treated wooden railway sleepers in 2020 in light of the evaluation for the renewal of creosote as an active substance under the EU Biocidal Product Regulation. Stakeholders came together to gather and share their experience and knowledge with alternatives to creosote containing products.

The European Chemicals Agency has supported EU member states in organising supply chain workshops to identify possible solutions to specific substitution-related challenges. In addition to fostering dialogue among the various concerned actors within the supply chain on the opportunities and challenges of substitution, the workshops can lead to concrete innovation projects and collaboration. Examples include a workshop held on bisphenols in thermal paper organised by Belgium in 2019 or a workshop on antifouling paints for recreational boats by Germany in 2018. Lessons learnt from these events have been shared on the relevant website by ECHA.[8]

Online Tools supporting substitution & informing consumers

Online tools and platforms remain a popular means to support substitution and alternatives assessments. In addition to France's previously mentioned Portal on Chemicals Substitution, the country's Agency for Food, Environmental and Occupational Health and Safety (ANSES) launched an online portal[9] on the substitution of carcinogenic, mutagenic, or toxic to reproduction (CMR) substances. The site, which contains information on 122 CMRs and provides almost 400 examples of substitution, has over 500 industry participants and continuously shares information on progress of research on substitution, actions taken and work in progress.

In 2020, the German Federal Institute for Occupational Safety and Health (BAuA) relaunched SUBSPORTplus[10], a substitution support portal including a database of restricted and priority substances with more than 35.000 entries from over 30 different lists and a database of case stories with more than 350 practical examples as inspiration source for substitution. The site is mainly intended to provide information on legislation and international agreements relevant to substitution, the substitution process including tools and evaluation methods, as well as sharing practical examples from companies, literature and other sources.

[8] European Chemicals Agency. (n.d.) *Supply Chain Workshops.* https://echa.europa.eu/substitution-supply-chain-workshops

[9] ANSES. (n.d.) *substitution-cmr.fr*. https://www.substitution-cmr.fr/

[10] Federal Institute of Occupational Health and Safety. (n.d.) *SUBSPORTplus.* https://www.subsportplus.eu/

Another German online initiative is the website "Biozid-Portal"[11] launched in 2010 that is aimed at non-professional users of biocidal products and provides information on how to substitute biocidal products in households.

This is only one of several similar initiatives that address end users and consumers specifically. In 2017, the LIFE AskReach Project[12] was initiated by a diverse consortium of authorities, NGOs, and research partners under the framework of the European Union's LIFE Program with the aim to reduce exposure to substances of very high concern (SVHCs) by raising awareness and changing consumer purchasing behaviour and product design approaches by market actors. To this aim, an app (Scan4Chem) was developed that allows consumers to exercise their right to request information about SVHCs in articles from the suppliers. It encourages consumers to send SVHC information requests to the supplier of a specific article of interest and also supports suppliers, allowing them to provide pertinent information on their article in the AskREACH database. The project was accompanied by targeted campaigns towards consumers and companies along the entire supply chain (article producers, retailers, etc.)

Fostering innovation

Compared to the survey results of 2019, there were fewer initiatives mentioned in 2022 that support research and innovation in the area of substitution. Denmark's Eco-Innovation Programme contains, alongside the establishment of innovation partnerships to promote cooperation and dialogue between stakeholders as well as international knowledge exchange, a subsidy scheme that supports research projects on the development of environmentally friendlier products and product processes including substitution of harmful chemicals. The German Federal Institute for Occupational Safety and Health has developed the Safe-to-use Concept[13], which combines requirements for substitution with concrete safety levels at the workplace and funds a number of on-going research projects.

Health Canada is engaged in an international, multidisciplinary research project between academia, government, and non-governmental organisations on responsible replacement of endocrine disrupting chemicals, including the use of new approach methodologies (NAMs). With a focus on flame retardants and plasticisers as example chemical classes, the main goals of the research project are to (1) determine potential exposure to replacement chemicals, (2) examine the toxicity and potential adverse health effects, and (3) engage with project partners from government, industry, and non-government agencies to discuss safer alternatives.

[11] Umweltbundesamt. (n.d.) *Biozid-Portal*. https://www.umweltbundesamt.de/themen/chemikalien/biozide/biozid-portal-start (German only)

[12] *LIFE AskREACH* (n.d.) https://www.askreach.eu/

[13] Federal Institute of Occupational Health and Safety. (n.d.) *Safe-to-use chemicals and products.* https://www.baua.de/EN/Tasks/Work-and-research-programme/Safe-to-use-chemicals-and-products.html

Setting standards

Labelling schemes for consumer products remain a frequent type of approach setting environmental standards. These schemes target the use phase of a product's life cycle and seek to inform and encourage consumers to choose safe(r) products.

In the United States, the US EPA Safer Choice Project[14] enables consumers and businesses to find products that perform and are safer for human health and the environment. In exchange for the use of the Safer Choice label, manufacturers and suppliers agree to use only chemicals that meet the program criteria.

Similarly, in Australia, the Recognised®[15] eco-label identifies environmentally preferable commercial cleaning products and has registered over 110 products to date. The Recognised® Environmental Credential Scheme establishes a set of criteria defining the characteristics of environmentally preferable cleaning products which is assessed and accredited by an independent third party.

Details on similar certification and labelling schemes such as the German "Green Button"[16] and Ecolabel "Blue Angel"[17], or Australia's National Laundry Product Phosphorus Standard[18] can be found in the annex of this report.

[14] United States Environmental Protection Agency. (n.d.) *Safer Choice.* https://www.epa.gov/saferchoice

[15] Accord. (n.d.) *Recognised.* https://accord.asn.au/sustainability/recognised/

[16] Green Button. (n.d.) https://www.gruener-knopf.de/en

[17] Blue Angel. The German Ecolabel. (n.d.) https://www.blauer-engel.de/en

[18] Accord. (n.d.) *Phosphorus Standard.* https://accord.asn.au/sustainability/phosphorus-standard/

3. Evaluating the impact of approaches and challenges to design and implementation

3.1. Identified benefits

Several respondents highlighted the difficulty of evaluating the impact of approaches that support substitution since their impact and final results often lie beyond the expiration of the respective project period. Nevertheless, various beneficial outcomes have been identified:

3.1.1. Improvements in health and environmental impacts of consumer products

A number of projects and programmes have resulted in tangible reductions in the use of harmful chemical substances such as the Australian PVC Stewardship Program that has led to the increased substitution of LMW phthalates and phasing out of lead and other chemicals, or the BeadRecede[19] Campaign that has resulted in a 99.3% phased-out removal of solid plastic microbeads from rinse-off personal care and cleaning products. Moreover, initiatives have the potential to drive innovation towards desirable alternatives as in the case of the Phosphorus Standard in Australia that has resulted in increasing numbers of products with negligible (less than 0.5%) phosphorus content.

A 2021 meta-analysis on the socio-economic impacts of REACH authorisations has found indications that considerable substitution has taken place as no applications have been received for almost half of the substances of very high concern on the Authorisation List since the implementation of REACH regulation. The findings suggest that the use volumes of the first 24 SVHCs for which authorisations have expired dropped by 97% at the review stage (European Chemicals Agency, 2021[2]). A causal effect between REACH authorisations and substitution can, however, not be demonstrated, as the observed reductions might also be brought about by efficiency gains, withdrawal or relocation of companies and/or overreporting of initial volumes.

3.1.2. Knowledge sharing and collaboration

A collaborative approach to support substitution remains a frequently cited way to share knowledge on safety, performance, and quality between established industry actors with new industry entrants, regulators, and consumers. This knowledge exchange is used by regulators to inform practices and policies and aims at nudging consumers towards choosing safer alternatives. Additionally, this helps stakeholders establish contacts for further exchange on the topic of substitution.

3.1.3. Access to tools and guidance

Of the above mentioned online tools and platforms, several address manufacturers and provide additional tools and guidance on substitution, related regulations, links as well as databases and lists designed to help manufacturers

[19] Accord. (n.d.) *BeadRecede.* https://accord.asn.au/sustainability/beadrecede/

find safer chemical alternatives. These platforms can also act as an entry point for industry actors with questions on substitution.

3.1.4. Adoption of life cycle thinking

Regulatory as well as voluntary approaches continue to contribute to a paradigm shift towards a more holistic approach to considerations of the environmental impact of products or processes beyond manufacturing. In particular, broad approaches that address substitution in a wide variety of forms can be appealing to many companies.

3.2. Challenges to implementation

The follow-up survey demonstrated that there remain a considerable number of challenges to the successful implementation of approaches supporting substitution of chemicals of concern. Notably absent from the mentioned challenges is regrettable substitution, which had been identified as a major challenge in the previous survey of 2019.

3.2.1. Impact of Covid-19 pandemic

The Covid-19 pandemic has not only led to new areas of interest for initiatives such as Australia's Accord Industry Hand Sanitiser Benchmark[20] that came into focus due to increased use by consumers as well as supply chain disruptions, but its impact can also be felt in additional challenges encountered in the implementation of approaches supporting substitution. Notably communication with overseas suppliers, in particular in the case of suppliers located in Asia, has been identified as a significant challenge.

3.2.2. Costs and economic incentives

Many respondents noted that substitution is an expensive and time-consuming process and that balancing environmental and economic incentives remains difficult, which may hinder certain companies from engaging in efforts to find safer alternatives. Similarly, a lack of resources and competing priorities of governments can slow down or hamper efforts to promote substitution.

3.2.3. Complexity

Complexity remains a frequently cited challenge in the implementation of approaches supporting substitution. Whereas the responses to the previous questionnaire highlighted the complexity of supply chains, this year's responses focused on the complexity arising from the broad range of products targeted by certain approaches. Biocidal products, for example, with a great variety of uses present a challenge as the resulting options for substitution are manifold and complex. Similarly, setting criteria for standards and labelling schemes require the weighing of risks and benefits of alternatives and can thus be very complex.

[20] Accord. (n.d.) *Hand Sanitiser Industry Benchmark for Non-Therapeutic Goods*. https://accord.asn.au/useful-links/hand-sanitiser-industry-benchmark-for-non-therapeutic-goods/

3.2.4. Lack of information, data, and knowledge

There continues to be a need for additional data and information to enable consumers to make informed decisions and allow regulators to provide specific and pertinent recommendations. In particular, the lack of efficacy information and evaluation criteria for alternatives was highlighted as an obstacle to encouraging substitution. Likewise, the lack of relevant data on low-hazard chemicals was also highlighted, as they are often not subject to extensive toxicological testing and data development.

A lack of knowledge on the part of consumers and resulting demand, can lead to a vicious cycle as noted by Germany in the case of the EU LIFE AskREACH project where companies expect consumers to show interest by sending information requests before they invest resources to provide the requested information on their products. Consumers, on the other hand, expect companies to have the information already provided and made accessible and do not submit requests when they cannot find the information.

3.2.5. Non-compliance

Non-compliance and the difficulty to monitor the implementation of actions in practice based on information shared on online platforms has been noted in several cases. Non-regulatory initiatives have experienced a reduced impact when compliance is low or participation remains limited, as it can be challenging to reach all target groups for the practical application of an initiative. This is the case especially for approaches aiming to phase out certain harmful substances as non-compliant actors continue to contaminate inputs into the supply chain via recycled content. In the case of Accord's BeadRecede campaign it was observed that broad membership reach and industry credibility aided the process of gaining voluntary commitments to the phase-out.

3.2.6. Continued support and regular updates

Maintenance of web portals and knowledge exchange platforms has been identified as a challenge as they require regular updates and thus resources to stay relevant and useful for the intended purposes.

4. Third-party approaches supporting substitution

For the Workshop on Government Approaches to Incentivise Substitution, a report detailing third-party approaches that support substitution of chemicals of concern was prepared, providing an overview and brief analysis of existing third-party approaches as well as an assessment of ways that governments can adopt or support elements of third-party approaches (OECD, 2023[3]). A summary is provided here, and readers are encouraged to consult the document for illustrative examples and more information.

Third-party organisations (not government or regulated industry) such as academic institutions, non-profit organisations and retailers actively support informed substitution through a wide range of approaches. Collectively, these approaches cover many different aspects of managing and reducing chemical risk and are targeted toward a variety of audiences.

Tools, frameworks and other technical resources have been developed that are relevant at different stages of the substitution process: they may provide steps or guidance to help practitioners conduct alternatives assessments; provide resources for identifying chemicals of concern and/or safer alternatives; or promote innovation and development of new alternatives.

Training and technical assistance, ranging from customised, person-to-person technical support to live or recorded trainings on chemical substitution principles or practices are available to retailers, manufacturers, non-governmental organisations, innovators, students and other interested stakeholders.

Third-party ecolabels help consumers and institutional purchasers identify products and services that meet specific health and environmental criteria and help manufacturers and other companies signal those traits to their customers. Labelling helps consumers make informed purchasing decisions and stimulates market demand for retailers and manufacturers to provide safer chemistries.

Advocacy efforts and other campaigns that target industry, retailers, governments and/or consumers aim to raise awareness of the need for and benefit of informed substitution and almost always include some element of outreach and awareness-raising to the general public, which further increases the impact of the campaign as companies and governments face pressure from their consumers or constituents.

Collaboration programmes and professional associations support knowledge sharing and capacity building, as well as collaboration on scientific and methodological advances.

Retailers have also developed different approaches to both reduce the volume of hazardous chemicals in the products they sell and educate their customers about purchasing products without chemicals of concern. For example, some retailers leverage chemical ingredient and chemical footprint disclosure as a tool to move toward safer chemistries, or they leverage ecolabels or other product rating systems to enable and encourage their customers to choose safer and more sustainable products, putting market pressure on suppliers to make safer options available rather than directly requiring those changes.

A common and important feature of third-party approaches is their complementarity to government initiatives on substitution. Many third-party approaches build on previous government efforts such as the GreenScreen® method for comparative hazard

assessment which was developed using a U.S. Environmental Protection Agency (EPA) alternatives assessment method as a starting point, or the SIN List, developed by ChemSec, which relies on criteria defined within REACH to identify chemicals of concern that should be prioritised for substitution. Likewise, third-party approaches support government efforts by disseminating and making more easily accessible government resources on substitution, providing tools and methods to support and inform policies pertaining to use of chemicals in consumer products, or providing feedback on policies related to chemical risk management implemented by authorities such as the Safer States campaign that provides a ranking of U.S. States with regard to protective policies that reduce exposure to harmful chemicals.

Other common features of third-party approaches are their wide use and adoption across the community of practice, their flexibility to respond to the latest science and methodological advances, the involvement of multiple stakeholders in development and implementation, and the ability to spur demand for safer chemicals and products in the marketplace.

5. Economic instruments to incentivise substitution

A scoping study on economic instruments to incentivise substitution (OECD, 2023[4]) was also prepared for the Workshop in order to give an overview of economic instruments, based on indicative examples. The report also addresses the challenges of the choice and design of economic policy instruments and outlines opportunities for using economic instruments to incentivise substitution. Highlights are provided here, and readers are encouraged to access the full report for further detail.

Economic instruments have been extensively used in many environmental domains but have so far been applied only rarely to chemicals. There has, however, been increasing interest in the potential of economic instruments to incentivise substitution of chemicals of concern, as evidenced by recent initiatives such as the review of policy instruments for enhanced chemicals management and sustainable funding initiated by the Department of Toxic Substance Control in California (Tickner J., 2022[5]), the SAICM review of cost recovery mechanisms and other economic instruments (SAICM, 2020[6]), and the attention paid to fiscal incentives for chemicals management in the Global Chemicals Outlook II (UNEP, 2019[7]).

By changing the relative price between chemicals of concern and their less hazardous alternatives, economic instruments can provide continuous incentives for industry to innovate and substitute with safer alternatives. Companies have an incentive to substitute the targeted chemicals as long as their marginal cost of substitution if lower than the cost of using the targeted chemicals.

The study identifies five types of economic instruments and provides examples for each type, as detailed in the report. This includes taxes, fees/charges, subsidies, and tradable permits.

One of the main reasons why price-based instruments are still relatively rare in chemicals regulation is that primary focus has been on very hazardous substances, where other regulatory measures such as bans and restrictions are more appropriate. Similarly, in situations where effects are location-specific or where threshold effects, i.e., an abrupt spike in the damage function after a given threshold, are likely, economic instruments are ill-suited. There are, however, cases where taxes and other market-based instruments ca provide important complements to other types of regulatory measures.

The main benefit of market-based instruments is their ability to stimulate cost-effective substitution and spur innovation. The above-mentioned instruments can incentivise substitution through 3 key mechanisms:

1. Making chemicals of concern more expensive by internalising environmental and health costs in the prices facing producers and consumers;
2. Generating revenue that can be used for information diffusion, technical assistance, and capacity building;
3. Generating revenue that can be used for research and innovation in alternatives.

It can be beneficial to combine economic instruments with restrictions on hazardous chemical exposure. Introducing a tax or fee that creates incentives for substitution and innovation can also ease the implementation of tougher use restrictions or bans at a later stage. An important lesson from the use of taxes on chemicals in consumer products is that supply chain transparency and access to information on chemical content in products are important pre-requisites for the effective design and implementation of economic instruments.

6. Information sharing to support substitution

Both the survey underlying the present report as well as the discussions at the September 2022 workshop on substitution have identified the lack of data and information as one of the primary barriers to advancing substitution. Regulators lack information and data of the contents and uses of products placed on the market, rendering the design of effective policy instruments challenging, and companies generally do not disclose information about the cost of substituting certain chemicals and the availability of alternatives (OECD, 2023[4]). Companies, on the other hand, frequently lack efficacy information and evaluation criteria for alternatives and data on low-hazard chemicals as these are often not subject to extensive toxicological testing and data development (see 3 3). Yet, at the same time, regulatory initiatives that include reporting requirements generate important data from businesses, the potential benefits of which are manifold:

- Serve as evidence of successful instances of substitution
- Amplify consideration to viable alternatives
- Create opportunities for follow-up inquiries and exchange of information
- Identify emerging alternatives
- Confirm trends and encourage others to adopt

Leveraging the gathered information, however, can be challenging and requires considerable financial and human resources. Table **1** outlines three regulatory initiatives containing reporting requirements and their experience in rendering publicly available the collected data and information.

Table 1: Regulatory approaches including reporting requirements

Regulatory approach	Information / Data gathered	Processing data
Toxics Release Inventory (TRI)	The U.S. Toxics Release Inventory (TRI) is an information resource about toxic chemical waste management that has gathered annual reports from facilities since 1987. The inventory constitutes a powerful resource as it is one of EPA's most current datasets, compiled annually and contains information on on-site releases into the air, water and land, on-site recycling, energy recovery, transfer of chemicals in waste to off-site locations for further management, as well as newly implemented source reduction activities, including substitution.	From 2005-2020, data from 46,035 source reduction comments were reported but underutilized and only explorable in downloadable formats with limited filtering options. An open-source R script was used to extract and process comments data based on filtering parameters and key word matches. This methodology allowed authorities to identify 1,926 comments related to solvent substitution.

Toxics Use Reduction Act (TURA)	TURA requires facilities that use large amounts of toxic chemicals to prepare annual reports on amounts used, wasted, shipped in product, released onsite, or shipped offsite as pollution, as well as conduct planning every two years which includes an assessment of potential alternatives. Moreover, businesses subject to the act are required to pay a progressive fee.	The fees paid by TURA filers support the work of the TURA implementing agencies and are used to provide a wide variety of services to toxics users, such as education, training, grant programs and technical assistance. This includes the processing, analysis and visualization of the data gathered under TURA, which is publicly available on the website of the Toxics Use Reduction Institute's (TURI)[21].The data is available both as searchable data extracts, and under the TURA Data online tool that allows for search by community, facility or chemical as well as trends and overviews of total uses and releases.
REACH Authorisation	In the context of REACH Authorisation process, companies applying for an authorisation for the use of an Annex XIV substance need to provide information on substances or techniques they identify as potential alternatives to the substance they currently use. This Analysis of Alternatives (AoA) contains information on technical and economic feasibility, availability and the risk reduction potential of identified alternatives. As this information is provided in the context of the application for authorisation and thus by businesses aiming to prove the inadequacy of alternatives, the information may be inherently biased.	Applicants to the Authorisation process present the required information in the AoA, which is submitted as part of their authorisation application and their public version is published in PDF format on ECHA's website. The key information on these alternatives is extracted into a spreadsheet for internal purposes, but this file is not published. The published AoAs contain information on the substance used including use descriptions, potential alternatives and reasons for rejecting them, as well as most promising alternatives. Applicants can request to maintain aspects of the information confidential to protect their business interests and, for example, the most promising alternative is published in only 10-15% of cases.

[21] Toxics Use Reduction Institute. (n.d.) TURA data. https://www.turi.org/Our_Work/Toxic_Chemicals/TURA_Data

7. Substitution, Innovation and Safe and Sustainable by design

Regulation and voluntary initiatives supporting substitution present an opportunity for industry to design and produce new products that are fit for the circular economy. In particular, regulation that stipulates alternatives assessments as well as voluntary approaches that support research on safer alternatives can drive industry innovation.

Similarly, the concept of safe and sustainable by design (SSbD) is being developed to support innovation in the chemicals industry. The relatively novel concept with no single agreed-upon definition has gained considerable attention in the past years. The integration of safety and sustainability considerations into a product's pre-market design phase, however, is very complex and requires the involvement of a great variety of stakeholders and clear criteria for what constitutes safe and sustainable. While the formulation, definition and operationalisation of the concept are still in early stages, there are currently several on-going initiatives supporting the development of SSbD criteria and its operationalisation. The below does not constitute an exhaustive list of on-going approaches but seeks to illustrate the current landscape of SSbD initiatives through a number of examples.

While the recent SSbD conceptualisation is on-going, the premise of the concept links with sustainable and green chemistry, safe by design, safe innovation and other similar approaches. The approach can also draw upon approaches and methodologies that have been used to support substitution and alternatives assessments.

7.1. Government initiatives

In the context of the European Green Deal, the EU Commission released the Chemicals Strategy for Sustainability (CSS), aiming at a transition towards safe and sustainable chemicals. As part of this political action plan, the EU Commission is developing a framework to define safe and sustainable by design criteria for chemicals and materials (Caldeira, 2022[8]) and support their design and development with research and innovation activities. The proposed framework follows a hierarchical approach in which safety considerations are prioritised, followed by environmental, social and economic aspects. It takes a stepwise approach, where a (re)design phase, in which design guiding principles are proposed to support the design of chemicals and materials, is followed by a safety and sustainability assessment.

In June 2022, the EC launched the International Ecosystem for Accelerating the Transition to Safe-and-Sustainable-by-design Materials, Products and Processes (IRISS) project[22]. The three-year project seeks to build a global, permanent network of experts and stakeholders and support companies with knowledge, the implementation of research and contribute to guiding principles for the

[22] European Commission. Cordis. (n.d.) *The International Ecosystem for Accelerating the Transition to Safe-and-Sustainable-by-design Materials, Products and Processes*, https://cordis.europa.eu/project/id/101058245

development of life cycle thinking in material and product design. The project will focus on six value chains: textiles, construction, electronics, energy, automotive and packaging.

The Dutch government, with support from stakeholders across Europe, has developed the Safe Chemicals Innovation Agenda (SCIA) (Netherlands Government, 2018[9]), a research agenda to guide R&D policies at the EU and Member State level. The initiative addresses not only policy makers and regulators, but also researchers directly and their funders. The SCIA focuses on seven research themes for further research into safer alternatives: Water, grease and dirt repellents; fire safety; preservation; plasticising; solvents; surfactants, and process regulators. In 2021, the Dutch government further launched a call for proposals under the Towards a practical Safe-by-Design approach for chemical products and processes, a thematic programme of the Dutch Research Agenda (NWA). The research programme aims to develop a practically applicable Safe-by-Design approach for the design of chemical substances and processes and to provide recommendations to the government to further implement and disseminate the approaches developed and insights acquired.

Another recently launched initiative is the European Partnership for the Assessment of Risks from Chemicals (PARC)[23] under the EU's Horizon Europe framework programme which brings together 200 partners from 28 countries as well as EU agencies to advance research, share knowledge and improve skills in chemical risk assessment. One of the partnership's goals is to support the operationalisation of SSbD criteria and methodology by translating them into a toolbox, integrating existing tools for safety and sustainability assessment as well as developing new tools.

Especially in the field of emerging technologies, such as nanotechnology, SSbD has gained notable interest and is the focus of several ongoing European projects with funding from the EU's Horizon 2020 programme. Sunshine[24], an industry-oriented project that seeks to develop a novel e-infrastructure to support dialogue, collaboration and information exchange between stakeholders along the entire product supply chain, focuses on developing and implementing SSbD strategies for materials and products incorporating advanced multi-component nanomaterials. The Development and scaled Implementation of Safe by Design Tools and Guidelines for Multicomponent and HARN Nanomaterials (DIAGONAL)[25] project aims to develop research on specific hazard and exposure properties of multicomponent nanomaterials (MCNMs) and high aspect ratio nanomaterials (HARNs) exhibit along their life cycle to inform adapted or novel risk management guidelines including safety and sustainability considerations. A further example is the Anticipating Safety Issues at the Design

[23] European Commission. Cordis. (n.d.) *European partnership for the assessment of risks from chemicals.* https://cordis.europa.eu/programme/id/HORIZON_HORIZON-HLTH-2021-ENVHLTH-03-01

[24] European Commission. Cordis. (n.d.) *Safe and Sustainable by Design Strategies for High Performance Multi-component Nanomaterials.* https://cordis.europa.eu/project/id/952924

[25] European Commission. Cordis. (n.d.). *Development and scaled Implementation of Safe by Design Tools and Guidelines for Multicomponent and HARD Nanomaterials*. https://cordis.europa.eu/project/id/953152

Stage of Nano Product Development (ASINA)[26] project, which seeks to support industrial uptake of nanotechnology by providing Safe-by-Design solutions and supporting tools and provide knowledge on and increase awareness of Safe-by-Design potential.

With support from the U.S. National Institute for Occupational Safety and Health (NIOSH), the U.S. Green Building Council (USGBC) developed a pilot credit called "Prevention through Design"[27] to test and evaluate the novel strategy that aims to prevent occupational threats to human health by eliminating hazards and minimizing risks to workers in the (re-)design of facilities, work methods, processes, equipment, tools and products.

In the United States, the White House's Office of Science and Technology Policy (OSTP) recently published a notice of request[28] for interested parties to contribute to the definition of "Sustainable Chemistry" as the term does not yet have a consensus definition and has often been used synonymously with the term "Green Chemistry". The definition will inform Federal agencies in the development of research agendas and programs to advance the implementation, characterisation and assessment of sustainable chemistry. The notice further requested information on how the definition of sustainable chemistry could impact the role technology, federal policies that may aid or hinder sustainable chemistry initiatives, future research to advance sustainable chemistry, financial and economic considerations as well as federal agency efforts.

7.2. Industry and Third-Party Approaches

Certification and labelling schemes are a frequent type of approach by industry and third parties in support of innovation by focusing on SSbD. The Cradle to Cradle Products Innovation Institute aims to set a global standard for products that are safe, circular and made responsibly[29]. The standard assesses products across five categories of sustainability performance: material health, product circularity, clean air and climate protection, water and soil stewardship, and social fairness. The initiative also supports businesses by providing guides on safe and circular design, including case studies and other educational material.

Another well established, global ecolabel is the Electronic Product Environmental Assessment Tool (EPEAT)[30], developed with a grant from U.S. EPA and owned and managed by the Global Electronics Council (GEC). EPEAT-registered products must meet environmental performance criteria addressing materials selection, supply chain greenhouse gas emissions

[26] European Commission. Cordis. (n.d.) *Anticipating Safety Issues at the Design Stage of Nano Product Development*. https://cordis.europa.eu/project/id/862444

[27] U.S. Green Building Council. (n.d.) *Prevention through Design*. https://www.usgbc.org/credits/preventionthroughdesign

[28] Federal Register. 4.4.2022. *Request for Information: Sustainable Chemistry.A Notice by the Science and Technology Policy Office on 04/04/2022*. https://www.federalregister.gov/documents/2022/04/04/2022-07043/request-for-information-sustainable-chemistry

[29] Cradle to Cradle Products Innovation Institute. (n.d.) *What is Cradle to Cradle certified?* https://www.c2ccertified.org/get-certified/product-certification

[30] Global Electronics Council. (n.d.) *EPEAT Registry.* https://www.epeat.net/

reduction, design for circularity and product longevity, energy conservation, end-of-life management and corporate performance.

The University of Massachusetts' Lowell Center for Sustainable Production and Beyond Benign, an organisation that develops and disseminates green chemistry educational resources, have established the expert committee on sustainable chemistry (ECOSChem), including experts from academia, EU and US authorities, international organisations, NGOs as well as industry, to create a definition and set of measurable criteria to advance the development and commercialisation of safer and more sustainable chemicals, products and processes.

7.3. OECD work on SSbD

Since 2021, the OECD's Chemicals Programme under the supervision of the Chemicals and Biotechnology Committee (CBC) has undertaken several activities in support of safe and sustainable chemicals.

In the context of plastics, the OECD Working Party on Risk Management (WPRM) published the report *A Chemicals Perspective on Designing with Sustainable Plastics: Goals, Considerations and Trade-offs* in December 2021 (OECD, 2021[10]). The report aims to enable the creation of inherently sustainable plastic products by integrating sustainable chemistry thinking in the design process. The report provides an integrated approach to sustainable plastic selection from a chemicals perspective, and identifies a set of generalisable sustainable design goals, life cycle considerations and trade-offs. The report was geared towards industry stakeholders and a workshop was organised in May 2022 to examine the practical challenges to implement the considerations in the report. The scope of the workshop was narrowed to the scenario of flexible food grade plastic packaging, and, building on two background reports, the workshop sought to understand the barriers the industry faces to more sustainable design from a chemicals perspective, discuss policies being put in place by governments, and identify areas where additional policies could help.

In addition, the OECD's *Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternatives* (OECD, 2021[11]), published in 2021, provides input to SSbD regarding guidance on the 'safe' aspect of SSbD.

In 2020, the OECD Working Party on Manufactured Nanomaterials published the report *Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable Nanomaterials and Nano-enabled Products* (OECD, 2020[12]), combining the Safe-by-Design (SbD) and Regulatory Preparedness (RP) concepts to formulate a novel Safe(r) Innovation Approach (SIA) for NMs and nano-enabled products. While the report did not address sustainability specifically, it nevertheless included some tools pertaining to sustainability assessments, such as Life Cycle Analysis (LCA) and Socio-Economic Analysis (SEA). Moving from a Safe(r) Innovation Approach to a Safer and Sustainable Innovation Approach (SSIA), the WPMN developed two working descriptions of Sustainability and Safe and Sustainable by Design (SSbD) to further the implementation of SSbD for nanomaterials and advanced materials.

8. Lessons from industry

In a session at the September 2022 workshop dedicated to the experience of industry in substituting hazardous substances in their products, three industry representatives have shared different approaches to substitution and their respective lessons learned. These approaches and lessons can also be informative to government in developing approaches to support substitution.

Estée Lauder, a manufacturer, marketer and seller of cosmetic products, has developed the Green Score methodology (Eckelman et al., 2022[13]), a hazard-based assessment tool to assess and measure ingredients and formulas by considering several human health, ecosystem health and environmental endpoints. The methodology was developed to complement the company's existing risk-based safety programme and constitutes a design tool to support the company's formulators to translate expected and identified hazards into a useful metric that not only assesses existing products but also supports the design of innovative, higher-performing products by substituting early in the design phase. Moreover, the score generates valuable data used to internally measure progress. To develop the framework, ingredient and chemical component data were gathered from manufacturers, open-source databases and computer model estimates. In early 2022, the Green Score methodology, data sources and framework were published in the academic journal Green Chemistry in order to make the methodology accessible and get important feedback for its continuous improvement and development.

Dow, one of the world's largest chemical producers, has launched, as part of their 2025 Sustainability Goals, a product safety blueprint[31] that is published externally and informs, among others, on the company's collaborations with governments, companies and academia conducted to advance science-based safety assessments. Product safety assessments are conducted with the help of predictive computational methods, such as grouping and read-across, and are an essential element early in the product design phase in the search for safer alternatives, As part of their sustainability strategy, the company further defined a set of criteria to advance products that reduce potential impact to humans and the environment, to develop products with an advanced life cycle to advance overall progress on sustainability and to ensure strong product performance to meet market and customer expectations.

Tarkett, a French multinational corporation specialising in the production of floor and wall coverings, has applied cradle-to-cradle principles to all of their product ranges which include material health, material reutilisation, renewable energy, water stewardship and social fairness. In determining material health, Tarkett collaborates with the Environmental Protection Encouragement Agency (EPEA), a third-party organisation and an accredited assessment body for the Cradle to Cradle Certified certification standard (see 77), to assess the hazard profile of a given product. This information is captured in their product material health statements that are produced by EPEA and are made publicly available for all Tarkett products. They disclose a product's chemicals content down to

[31] Dow. (n.d.) *Dow's blueprint for product safety.* https://corporate.dow.com/en-us/science-and-sustainability/2025-goals/blueprint/product-safety.html

0,01%, the result of the EPEA risk assessment, as well as regulatory compliance status. This collaboration with an independent third-party organisation has helped Tarkett in ensuring external expertise in toxicology and eco-toxicology, securing the confidentiality of suppliers proprietary and strategic information and providing trustworthy information to customers on product formulation and results of chemicals risks assessment in the intended product use.

Industry representatives have emphasised the hurdles that regulation can present to their substitution efforts:

- regulatory compliance requires considerable resources, especially for multinational organisations that manufacture and sell in many different regions and countries;
- regulation can slow down reformulations with safer alternatives as the case of Dow's ECOSURF surfactants, a biodegradable alternative to alkylphenol ethoxylates (APEs), that did not see increased sales for almost a decade as regulatory hurdles impeded manufacturers to reformulate their products.

The need for access to data as well as traceability and transparency in the supply chain has been highlighted as crucial for collective progress in substitution efforts, in particular in light of a pronounced demand for it by end-users and consumers. The experience of Tarkett, which is collaborating with an independent third-party organisation to protect their suppliers' data confidentiality, was described as crucial to their substitution efforts. There is an opportunity for governments to support the sharing of experience amongst industry stakeholders on how they have managed to enhance transparency along the value chain and how they have used this to support their substitution efforts.

Moreover, more transparent and flexible data and information exchanges, as well as the development of standardised and harmonised methodologies present opportunities for industry actors to accelerate their substitution efforts.

9. Lessons learned: the role of governments in driving substitution

Discussions between country delegates and stakeholders at the September 2022 workshop identified a set of priorities actions for governments to focus on in order to further the substitution of harmful chemicals.

9.1. Fostering communication and collaboration

If important progress has been made in the past decade to improve communication amongst stakeholders on substitution challenges, there is still a need to strengthen dialogue to help in the sharing and provision of information that remains a key barrier to sustainable substitution practices. The workshop highlighted the need to foster dialogue amongst industry along the supply chain, trade unions, public authorities, regulators, and NGOsPublic authorities should include all relevant authorities bringing their different perspectives and priorities being for example, growth, sustainable business, and the protection of health and the environment. Such a dialogue should be a continuous practice as the field and knowledge evolve and would allow to provide a comprehensive approach covering all aspects of substitution for the development of safer and more sustainable products, including economic and social aspects.

Strengthening communication was pointed out as one of the best means to help address the complexity of substitution, the numerous trade-offs and the "fear of the unknown" that might affect industry when engaging in substitution. It is also a way to share more effectively existing resources, in particular case studies of both successful and regrettable substitution and take them more accessible to businesses.

Governments are in a unique position to foster collaboration not only between government and industry, but also among industry stakeholders as well as third parties. Dialogue and close collaboration that goes beyond the mere provision of regulatory frameworks, sharing of best practices and case studies to make information practicable are seen as promising actions to promote substitution.

Collaboration through financial means constitutes a further possible measure of how governments could leverage their purchasing power and support third-party ecolabels (see 4).

Provision of information on properties of chemicals and remaining data gaps

The lack of comprehensive and quality data and information on properties of chemicals in use and alternatives remains a major barrier to substitution for many industry actors (see also 3 and 6) and the workshop emphasised the role governments can play to support the filling of important remaining data gaps. The workshop also raised the need to leverage the data already available in public agencies and to find ways to share this data effectively while considering the different information needs from industry, consumers, and manufacturers.

Governments that decide to implement economic instruments to regulate hazardous chemicals could utilise revenues from fees and taxes to fund research

and development and leverage industry and third-party generated data and information on chemical uses and alternatives.

Participants moreover voiced the need for additional research and information on more complex chemistries and challenges, such as complex substances or articles, which amplify life cycle implications, as well as manufacturing processes. An increased focus on function rather than substance to move away from drop-in substitution was also highlighted.

9.2. Promoting transparency

Both industry and government representatives have voiced the need for increased transparency in chemicals produced, used and released along the life cycle of substances and products. Industry is experiencing a growing demand for transparency from consumers but face constraints by limited transparency in the supply chain. A lack in transparency in the reporting of uses, alternatives, functions, performance and toxicity also constrains the design of effective policy instruments.

This is an issue that was identified since the initiation of the OECD work on substitution and alternatives assessment, and it remains a bottleneck for the field. Often the issue of confidentiality is raised by industry, but some strategies are being developed, for example through the use of a third-parties that play the role of intermediary between chemical manufacturers and downstream-users, helping to secure the confidentiality of suppliers proprietary and strategic information while allowing to provide trustworthy information to customers on product formulation. Efforts of this type that aim to foster transparency should be incentivised and further discussions are needed on concrete means to do so. Enhanced transparency required by regulatory measures could create strong incentives to eliminate hazardous substances and reduce pollution to be a "good neighbour".

9.3. Strengthening governance for substitution: Creating regulatory stability and predictability

The workshop raised the need to create a policy framework for the field to be able to expand:

- Workshop discussions have highlighted the strong signal the prospect of regulation sends to the market and industry, and the importance of these signals being sent early in the preparations of new regulatory measures. Industry representatives emphasised the strong role regulators play in guiding industry trends and developments by communicating their priorities and preferences;
- Regulatory consistency and predictability have also been stressed as critical prerequisites for a level playing field and conditions conducive to industry development away from substances of concern and toward safer alternatives. Clear definitions (in particular of "regrettable substitution"), benchmarks and a science-based framework are essential aspects of such regulatory predictability;
- Moreover, the possibility to align regulations globally was highlighted.

9.4. Potential collaborative topics at the OECD

The workshop discussions also noted opportunities for countries to collaborate at the OECD, including on the following activities:

- Develop broader considerations (safer and more sustainable alternatives) as a follow–up to the Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternatives (OECD, 2021[11]);
- Analyse policy learnings on economic policies used to support substitution;
- Examine quota-based management of chemicals to encourage substitution - in particular for PBTs, vPvBs and other environmentally hazardous substances;
- Share information on substitution solutions across countries;
- Synthesise the best possible frameworks for evaluating substitutions.

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Annex A. Approaches to Support Alternatives Assessment and Substitution of Chemicals of Concern – Survey responses from 2022

Australia									
Name of the programme	Goal and Year of implementation	Factors or considerations that led to its development	Type of approach (non-regulatory or regulatory), incl. roles and responsibilities	Focus on products, articles or processes	Life cycle stage(s) addressed	Chemical(s) addressed	Challenges to implementation	Identified Benefits of the programme	Additional information
Australian Packaging Covenant Organisation Action Plan to Phase Out PFAS in Fibre-based Food Contact Packaging	Support businesses in Australia with the voluntary phase out of intentionally added PFAS in fibre-based food contact packaging by late 2023/mid 2024 (date TBD at time of writing)	The Australian Governments National PFAS Position Statement (2018). The Australian Department of Agriculture, Water and the Environment (DAWE) engaged and funded APCO and Planet Ark to conduct research into PFAS in fibre-based food packaging and produce a report in 2021. The Action Plan follows this report and supports Government intentions.	Non-regulatory Under the current agreement, APCO is to produce the Action Plan. Businesses can also reach out to APCO with questions re. testing and alternatives. Further discussion needed, but APCO is likely to manage the implementation and operation of a reporting mechanism and pass the data across to DAWE.	Focus on products – with option to identify/test for PFAS (total fluorine) in final products, product families or raw materials. Substitution can be made at the final product level or at the raw material input level to the packaging.	Option to address final product or raw materials	PFAS	Voluntary and non-regulatory: risk of free riders continuing to contaminate the inputs via recycled content. Current supply chain issues may render some alternatives unfeasible – meeting demand is an important part of selecting alternatives. Rising cost of living may see businesses not consider this process too costly and not a priority action.	Clearing up the compostable stream from chemical contaminants. Clearing up the recycling stream from chemical contaminants	The Action Plan is not recommending specific alternatives, rather setting out criteria for the selection of alternatives. It does however include links to supporting resources for selecting alternatives.

PVC Stewardship Program (PSP)	2002 - The aim of the Australian PVC Stewardship Program is to enable raw material suppliers, products manufacturers and distributors to be joint stewards of the safe and beneficial production, use and disposal of PVC products. All are to share in the management of health, safety and environmental aspects of PVC products throughout their entire life cycle.	The VCA was created in 1998 as the peak body representing the Australian PVC industry. In 2001, VCA commissioned the CSIRO to review the life cycle of PVC products and highlight potential concerns. The CSIRO's findings, followed by an extensive stakeholder consultation, formed the basis of the PVC Stewardship Program, a voluntary initiative launched in the following year.	Non-regulatory – While the Industry Sustainability Officer has the responsibility to manage the program, the PSP Technical Steering Group (made up of PSP Signatories and external stakeholders (government and non-government)) holds the responsibility to develop the program to ensure it remains relevant and ambitious. This includes any updates to commitments, or development of new commitments. The TSG meet quarterly.	Focus on PVC products through all stages of the life cycle. This includes product development, manufacturing, raw materials, additives, waste, recycling etc.	<--- See previous	Lead, cadmium and hexavalent chromium stabilisers and/or pigments; and low molecular weight phthalates	Communication with upstream overseas suppliers continues to be a challenge, particularly within the current COVID environment. This is particularly relevant when dealing with suppliers in Asia. Balancing out the environmental and economic incentives of substitution also continues to be challenging in some aspects.	The program has resulted in improvements in health and environmental impacts of PVC products in Australia through avoidance of mercury in upstream processes, progress in the substitution of LMW phthalates, phasing out lead, cadmium and hexavalent chromium, and the adoption of life cycle thinking in the development of new products.	We are currently looking at an update to the Open Disclosure commitment to have an increased focus on chemicals of concern, including the inclusion of a requirement that Signatories confirm the avoidance of any REACH SVHC (or equivalent listed substances.
BeadRecede Campaign	Voluntary phased-out removal of solid plastic microbeads from rinse-off personal care	Potential pollution of marine/aquatic environments by plastic microbeads. Australia's Environment Ministers endorsed	Non-regulatory. Accord Australasia coordinated the campaign. Federal Environment Department oversighted Accord actions and conducted both audits and	Focus on products and removal of a problematic ingredient (solid plastic microbeads)		Solid plastics – as abrasive beads mainly comprised of polyethylene. Alternatives substituted	Accord Australasia – a national industry body – absorbed all the costs of running the	The strong market knowledge Accord possessed as well the association's broad membership reach and industry credibility aided the process of	For more details – https://www.awe.gov.au/environment/protection/waste/plastics-and-packaging/plastic-microbeads#progr

	and cleaning products Commenced 2017. Phase-out mostly complete mid-2018. And 99.3% complete in 2020.	a voluntary approach led by the Australian industry.	retail store surveys to monitor compliance.	in rinse off products.		included mineral-based ingredients (e.g., silica) and plant-based ingredients (e.g., cellulose, nut kernels).	BeadRecede campaign. No funding from govt was sought or provided. More resources could have aided with the efficiency of the campaign. Though ultimately the campaign was successful.	gaining voluntary commitments to the phase-out.	ess-of-the-voluntary-phase-out
Recognised® Environ-mental Credentials Scheme	Third-party verified labelling scheme to identify environmentally preferable commercial B2B cleaning products. Commenced 2010.	Lack of consistency in environmental labelling claims and potential for green-washing. Scheme allows the market to identify and reward products containing safer ingredients and formulations.	Non-regulatory. Accord offers and licences use of the Scheme logo on a cost-recovery basis. Independent product formulation assessment against scientifically rigorous criteria (based in part on US EPA Design for the Environment criteria) by Davoren Environmental. Scheme subject to regular independent third-party probity audits.	Focus on products and their ingredients/formulation. Criteria encourages use of safer lower hazard/risk ingredients.		No specific chemicals addressed. However, for successful assessment against the Scheme criteria lower hazard/risk ingredients must be used.	Various costs of establishing the Scheme arrangements such as IP protection for logos were absorbed by Accord Australasia.	There are more than 110 products registered in the Scheme	For more information – https://accord.asn.au/sustainability/recognised/
Accord National Laundry Product Phosphorus Standard	To set a cap on phosphorus content in laundry product to reduce environmental pollution by phosphorus entering waterways via STPs. To introduce	Concerns over algal blooms and oxygen depletion in Australian inland waterways. Standard was established initially via an MoU with the NSW Government.	Non-regulatory. Accord administers the Standard.	Product formulation focus.		Phosphorus-based chemicals in laundry products (e.g., STTP).		While initially the Standard set an upper cap on P content and most marketed products used the related P logo, the Standard has encouraged a progressive move across the laundry market to the NP (negligible phosphorus) logo.	https://accord.asn.au/sustainability/phosphorus-standard/

	consumer labelling logos. Commenced 1994.								
Accord Industry Hand Sanitiser Benchmark	To provides detailed safety, performance and quality standards for hand sanitisers used by consumers and in various workplaces and industries.	COVID-19 pandemic and supply chain disruptions for hand sanitisers and increased used by consumers.	Non-regulatory	Products	Manufacture and supply	Chemicals used in alcohol-based hand sanitisers	Addressing a market already disrupted with problematic formulations available to consumers.	Sharing established industry knowledge on safety, performance and quality of hand sanitiser with new industry entrants and providing a frame of reference for regulators and consumers on acceptable industry practice.	https://accord.asn.au/wp-content/uploads/2020/12/20-11-15-Hand-sanitiser-industry-benchmark-V2.pdf
Model WHS Regulations	Model Workplace Health and Safety Regulations contains a provision for Risk management, which relies on risk management hierarchy i.e. 1. Elimination 2. Substitution 3. Engineering controls 4. Administrative controls 5. PPE. Implemented in 2011	National harmonisation of workplace health and safety regulations and GHS implementation.	Regulatory National Model legislation implemented by States and Territories Risk management responsibilities with PCBU.	Processes	Workplace use, which could be manufacturing or use.	All workplace chemicals	None that are relevant to risk management hierarchy, which is a well-accepted and practiced method of risk management.	Graduated consideration of risk management based on the hazard of the substance and the need/use of the substance.	Risk management hierarchy of controls were in place even before the 2011 Model WHS Regulations were put in place and is a long standing accepted good practice.

Canada

Name of the programme	Goal and Year of implementation	Factors or considerations that led to its development	Type of approach (non-regulatory or regulatory), incl. roles and responsibilities	Focus on products, articles or processes	Life cycle stage(s) addresses	Chemical(s) addressed	Challenges to implementation	Identified Benefits of the programme	Additional information
Labelling of toxic substances in certain products under the Canadian Environmental Protection Act, 1999 (CEPA)	Taking actions to provide Canadians with greater access to information about toxic substances to which they may be exposed and allow for more informed purchasing decisions in order to help protect the environment and human health. 2019-2021	Consumer, workplace, industrial, and other products contain a wide range of chemical ingredients, some of which can have impacts on the health of Canadians or on the environment, and there is growing demand for increased transparency about these ingredients and their potential risks.	Regulatory actions, as well as voluntary and collaborative initiatives, are being explored. Environment and Climate Change Canada will lead development of criteria for when labelling will be used. Environment and Climate Change Canada as well as Health Canada will be responsible to implement the labelling requirements.		All	The Government of Canada intends to propose labelling requirements for some of the substances that are listed on Schedule 1 of the Act in circumstances where providing information to consumers on the presence of those substances would help reduce risks to the environment or human health.			The Government of Canada announced the publication of a Notice of intent (NOI) for the labelling of toxic substances in consumer products in 2022.

Substitution of chemicals of concern is an area being explored as part of the modernization of the Canadian Chemicals Management Plan (CMP). Past Efforts to support informed substitution have been deployed under the CMP and include the grouping of substances that share characteristics of concern for risk assessment (e.g., flame retardants) and the prioritization of certain substance groups for earlier assessment where they may be potential substitutes to previously identified harmful substances (e.g., TDIs and MDIs, BNST and SDPAs). In terms of risk management, in some cases, pollution prevention planning notices have required that persons subject to the Notice consider alternatives to reduce risk, consider alternatives that would not be harmful, and, where available, identified alternatives that would not be suitable substitutes.

Health Canada is involved in a project funded by the Canadian Institutes of Health Research with a focus on responsible replacement of endocrine disrupting chemicals, including the use of new approach methodologies. There continues to be a growing concern related to the impact of chemical exposures on the endocrine system. Over the past decades, Canada under the *Canadian Environmental Protection Act*, 1999, as well as other international governments, have regulated the production and use of chemicals shown to act as endocrine disruptors. As a consequence, this has lead to an increased use of alternative chemicals to address market needs. The challenge is that toxicity data is limited or not available for many of these replacement chemicals. With a focus on select flame retardants and plasticizers as example chemical classes, the main goals of this research project, advanced by a multidisciplinary team that includes members from academia, government and non-government organizations internationally are to (1) determine potential for exposure to replacement chemicals, (2) examine the toxicity and potential adverse health effects, and (3) engage with project partners from government, industry and non-government agencies to discuss safer replacements.

As part of this project, non-animal methods are used to assess the toxicity of exposure to concentrations of the emerging chemicals found in food and drinking water as detected in human biomonitoring studies. A range of cell lines representing key endocrine functions show that exposure to various replacements result in cell-line and chemical specific effects on cell viability and phenotypic endpoints. This project contributes to a global effort to reduce animal testing and provides an improved understanding of the potential for toxicity of chemicals that currently lack health effects data. These methods can provide evidence in a screening strategy to identify chemicals with the potential for reproductive and endocrine effects to set priorities for further assessment.

Denmark

Name of the programme	Goal and Year of implementation	Factors or considerations that led to its development	Type of approach (non-regulatory or regulatory), incl. roles and responsibilities	Focus on products, articles or processes	Life cycle stage(s) addresses	Chemical(s) addressed	Challenges to implementation	Identified Benefits of the programme	Additional information
Centre for Circular Chemistry	To promote the protection of the environment and health by focusing on substituting, reducing and eliminating use of harmful substances that also pose a barrier to the circular economy.	Continuation of the former substitution programme "Kemi I Kredsløb". Political decision to continue the initiative for substitution.	Non-regulatory The funding for the partnership was part of a national action plan on chemicals. The participation was voluntary.	Focused on substitution of problematic chemicals within three sectors: construction, packaging and food production (e.g. cleaning chemicals)	Not specified.	Harmful chemicals within the chosen sectors.	Substitution is an expensive and time-consuming process and the final results lie beyond the expiration of the project period. Therefore, it is difficult to quantify the benefits.	The program was supporting substitution in its broadest definition (green chemistry) which was appealing to a broad range of companies. The support offered to each company in the programme was very limited, but	A continuation of the Centre for Circular Chemistry was not prioritized in the new national action plan, Chemicals Initiatives 2022-25: https://mim.dk/media/230134/aftaletekst-kemiindsats-engelsk-pdf.pdf

	2019-2021							it allowed for more companies to be involved and participate actively within budget. Support was given through: webinars, workshops, webpage, publications, 1:1 counselling (25 hours).	
The Danish Eco-Innovation Program (MUDP)	*The Danish Eco-Innovation Program features i.a. a subsidy scheme with a general focus on: Water; climate change adaptation; circular economy and recycling of waste; cleaner air; less noise; fewer hazardous chemicals; the industry's environmental performance; and ecological and sustainable construction. 2007*	*Government action plan to support growth and environmental technologies*	*Voluntary, multi-stakeholder partnership program of industry, research/academic community, NGOs, government, and public*		*The eco-innovation programme considers all lifecycle stages from production to end-of-life.*	*All hazardous chemicals are within the scope such as e.g. HFC's, MI, chromates and more*			*http://eng.ecoinnovation.dk/*
Workers health legislation	*There is a requirement in Danish Workers*	*Workers health considerations*	*Regulatory, generic*		*Production-workplace*	*CMR + stot*			http://engelsk.arbejdstilsynet.dk/en/regulations/acts/wor

	health legislation to choose safer alternative if available 2003 or before								king-environment-act/arbejdsmiljoeloven1
Ecolabelling: The EU flower and the Nordic Swan	*To enable suppliers of goods to be able to use a label showing that the products live up to certain standards of environment friendliness. The label is controlled by an independent official body*	*Considerations for the environment*	*Voluntary*		*All . Mainly from environment considerations but also health*	*Various, depending on product*			https://www.ecolabel.dk/da/in-english http://www.nordic-ecolabel.org/ http://ec.europa.eu/environment/ecolabel/

France

Name of the programme	Goal and Year of implementation	Factors or considerations that led to its development	Type of approach (non-regulatory or regulatory), incl. roles and responsibilities	Focus on products, articles or processes	Life cycle stage(s) addresses	Chemical(s) addressed	Challenges to implementation	Identified Benefits of the programme	Additional information
Portal on chemicals substitution	Since 2015 This website, set up at the request	Strongly linked to the evolution of chemical	The choice of the addressed chemicals is		All stages	Bisphenols Phthalates	Regular updates	"showcase" of the chemical	Includes repository of useful reports on

Substitution.ineris.fr/en	of the French Ministry of Ecology, provides support to economic operators engaged in a substitution approach in order to promote the dissemination and sharing of information.	regulation in Europe and the substitution issues raised by Reach	based on Reach regulation, but the scope is wider (e.g. all bisphenols are addressed, not only BPA)			Alkylphenol ethoxylates PFAS (expected extension to other PMT substances)		substitution issue Entry point for industry with questions on substitution	substitution issues 2-3 newsletters / year
Supply chain workshops	2021 workshop on the challenges of substituting substances of concern in the textile sector	This event is part of the approach promoted by ECHA which consists of developing supply chain workshops, so that the stakeholders can share their difficulties or, on the contrary, some solutions they could provide.		Articles	All stages	CMRs PFAS Formaldehyde Etc.	The complementarity of the topics was highly appreciated (The event was divided in 4 parts: (i) regulatory context, (ii) methodological resources, (iii) feedbacks from stakeholders, (iv) presentation of ongoing research projects.		https://www.ineris.fr/fr/ineris/actualites/enjeux-substitution-filiere-textile-
Portal on CMR substances substitution	This website is intended for all professionals and prevention stakeholders who wish to take steps to replace	CMR substitution became a permanent mission for the Anses in 2010			All stages	CMRs More than 50 substances addressed in substitution sheets	Regular updates		

	CMR chemical substances. It aims to publicise the actions taken, the work in progress and the progress of research in the field of substitution.					(see : https://www.substitution-cmr.fr/index.php?id=18&no_cache=1)			
Ineris support activities to the French Ministry of Ecology	Specific socio-economic studies linked to chemical management measures are part of those activities. Substitution issues are widely addressed, as is the link between chemical risks and recycling.	Chemical regulation in Europe (Reach, Biocides, etc.) The choice of studies is based on anticipating regulatory needs (e.g. biocidal substances whose authorisation period is coming to an end)				Nearly one specific study per year In 2021, the substitution of biocides used for wood treatment were addressed		In-depth surveys to assess the availability of alternatives (taking into account in particular the efficiencies sought)	(English translation in progress)

Germany

Name of the programme	Goal and Year of implementation	Factors or considerations that led to its development	Type of approach (non-regulatory or regulatory), incl. roles and	Focus on products, articles or processes	Life cycle stage(s) addresses	Chemical(s) addressed	Challenges to implementation	Identified Benefits of the programme	Additional information

			responsibilities						
SUBSPORT plus	Goal: Information platform on substitution Year of implementation: 2012-2014 (EU-LIFE project), relaunch in 2020 by BAuA	The overall need for information on alternatives and tools with growing requirements from chemical legislation for substitution.	The information platform is non-regulatory. Host of platform: Federal Institute for Occupational Safety and Health (BAuA)	All	All	Substances are addressed, which are restricted and prioritized according EU regulations, international agreements, governmental lists, NGO or trade union lists and company or sector lists. The hazard properties concern human health and environment.	To reach all target groups for the practical application	Compact information on substitution with an overview on regulations, tools, links, and two databases: database of hazardous and priority substances Case story database: more than 350 examples Main languages: English and German	Link to website: https://www.subsportplus.eu/subsportplus/EN/Home/Home_node.html

Safe to use concept	Goal: Combining requirements of substitution for human health with concrete safety levels at the workplace taking into consideration the adequate protection measures for workers Year of implementation: 2017 (integration into work and research programme)	With reference to chemical risks, the idea of "safe-to-use chemicals" goes back to the initiative "New Quality of Work" of the German Federal Ministry of Labour started in 2002. The focus was on a vision that chemicals should be placed on the market by manufacturers and importers in a form that largely excludes risks to humans and the environment.	The approach is non-regulatory. Concept is one strategic field of action for work and research of the Federal Institute for Occupational Safety and Health (BAuA).	All	All	All	To ensure communication between developers of products or materials and risk assessors/regulators	Possibility to combine this concept with sustainability aspects (see JRC concept of safe and sustainable by design in 2022) The BAuA uses learnings and research results for transfer into practice, to consult policy and to fulfil statutory and sovereign tasks.	*Ensure safe-to-use chemicals, materials and products - A contribution of occupational safety and health to "safe and sustainable by design":* *https://www.baua.de/EN/Service/Publications/Focus/Sustainability.html* *Work and research programme of BAuA 2022-2025:* *https://www.baua.de/EN/Tasks/Work-and-research-programme/All-projects.html*
"Der Grüne Knopf" or the "Green Button" Textile certification label for corporate social responsibility	Goal: social and environmental sustainable textile production Year of implementation: 2019	Consideration of the due diligence requirements based on the UN Guiding Principles for Business and Human Rights and the recommendations of the OECD for the textile sector.	Government-run certification label for sustainable textiles Scheme owner: Federal Ministry for Economic Cooperatio	Enterprises, manufacturing and articles	Manufacturing: cutting and sewing, and bleaching and dyeing	Criteria for environmental-safe substances are defined, i.a. substances with bans, with limits for wastewater etc.	Voluntary action	Combination of social and ecological standards according to 46 stringent, defined criteria for production and products on the market.	*Link:* *https://www.gruener-knopf.de/en/gruener-knopf*

			n and Development Support by independent expert advisory board					The Green Button is a global certification label without license fees, following harmonised international standards (EU and WTO law). Further development for expansion to other supply chain stages is planned.	
SCOTTY (Sustainable Control of Harmful Organisms in the 21st century)	Founded in 2021 to support the development of holistic management approaches for harmful organisms according to EU Biocidal Products Regulation to minimise use of biocides to the	Sustainable substitution of biocidal products is complex and mostly not a 1:1 substitution by other chemical products but rather a systemic change including preventive measures and non-chemical alternatives. Other than chemical products, these options have no representation in discussions on substitution and due to missing regulation, there is a lack of knowledge regarding these options. SCOTTY wants to fill these gaps.	Non-regulatory initiative by the German Environment Agency, related to Article 17(5) of the EU Biocidal Products Regulation	According to the holistic approach of the initiative, all possible management options are considered.	Focus lies on use-phase	Biocidal products	Complex substitutions in a great variety of uses with various stakeholders due to the broad range of product types under the EU Biocidal Products Regulation.	Initiative can fill important knowledge gaps on alternatives and support their representation in discussions on substitution options.	*https://www.umweltbundesamt.de/en/topics/chemicals/biocides/sustainable-control-of-harmful-organisms-in-the*

	minimum necessary by substitution with non-chemical alternatives and preventive measures.								
Ecolabel "Blue Angel"	"Blue Angel" was founded in 1978, the latest new basic award criteria in the biocides context have been published in 2022 for biocide-free underwater coatings (see separate entry on anti-fouling).	Ecolabel can provide guidance to users to choose the products with the least effects for the environment. Furthermore, they can facilitate public procurement of environmentally friendly products and can serve as a prove of efficacy for products not falling under the EU Biocidal Products Regulation.	Non-regulatory approach, the ecolabel is supported with expertise by the German Environment Agency, the basic awards criteria are decided by an independent jury, and the RAL gGmbH (a non-profit private limited company) checks the compliance of the applications.	Ecolabels can be given to products, articles and services.	Focus lies on use-phase	Biocidal products (especially alternatives to: rodenticides, insecticides, film preservatives, preservatives for products during storage, anti-fouling products)	Defining basic award criteria for new ecolabel is complex and requires a weighing of risks and benefits of alternatives. Acceptance on the market is based on many different factors.	User can identify the products with the least effects for the environment more easily. The basic award criteria can be used in public procurement.	*Eco-label "Blue Angel" on biocide-free pest control (incl. efficacy requirements)* *Eco-label "Blue Angel" on thermal indoor pest control (incl. efficacy requirements)* *Eco-label "Blue Angel" on thermal pest control of wood (incl. efficacy requirements)* *Eco-label "Blue Angel" for external thermal insulation composite systems* *Eco-label "Blue Angel" for biocide-free anti-fouling solutions (incl. efficacy requirements)*

Website "Biozid-Portal"	Started in 2010 to inform consumers and multipliers on preventive measures and alternatives to biocides	For non-professional users of biocidal products, there is little information on how to substitute biocidal products best.	Non-regulatory approach, website is provided by the German Environment Agency	Website provides information for all options to substitute biocidal products in households but does not name specific products.	Focus lies on use-phase	Biocidal products	Use of biocidal products in households is manifold making the information to be provided complex. Lack of efficacy information for alternatives makes it difficult for the agency to provide specific recommendations.	Non-professional users find information how to handle harmful organisms in the household best.	www.biozid.info *(in German)*
Efficacy testing of rodent traps under the German Infection Protection Act (§18)	Statutory task that originated in the Federal Epidemics Act of 1979, which was transferred to the Infection Protection Act in 2001. The purpose of the Infection Protection Act is to protect the population from	Efficacy testing and evaluation of products (chemical as well as non-chemical) for the control of health pests (i.e. animals that transmit pathogens to humans) is a permanent legal task to fulfil the requirements of the Infection Protection Act. In this framework, amongst others, rodent traps are being tested.	Regulatory. The German Environment is responsible for efficacy testing of products against health pests in the framework of the Infection Protection Act. Tests of rodent traps and other	Products and articles.	Use-phase	Biocidal products (rodenticides)	Development of test protocols and criteria for evaluation for assessment of efficacy and animal welfare impact of rodent traps.	Publication of a list of rodent traps which are sufficiently efficient and fulfil the animal welfare criteria. The list provides information about which traps are suitable as an alternative to rodenticides for rodent control.	https://www.umweltbundesamt.de/themen/chemikalien/infektionsschutz *(in German)*

	infectious diseases.		products are conducted in the laboratory of the German Environment Agency. All products which have been tested positively are included in a public list of approved products.						
NoCheRo – Assessment of efficacy and humanness of snap traps	The NoCheRo (Non-Chemical Rodent Control)-Initiative was started in 2018. The initiative aims to provide objective information about the suitability and performance of rodent	The comparative assessment of anticoagulant rodenticides in the framework of EU Biocidal Products Regulation (EU 528/2012) has revealed that unsufficient information on alternatives to anticoagulant rodenticides are available. It was subsequently decided on an EU-Workshop (1st NoCheRo-Workshop 2018) that a guidance for evaluation and testing of rodent traps should be prepared, which was	Non-regulatory initiative by the German Environment Agency, based on EU Biocidal Products Regulation	Products	Use-phase	Biocidal products (rodenticides)	Development of test protocols and criteria for evaluation for assessment of efficacy and animal welfare impact of rodent traps	Publication of a list of rodent traps which are sufficiently efficient and fulfil the animal welfare criteria. The list provides information about which traps are suitable as an alternative to rodenticides	*https://www.umweltbundesamt.de/en/topics/chemicals/biocides/non-chemical-alternatives-for-rodent-control* *https://www.umweltbundesamt.de/publikationen/nochero-guidance-for-the-evaluation-of-rodent-traps* *(Guidance document)*

	traps as an alternative to rodenticides.	published in 2020 and accepted as a tool for comparative assessment by the ECHA in 2021.						for rodent control. Provision of methods for testing to generate unbiased information on non-chemical alternatives in order to enable decisions to replace rodenticides with traps.	
Stakeholder dialogue concerning the substitution of creosote-treated wooden railway sleepers	In 2020, German Environment Agency organised a stakeholder dialogue in the light of the evaluation for the renewal of creosote as active substance (a.s.) under the EU BPR 528/2012	Due to creosotes intrinsic properties (carcinogen category 1B and PBT as well as vPvB) the exclusion criteria according to art. 5(1), (a) and (e) of the EU Biocidal Products Regulation are fulfilled and creosote-containing biocidal products (b.p.) should only be authorised if there are no alternatives for the intended use. Therefore, the insights and the knowledge of the stakeholders should be compiled and shared. Thus, finding alternatives and phasing-out creosote in railway sleepers should be enabled as soon as possible.	Non-regulatory approach by the German Environment Agency, based on the outcome of the initial a.s. approval and its renewal as well as the analysis of the national situation before re-authorisation of b.p.	The focus lies on the classification of available alternatives to creosote-treated wooden railway sleepers and possible consequences of a non-authorisation of b.p. on the national level.	Focus lies on use-phase	Biocidal products (wood preservatives)	Variability of alternatives available on the European market (other materials for railway sleepers such as concrete or plastic sleepers, wooden sleepers from durable wood or treated by other a.s.) and their costs, (rapid) availability as well as other impact on the environment, e.g. switching	Stakeholders organised in the Association of German Transport Companies (VDV) were informed about progress made by Deutsche Bahn (DB, German national railway company) on their efforts to replace creosote-treated wooden railway	*Preceding report on the market situation in Germany on the use of creosote-treated wood (only available in German, including English abstract):* https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte_48_2015_zulassung_kreosothaltige_holzschutzmittel.pdf

							transport from trains to trucks.	sleepers and contacts for further exchange were established.	
Reducing use of anti-fouling products	Published in 2019/2020 to inform consumers on the proper use of antifouling, on fouling pressure in German waters and on alternatives to biocidal antifouling products.	End users should be motivated to conduct biofouling protection in an environmentally friendly way. This is achieved by explaining the risks that arise from the use of biocidal antifouling products and information about possible alternatives. With the help of the Blue Angel eco-label, this should also be possible for specific products in the future.	Non-regulatory approach, website is provided by the German Environment Agency	The information offered covers several aspects in the life cycle of antifouling products (choice, use, disposal, maintenance) and targets not only products but also alternative measures.	Focus lies on use-phase.	Biocidal products (anti-fouling)	The mobility of ships in combination with variing fouling conditions in different waters and the lack of efficacy information for alternatives makes it difficult for the agency to provide specific recommendations.	The information provides helpful information for end users, which is also accepted positively. We hope to be able to close a gap in product recommendations with the Blue Angel Antifouling. However, this requires a sufficient number of products which will be labelled. One challenge is the map on fouling pressure, which should be updated more regularly in order to better inform	*Anti-fouling use in water sports* *Map on fouling pressure on boats in Germany* *Eco-label "Blue Angel" for biocide-free anti-fouling solutions (incl. efficacy requirements)*

								the end user about the fouling conditions and thus provide better support in the product selection.	
LIFE AskREACH Project	Main goal: substitution of SVHCs (SVHC: substances of very high concern; see EU REACH regulation) in articles. Facilitation of SVHC article information dissemination within value chains down to end-users. Project duration 09/2017-03/2023, developed IT tools will be maintained for at least 3 more	Lack of proper implementation of REACH Art. 33 (2). Lack of awareness on REACH Art. 33 (2) both at consumer and supplier (manufacturer/ importer/ distributor/retailer) level. Art.33(2) grants consumers a right to get – on request – information about SVHCs in articles from the suppliers, when a concentration of 0.1 % is exceeded. AskREACH helps consumers exercise this right. It also supports suppliers to respond to the requests. Suppliers have to deal with the subject and are encouraged to replace SVHCs in their articles	Non-regulatory approach. AskREACH developed a European app (Scan4Chem) that supports consumers to send SVHC requests to suppliers. At the same time, it supports suppliers, as they can provide their SVHC article information in the AskREACH database	Articles	Whole article life cycle, down to the end-stage, as the developed IT tools can be used for information dissemination by all actors within the supply chain and waste stage. Main focus lies with the use stage (consumers)	Substances of very high concern according to the EU REACH Regulation	Lack of awareness on both sides difficult to overcome. Companies are often not compliant. Legal gap of Art.33: legal obligation to provide SVHC article information kicks in only when SVHC >0.1% are present. Lack of responses to information requests is common, leaving consumers in the dark whether this is because of absence of SVHCs (<0.1%), supplier non-	Consumers and suppliers are made aware of the subject in long term public campaigns in more than 18 countries. Up to now about 215.000 articles have been scanned and about 70.000 requests have been sent to 28,000 suppliers by 22,000 consumers. 320 suppliers registered in the database. Experiences and options	*Please see project website:* *https://www.askreach.eu*

	years after project end.		to have it directly shown to app users when the article barcode is scanned (or the name searched). AskREACH also further optimised an IT tool for suppliers communication about SVHCs throughout the supply chain.				compliance or no-receipt of the information request. Vicious circle: companies expect consumers to show interest by sending information requests before they invest resources to submit their article information. Consumers expect companies to have article information provided and do not submit a request and wait up to 45 days for a response. Many of them download the app, but only few send requests.	fed into policy development processes (e.g. REACH review process). Information and experience exchange/close collaboration with the ECHA SCIP database, given the similarity in nature of the two databases.	

European Union

Name of the programme	Goal and Year of implementation	Factors or considerations that led to its development	Type of approach (non-regulatory or regulatory), incl. roles and responsibilities	Focus on products, articles or processes	Life cycle stage(s) addresses	Chemical(s) addressed	Challenges to implementation	Identified Benefits of the programme	Additional information
EU REACH Authorisation process (SVHC identification and recommendation for inclusion in REACH Annex XIV steps)	The authorisation process aims to ensure that substances of very high concern (SVHCs) are progressively replaced by less dangerous substances or technologies where technically and economically feasible alternatives are available. Two first steps: 1. identification of substances as SVHCs and inclusion in the Candidate List 2. Recommendation for inclusion in Authorisation List: assessment of the substances from the Candidate List to determine	Revision of previous EU legislations on manufacture and use of chemicals	Regulatory approach. Type and role of stakeholders depending on the procedure stage: 1. SVHC identification: EU Member State or ECHA, at the request of the Commission, proposes a substance to be identified as an SVHC. Stakeholders are invited to comment on the identification during a consultation. If the MSC is not triggered (by relevant comments) then ECHA takes the Decision to add the substance on whether to add the substance to Candidate List. If	Substances At the recommendation for inclusion in REACH Annex XIV step, the focus is on uses within the scope of authorisation. For uses generically exempted from authorisation, see: https://echa.europa.eu/documents/10162/17232/generic_exempt_auth_2020_en.pdf For substances included in Annex XIV (Authorisation List), if ECHA considers that the risk from the use of such a substance in articles is not adequately controlled, it shall prepare a	No specific life-cycle stage addressed. The manufacturing stage is exempted. According to the agreed prioritisation approach (https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_2020_en.pdf), the wide-dispersiveness, as one of the three priority criteria, decreases from substances used by consumers, to those used by professionals or by industrial users. Article service life can be considered to further refine the priority score.	List of SVHCs included in the Candidate List: https://echa.europa.eu/candidate-list-table Recommendation for inclusion in Authorisation List: https://echa.europa.eu/recommendations-for-inclusion-in-the-authorisation-list	Insufficient knowledge about users, uses and tonnage of substances	Both steps, and the next step (application for authorisation – see below) have been recognised as providing strong incentives for substitution. See https://echa.europa.eu/documents/10162/17229/socioeconomic_impact_reach_authorisations_en.pdf/	Info on SVHC identification: https://echa.europa.eu/substances-of-very-high-concern-identification-explained Inclusion in the Candidate List leads to legal obligations related to the use of substances in their own, in mixtures and in articles: https://echa.europa.eu/candidate-list-obligations Info on recommendations for inclusion in Authorisation List: https://echa.europa.eu/regulations/reach/authorisation/recommendation-for-inclusion-in-the-authorisation-list

	which ones should be included in the Authorisation List (Annex XIV of REACH) as a priority The next step is application for authorisation (see below) Year of implementation: 2007		triggered, the Member State Committee (MSC) seek to agree on the identification of the substance as an SVHC. If the MSC reaches a unanimous agreement, the substance is added to the Candidate List. If not, the matter is referred to the Commission. 2. Recommendation for inclusion in Authorisation List: ECHA makes an assessment of priority of all substances on the Candidate List not yet recommended. Stakeholders are invited to comment the recommendation during a consultation. The Member State Committee then prepares its opinion on the draft	restriction proposal (see EU REACH Restriction process below).					Both steps, and the next step (application for authorisation) have been recognised as providing strong incentives for substitution. See Impacts of REACH Authorisation study

			recommendation taking into account the comments received during the consultation. On this basis, ECHA finalise its recommendation which is submitted to the European Commission, who takes the decision on the substances to be included in the Authorisation List.						
REACH - Applications for Authorisation process	While ensuring the good functioning of the EU internal market, assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternatives. The process includes the preparation of an analysis of	Revision of previous EU legislations on manufacture and use of chemicals	Regulatory approach. Type and role of stakeholders depending on the section of REACH Regulation. Regarding applications for authorisation: industry (applicants, third parties commenting on alternatives). All stakeholders (e.g. third parties commenting on alternatives). ECHA (secretariat,	Substances and incorporation of substances into articles as part of industrial processes	Stage of the use of the substance and, when relevant, assessment of risks arising from the use of articles made with the substance	Substances or group of substances under the Authorisation List (Annex XIV of REACH): https://echa.europa.eu/authorisation-list Examples of substances included in this list (non-exhaustive): •Hexabromocyclododecane (HBCDD) • Bis(2-ethylhexyl)	Uncertainty on number of applications to be received and peaks of applications given capacity of opinion and decision making of authorities	Both steps, and the next step (application for authorisation – see below) have been recognised as providing strong incentives for substitution (repeated from above). See https://echa.europa.eu/documents/10162/17229/socioeconomic_impact_reach_authorisations_en.pdf/	Support material including Guidance on how to prepare an Annex XV report for a restriction proposal (which includes how to prepare an analysis of alternatives) and Guidance on socio-economic analysis for restriction are available here: https://echa.europa.eu/fr/support/restriction/how-to-prepare-an-

	alternatives to the substance applied for continued use. Year of implementation: 2007		Committee for Risk Assessment and Committee for Socio-economic analysis): opinion-making process. European Commission and Member States Competent Authorities for REACH and CLP: decision-making process			phthalate (DEHP) • Lead chromate molybdate sulfate red and Lead sulfochromate yellow • Chromium trioxide •Trichloroethylene • Anthracene oil • Pitch, coal tar, high-temp. • Etc.			annex-xv-report/general-instructions https://echa.europa.eu/fr/support/socio-economic-analysis-in-reach
EU REACH – Restriction process	Restricting the manufacture, the placing on the market or the use of substances which pose an unacceptable risk for human health or the environment and where an EU wide action is necessary. The conditions of the restrictions are specified in Annex XVII of REACH. The process includes the preparation of an analysis of alternatives to	Revision of previous EU legislations on manufacture and use of chemicals	Regulatory approach. Type and role of stakeholders depending on the section of REACH Regulation. Regarding restriction process: Member States Competent Authorities for REACH and CLP or ECHA Secretariat on request of European Commission: preparation and submission of restriction proposal. ECHA	Substances and group of substances	The restriction targets the stage(s) where the substance causes a concern but the analysis can be broader.	Substances or group of substances under the Restriction List (Annex XVII of REACH): https://echa.europa.eu/substances-restricted-under-reach Examples of substances included in this list (non-exhaustive): • Tattoo inks • Microplastics • 1,4-Dichlorobenzene in air freshener or deodoriser		See the report on Costs and benefits of REACH restrictions proposed between 2016-2020 https://echa.europa.eu/documents/10162/17228/costs_benefits_reach_restrictions_2020_en.pdf/a96dafc1-42bc-cb8c-8960-60af21808e2e	Support material including Guidance on how to prepare an Annex XV report for a restriction proposal (which includes how to prepare an analysis of alternatives) and Guidance on socio-economic analysis for restriction are available here: https://echa.europa.eu/fr/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions

	the substance considered for the restriction. Year of implementation: 2007		(secretariat, Committee for Risk Assessment and Committee for Socio-economic analysis): opinion-making process. All stakeholders (e.g. commenting on opinions from RAC and SEAC). European Commission and Member States Competent Authorities for REACH and CLP: decision-making process.			• Bisphenol A in thermal paper • Nonylphenol and Nonylphenol ethoxylates in various applications • DEHP, DBP and BBP in in toys and childcare articles • decaBDE (manufacture and placing on the market)			https://echa.europa.eu/fr/support/socio-economic-analysis-in-reach
EU Classification, Labelling and Packaging (CLP) Regulation	The regulation requires manufacturers, importers and downstream users of substances or mixtures to classify, label and package their chemicals appropriately before placing them on the market. One of the main aims of CLP is to determine	Revision of previous EU legislations on manufacture and use of chemicals	Regulatory. The obligations placed on suppliers of substances or mixtures under CLP will mostly depend upon their role towards a substance or mixture in the supply chain. Member States and manufacturers, importers or	Substances: Can be subdivided in Industrial chemicals, Biocides and pesticides Priority is given to suspected CMR and sensitising substances	No specific life-cycle stage addressed.	Table of harmonised entries in Annex VI to CLP: https://echa.europa.eu/information-on-chemicals/annex-vi-to-clp C&L inventory: https://echa.europa.eu/information-on-chemicals/cl-inventory-database		Benefits of the program: Have great impact on downstream regulations and directives (OSH, Seveso III, transport of dangerous goods, BPR, Cosmetics, etc.)	Info on CLP: https://echa.europa.eu/regulations/clp/understanding-clp CLP-based classifications are linked to several other legislations including REACH, BPR, PPPR, Cosmetics Regulation, and several other EU

	whether a substance or mixture displays properties that lead to a hazard classification. The regulation also includes the harmonised classification and labelling process under which the classification and labelling of certain hazardous chemicals is harmonised to ensure adequate risk management throughout the EU. Year of implementation: 2009		downstream users may propose a harmonised classification and labelling (CLH) of a substance. Only Member States can propose a revision of an existing harmonisation, and submit relating CLH proposals. ECHA also manages the C&L inventory and provides Member States and the institutions of the Union with scientific and technical advice on questions relating to CLP. ECHA and Members States' role also include responsibilities related to information relating to emergency health response, see https://poisoncentres.echa.europa.eu/.						Regulations and Directives. The classification of a substance as hazardous can be an important incentive for its substitution by safer alternatives.

EU Biocidal Products Regulation (BPR) – Exclusion provisions	Regulating the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, by the action of the active substances contained in the biocidal product. This regulation aims to improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans and the environment. The BPR provides for exclusion criteria (article 5(1) of the BPR) for active substances of very high concern, covering CMR 1A and 1B,	Revision of previous EU legislation on the placing on the market and use of biocidal products (Directive 98/8/EC from 1998)	Regulatory approach. Type and role of stakeholders depending on the stage of BPR process for approval of an active substance, or for authorisation of a biocidal product. For the approval process of an active substance: - industry submit an application for approval in an evaluating Member State - an evaluating Member performs a hazard/risk/efficacy assessment, and submits its draft assessment to the European Chemicals Agency (ECHA) - a peer review with all EU Member States is organised by ECHA within its Biocidal Product Committee.	All biocidal products require an authorisation before they can be placed on the market, and the active substances contained in that biocidal product must be previously approved. There are, however, certain exceptions to this principle. For biocidal products containing substances meeting the substitution/exclusion criteria, a comparative assessment of alternatives at product level should be performed. See details besides and below: https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr	The manufacturing stage is not assessed, but the risks linked to use of the biocidal products are assessed in all its phases and consequences: primary exposures, secondary exposures, fate and behaviour in the environment. Derogation criteria are assessed before deciding on an approval of active substance, and by each Member State before delivering an authorisation on a product containing a substance subject to exclusion.	List of Biocidal Active Substances under the BPR process: https://echa.europa.eu/information-on-chemicals/biocidal-active-substances List of substances subject to exclusion or substitution: https://circabc.europa.eu/w/browse/e379dc27-a2cc-46c2-8fbb-46c89d84b73d Ex : anticoagulant rodenticides (warfarin, brodifacoum, difenacoum etc.), creosote, boric acid, hexaflumuron, etc.	At active substance approval level: insufficient knowledge on the uses and on the possible alternatives	A guidance on analysis of alternatives at active substance level is under development to support a better search and assessment of chemical and non-chemical alternatives	Additional information on approval of active substances including exclusion criteria: https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances https://echa.europa.eu/public-consultation-on-potential-candidates-for-substitution Public consultation on the conditions for derogation to exclusion: https://echa.europa.eu/derogation-to-the-exclusion-criteria-current-consultations https://circabc.europa.eu/w/browse/1cba444c-5885-4886-9ef3-cc3a8add38cb

	endocrine disruptors, and PBT/vPvB substances. These active substances and biocidal products containing them should normally not be approved or authorised. Derogations are possible in case of negligible risk, essential to control a serious dangers to human/animal health or the environment, or in case of disproportionate negative impact of a ban for society compared to the risks of using of using the substances/products. For such substances, approvals are more limited in time, and authorisation of products containing them are also more limited in time than for		- ECHA delivers an opinion to the EU Commission on whether or not the active substance can be approved. - the EU Commission, after consultation of the Standing Committee on Biocidal products (composed of EU Member States' representatives) decides on the approval or non-approval of the substances at EU level. For substances subject to exclusion, two public consultation are performed during the review process: - one to gather information on alternatives during the review at ECHA level - one to study whether the						

	approvals/authorisations in general. Year of implementation: 2013		conditions for derogation to exclusion are fulfilled, during the final stages of the decision-making process For the authorisation process of biocidal products containing active substances: - industry submits an application for authorisation in one evaluating Member State - the EU Member State receiving the application assesses the application, and decides on the authorisation of the biocidal product on its territory. - industry can apply for mutual recognition of the authorisation in other Member States						
EU Biocidal Products Regulation (BPR) –	The BPR also provides for substitution criteria with the	Revision of previous EU legislation on the placing on the	Same process as above for substances subject to	See above.	The manufacturing stage is not assessed, but	List of Biocidal Active Substances	See above.	See above.	Additional information on approval of active

Substitution provisions	concept of candidates for substitution for certain active substances presenting a concern (Article 10(1) of the BPR): 2 out of 3 PBT criteria, respiratory sensitizer etc. Products containing active substances that are candidates for substitution are subject to a comparative assessment before any authorisation is granted. For such substances, approvals are more limited in time, and authorisation of products containing them are also more limited in time than for approvals and authorisations in general. Year of implementation: 2013	market and use of biocidal products (Directive 98/8/EC from 1998)	exclusion, and products containing them. During the approval process for substances that are candidates for substitution, a public consultation is performed to gather information on alternatives during the review at ECHA level.		the risks linked to use of the biocidal products are assessed in all its phases and consequences: primary exposures, secondary exposures, fate and behaviour in the environment. A comparative assessment with potential alternative has also to be performed by Member States when considering applications for authorisation of products containing substances that are candidates for substitution.	under the BPR process: https://echa.europa.eu/information-on-chemicals/biocidal-active-substances List of substances subject to exclusion or substitution: https://circabc.europa.eu/w/browse/e379dc27-a2cc-46c2-8fbb-46c89d84b73d Ex : spinosad, glutaraldehyde, imidacloprid, PHMB etc.			substances including substitution criteria: https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances Public consultation on alternatives for substances under substitution https://echa.europa.eu/public-consultation-on-potential-candidates-for-substitution

ECHA Strategy to promote substitution to safer chemicals through innovation	Support informed and meaningful substitution of chemicals of concern in the EU and to boost the availability and adoption of safer alternative substances and technologies. This would take place through further improved access to ECHA data, as well as increased capacity of Member States and stakeholders to carry out analysis of alternatives, through support to innovation and through networking, i.e. to accelerate substitution, supporting and complementing the stimulus provided by the chemicals regulations.	Realisation with stakeholders that ECHA could play a more important role in supporting substitution	Voluntary approach. ECHA wishes to support and facilitate substitution-related activities where possible and identified four main action areas.	No specific focus	No specific life-cycle stage	Support informed and meaningful substitution of chemicals of concern in the EU and to boost the availability and adoption of safer alternative substances and technologies. This would take place through further improved access to ECHA data, as well as increased capacity of Member States and stakeholders to carry out analysis of alternatives, through support to innovation and through networking, i.e. to accelerate substitution, supporting and complementing the stimulus provided by the chemicals regulations	Competing priorities and lack of resources.		Support and complement the stimulus provided by the EU chemicals legislation comprising REACH, CLP and the Biocidal Products regulations. This strategy is also linked to the current general EU priorities around the circular economy, the sustainable manufacture and use of chemicals, a non-toxic environment and a bio-based economy. Link to the strategy document: https://echa.europa.eu/documents/10162/13630/250118_substitution_strategy_en.pdf

Luxemburg

Luxembourg has no specific programmes or initiatives dedicated to substitution of substances of concern. The national Helpdesk for the two European Legislations REACH&CLP (www.reach@list.lu) run by the Luxembourg Institute of Science and Technology (LIST) on behalf of the Ministry of the Environment, Climate and Sustainable Development (MECDD) and the Ministry for the Economy (MECO) promotes the substitution of hazardous substances by information and awareness raising via dedicated events, trainings, a targeted alert newsletter on upcoming SVHCs and restrictions, a website section on substitution and answering company questions. Furthermore, LIST was an active partner in the LIFE AskREACH project."

The Netherlands

Name of the programme	Goal and Year of implementation	Factors or considerations that led to its development	Type of approach (non-regulatory or regulatory), incl. roles and responsibilities	Focus on products, articles or processes	Life cycle stage(s) addresses	Chemical(s) addressed	Challenges to implementation	Identified Benefits of the programme	Additional information
Research programme: Towards a practical Safe-by-Design approach for chemical products and processes	1. Development of practically applicable Safe-by-Design approach for the design of chemical substances and processes 2. Recommendations and suggestions for the government to further implement and disseminate the approaches developed and insights acquired. 2023-2026	Need for practical approaches for Safe-by-Design. Link with EU Chemical s Strategy for Sustainability, especially Safe and Sustainable by Design.	Research		All	Focus on alternatives for persistent, mobile and toxic substances. Development of integrated tools to select alternatives and produce SSbD. Methods for preventing the use of substances of concern in product development (Safe & Circular by Design)			https://www.nwo.nl/en/researchprogrammes/dutch-research-agenda-nwa/thematic-programming/towards-practical-safe-design-approach-chemical-products-and-processes
National Policy on 'Zeer Zorgwekkende	Reduction and prevention of ZZS emissions,	National policy, link to REACH	Regulation		Potentially all life cycle stages, however, effect often in	All ZZS substances,			http://www.rivm.nl/rvs/Stoffenlijsten/Zeer_Zorgwe

Stoffen' (ZZS≈SVHC)	substitution of ZZS Ongoing				production stage.				kkende_Stoffen (in Dutch)

United States

Name of the programme	Goal and Year of implementation	Factors or considerations that led to its development	Type of approach (non-regulatory or regulatory), incl. roles and responsibilities	Focus on products, articles or processes	Life cycle stage(s) addresses	Chemical(s) addressed	Challenges to implementation	Identified Benefits of the programme	Additional information
US EPA Safer Choice program	Help consumers, businesses, and purchasers find products that perform and are safer for human health and the environment. Implemented in 2002 (Initially named Design for the Environment, renamed to Safer Choice in 2015)	Response to stakeholders, industry, NGOs, and retailers, to encourage green chemistry up and down the value chain.	Voluntary; multi-stakeholder partnership with industry (chemical manufacturers/suppliers and product manufacturers/formulators), NGOs, and retailors. Product manufacturers agree to use only chemicals that meet program criteria in exchange for use of Safer Choice label	Products	Safer Choice program is focused on the use stage. Safer Choice recognized products must also not contain ozone depleting substances and must meet product level sustainability requirements for packaging	The Safer Chemical Ingredients List is a living list of chemical ingredients, arranged by functional-use class, that the Safer Choice program has evaluated and determined to be safer than traditional chemical ingredients. https://www.epa.gov/saferchoice/safer-ingredients	Low-hazard chemicals are often not subject to extensive toxicological testing and data development	Products with the Safer Choice label help consumers and commercial buyers identify products with safer chemical ingredients, without sacrificing quality or performance. The Safer Chemical Ingredients List is designed the help manufacturers find safer chemical alternatives that meet the criteria of the Safer Choice program.	Safer Choice program Standard and Criteria: https://www.epa.gov/saferchoice/standard

US EPA Toxic Substance Control Act (TSCA) Section 6(c)(2)(C) analysis	Consideration of whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available when deciding whether to prohibit or substantially restrict a specific condition of use of a chemical substance. First analyses in 2022 with proposed rules.	Statutory requirement for risk management under 2016 Toxic Substance Control Act (TSCA) section 6.	Regulatory; EPA does a review of available alternatives and performs screening assessments of hazard and other endpoints.	All conditions of use of a chemical substance or mixture being substantially restricted which can include products, articles, and processes.	All conditions of use of a chemical substance or mixture being substantially restricted which can include all lifecycle stages.	There are currently nine chemicals undergoing risk management under TSCA Section 6: Asbestos, 1-Bromopropane, Carbon tetrachloride, C.I. Pigment Violet 29, Cyclic Aliphatic Bromide Cluster (HBCD), Methylene Chloride, N-Methylpyrrolidone (NMP), Perchloroethylene, and Trichlorethylene (TCE).	Limited in scope to screening of hazard information on available chemical alternatives. Does not recommend or endorse an alternative.	Expected benefits are to support risk management rulemaking to prohibit or restrict the use of a chemical determined to have unreasonable risk.	Chemicals undergoing risk evaluation and potentially risk management under TSCA Section 6 https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca