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Cross Country Analysis: Approaches to Support Alternatives Assessment and Substitution of Chemicals of Concern

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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 COOPERATION AND DEVELOPMENT
Paris 2019

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Cross Country Analysis: Approaches to Support Alternatives Assessment and Substitution of Chemicals of Concern

In 2017, the OECD Ad Hoc Group on the Substitution of Harmful Chemicals initiated a project, the objective of which was to have a better understanding of approaches developed across countries and by different stakeholders to support alternatives assessment and substitution of chemicals of concern. A questionnaire was used to collect experiences, and responses were received from Canada, Denmark, Germany, Luxembourg, the Netherlands, the United States, the United States State of California, the European Union, the European Environmental Bureau, ChemSec, the University of Massachusetts Lowell and the International Union of Pure and Applied Chemistry (IUPAC).

The goal of the questionnaire was to collect information on:

- Approaches used to support alternative assessments and substitution within countries;
- The strengths of the approaches and challenges to design and implementation;
- If and how these approaches are linking with innovation strategies;
- Gaps in moving the field forward.

This report presents analysis of the responses received to the questionnaire. It describes approaches in place (policy, regulatory and non-regulatory/voluntary approaches), their impact and the context in which they have been developed, as well as gaps and opportunities for advancing alternatives assessment practice and substitution of chemicals of concern.

Following an OECD Expert Workshop organised on 2-3 May 2018, this report was completed with information from presentations and discussions at the workshop.

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

The first question in the questionnaire aimed at collecting a list of approaches per country/stakeholder used to support alternatives assessment and substitution. Feedback received is shown in Annex A of this report.

A combination of regulatory and voluntary approaches to support substitution

One trend emerging from the responses is the widespread use of voluntary approaches to support substitution. All the respondents who answered the questions on which type of approaches are the most effective to support substitution, indicated that a combination of voluntary and regulatory approaches was necessary. Regulation is a strong, and often necessary, driver but does not provide support in itself to companies in their substitution efforts. Voluntary initiatives reduce the risk of regrettable substitution and encourage a more sustainable vision of change. Other initiatives were also noted as important: capacity and knowledge building, knowledge sharing and creation of networks.

For example, in addition to the regulatory framework provided by the European Union, through REACH and other relevant EU regulations, European countries are developing voluntary approaches, most of them multi-stakeholder. The goal of these approaches is to establish partnerships with companies who are willing to integrate programmes. The initiatives provide support for assessing chemicals as well as establishing standards/criteria that companies aim to follow. Most of these voluntary approaches also include NGOs, academia and the public. In the United States, at the federal level, multi-stakeholder, voluntary approaches have also been used with the same intent. The US State of California has developed a regulatory approach; however the regulatory framework has been developed as a complementary mix of regulatory and voluntary approaches offering flexibility and incentive to voluntarily substitute/remove chemicals of concern. A number of examples showed that regulatory approaches are often used in the case of worker health protection so that they are not exposed to hazardous chemicals when alternatives are available.

What are the main goals of the voluntary approaches developed?

As mentioned above, voluntary approaches often aim at engaging a variety of stakeholders, in particular industry, to stimulate alternatives assessment and substitution. They aim to send clear signals to industry on what is expected of them (for example in response to a regulation) and bring support and knowledge. These approaches are developed for encouraging sustainable development and sustainable chemistry practices.

Often the following key words were used to describe the factors influencing the development of voluntary approaches showing how critical substitution has become to address major policy issues:

- reduction of pollutants emission,
- climate change adaptation,
- chemicals in the circular economy;
- industry's environmental performance.

As summarised below, approaches described by respondents have different goals and means.

Providing tools and platforms to support substitution

A number of initiatives have been developed to provide tools and platforms to support alternatives assessment and substitution. For example Germany has developed the IT tool SubSelect to help producers and operators evaluate sustainability through a set of criteria applicable to substances and mixtures. Another example is the MarketPlace website developed by ChemSec. This website is a user-created content website, where you can create your own advertisement – marketing that you either have an alternative to sell or that you are looking to buy one. Denmark's Partnership for Substitution aims to provide practical tools for companies on alternatives assessment as well as tools for assessing the technical and economic aspects of substitution.

Integrating substitution into research agendas and innovation strategies

A number of the approaches described by the respondents aimed at advancing science to assess alternatives and identify opportunities for innovation through the supply chain. These approaches can intervene via the development of specific agendas for R&D or use policy instruments to stimulate green innovation and more sustainable products. For example, the Netherlands Safe Chemicals Innovation Agenda aims to develop an agenda for R&D for safe chemicals, materials and products. The Danish Eco-Innovation Programme is a subsidy scheme with a 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. The European Chemicals Agency (ECHA) has developed a strategy to promote substitution to safer chemicals through innovation.

Innovation programmes are aimed at supporting the development of solutions that can perform in the market and be accepted in the marketplace.

A number of research projects were also mentioned aiming to collect information on alternatives to specific substances, often substances that are or will be listed as substances of concern (e.g. BPA in thermal paper, a certain phthalates). There were also approaches aiming to generate information on bio-based alternatives to certain substances. For example, the Netherlands SafeBBE aims to support safe and sustainable design of bio-based chemicals and products by providing an overview of applicable sustainability assessments and identifying safety and sustainability indicators for R&D stages.

Setting standards

Some approaches were directly setting "green" standards. For example, the EU Flower and the Nordic Swan programmes enable suppliers of goods to be able to use a label showing that the products meet a certain standard of environment friendliness. The label is controlled by an independent official body.

Protecting the population and the most exposed

In a number of approaches, a direct goal was the development of safer consumer products. These approaches also help companies in creating new business opportunities and makes it easier for consumers and businesses to identify what substances are in particular products.

For example, the US EPA Safer Choice programme helps consumers, businesses, and purchasers find products that perform and are safer for human health and the environment.

Other approaches aim at the removal of chemicals of concern in locations where the population is directly exposed. For example, the Netherlands Green Deal plant protection products programme has a goal to end by 2020 the use of chemical plant protection products at sports and recreation fields, unless in exceptional cases. There is also the Pesticide Free Towns initiative to avoid pesticide use in public areas of European cities.

What are regulatory approaches focusing on?

A number of regulatory approaches are described in the responses from countries: in Europe, REACH and other relevant EU regulations; in the US State of California, the California Safer Consumer Products (SCP) Regulations; and a number of countries mentioned they have workers protection regulations linking to substitution.

In Europe, the focus is on the following themes:

- EU REACH Authorisation process: aiming 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;
- EU REACH Application for authorisation process: including the preparation of an analysis of alternatives;
- 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;
- EU Classification, Labelling and Packaging 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;
- EU Biocidal Products Regulation: 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;
- EU Plant Protection Products Regulation: exclusion provisions, substitution and low risk provisions.

In the case of the California SCP Regulations, the goals of the approach are the following:

- To have a statutory and regulatory requirement to avoid regrettable substitution;
- To provide a mechanism to address chemicals of concern in products and reduce the number of legislative bills introduced on individual chemicals;
- To provide a regulatory structure that incentivizes innovation and green chemistry.

More information on these approaches is available in Annex A.

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

Successes in implementation

The questionnaire asked if successes could be identified from the approaches developed. A number of common elements can be highlighted from the responses received:

- Regulations and policy provides an important incentive for substitution;
- A collaborative approach between industry, government agencies (federal/state/local) and NGOs is frequently used to support a move toward safer and more "sustainable" alternatives and prevent regrettable substitution;
- Support to R&D and innovation in relevant areas is critical to increase the availability of alternatives;
- Access to tools and guidance as well as facilitation of supply chain communication and information on possible alternatives, including chemicals and technical solutions are important enabling factors;
- Many companies have proactively adopted alternatives assessment and green chemistry approaches to inform chemical substitution and promote innovation. One respondent raised the importance of "embedding substitution thinking into standard business practice". It was also noted that an in depth engagement with stakeholder groups can create a mind-set change. This change has been particularly visible with chemical users (e.g. textile industry) who are motivated to find functional solutions for safer alternatives without being "attached" to the use of a particular chemical;
- Partnerships are in general attracting quite a lot of interest. There is interest, for example, when sponsorship programmes are available to support alternatives assessment and substitution research, in particular for small and medium-size enterprises SMEs. It is important to advertise these initiatives so that the opportunities are made available to those in need;
- Having contact points in countries who can answer queries from companies and provide support is also important. These resources should be made well known to companies.

Challenges to implementation

The questionnaire asked what were the challenges to implementation of the approaches mentioned. Respondents highlighted the following points:

- Regrettable substitution, often with a substance structurally similar to the chemical of concern, is a common problem to successful implementation of approaches. Some approaches can help to overcome regrettable substitution, such as creating robust multi-stakeholder partnerships and support to R&D and innovation programmes;
- Some companies, in particular SMEs, can lack knowledge, access to information and/or resources, which makes it hard to engage with them;
- Implementation of approaches can be a challenge because of the complexity of supply chains. It was highlighted by some respondents that there should be more

consideration of approaches aiming to stimulate communication in the supply chain;

- Some sectors might be more difficult to engage with than others. In the textile industry important steps have been taken to move toward safe and sustainable products. Other sectors are more challenging to work with, for example because of confidentiality issues or less sectoral collaboration and organisation.
- Risk trade-offs remain an issue that substitution efforts need to address, and are impediments to sustainable substitution;
- Market/consumer demands are important drivers of substitution, but often the process chemistry side of the supply chain is overlooked. Risks to workers should stimulate the same level of engagement for substituting harmful chemicals as safer consumer products.

Specifically in the case of a regulatory approach, the following challenges could be identified from responses to the questionnaire:

- There is a lack of relevant data, in particular hazard data (including human health and ecological toxicity), on chemicals in general. This makes it difficult for consumers to make decision on the product they purchase, for downstream users that want to design safe products, and for regulators to identify which chemicals should be substituted and what suitable alternatives there are;
- There is a need for more training and tools to support the regulated community, in particular guidance to improve the quality of the information provided in response to the EU authorisation process and harmonisation of this information.

Evaluation of the benefits and costs

The questionnaire asked whether approaches had been evaluated, in particular in terms of costs and benefits. In most cases the approaches had not been evaluated because they have recently been developed. Evaluating benefits and costs of voluntary approaches can also be a challenge. However the obvious benefits of these voluntary approaches for assuring a sustainable substitution practice was strongly highlighted by most respondents. The U.S. EPA's Design for the Environment (DfE) Chemical Alternatives Assessment Programme did not formally evaluate how alternatives assessment partnerships influenced substitution decisions or the marketplace. However, the programme has been able to document market outcomes, for example pentaBDE and HBCD were removed from production in U.S. after the completion of alternatives assessments for those chemicals. In the case of the U.S. EPA's Safer Choice Programme, it has developed a suite of metrics for tracking progress/status; these include documentation of increased production and use volume of Safer Choice-certified products, as well as increases in the number of chemicals meeting Safer Choice criteria.

In the case of regulatory approaches, at the European level, the REACH authorisation process (including the steps of identification as substances of very high concern, recommendation for inclusion in Authorisation List and applications for authorisation) has been recognised as an effective driver for substitution, as shown in a study to measure the impacts of REACH Authorisation[1]. An assessment of the cost and benefits in REACH restriction dossiers has also been performed[2]. The European Commission has published, in March 2018, the evaluation of the performance of REACH in its first ten years of operation (second REACH review) that looks into the substitution of SVHCs (substances of very high concern) achieved so far[3]. Further substitution related considerations will be included in the ongoing Fitness Check of most chemicals legislation (excluding REACH), expected to be finalised by the end of 2018[4].

In the State of California, the SCP regulations require cost/benefit analysis in the Alternatives Analysis (AA) Reports that manufacturers of Priority Products must submit. For example, chemical quantity and market information, public health and environmental costs, and costs to governmental agencies and non-profit organisations, should be provided. However, the regulations do not require manufacturers to generate new data if they are not available at the time of submission. Since these analyses will be evolving, the goal is that these AA Reports and other notifications can be used as a basis to evaluate the benefits and costs of implementation of the approach. To date SCP has neither received any AAs or notifications, nor evaluated the benefits and costs of implementation of the programme. The first notifications and AAs are expected before the end of calendar year 2018.

1 See, https://ec.europa.eu/DocsRoom/documents/26847

2 See, http://echa.europa.eu/documents/10162/1 3630/cost_benefit_assessment_en.pdf

3 See, https://ec.europa.eu/growth/sectors/chemicals/reach/review_en

4 See, http://ec.europa.eu/environment/chemicals/better_regulation/index_en.htm

Considering new approaches

The questionnaire asked if other approaches –ones that haven't been considered or implemented in the respondent's country– should be explored and could potentially be highly beneficial to support substitution.

The development of approaches aiming to involve a whole supply chain (sector specific) in a common effort was mentioned as very valuable. Platforms where companies can directly exchange on availability of alternatives for specific usage were also seen as important (such as the MarketPlace from ChemSec).

There was also interest in linking technology innovation research programmes with safer chemical/material assessments.

A number of respondents noted the importance of thinking in terms of circular economy for chemicals management.

III. Linking Substitution and Innovation

The questionnaire asked whether governments have sponsored innovation programme linking to substitution, and if an increase in innovation had been found as a result of a substitution programme.

Almost all respondents indicated that sponsorship/funding programmes have been established in their country that link to green chemistry/sustainable development. Often the link is not sufficiently clear that these can also encourage alternatives assessment and substitution.

IV. Moving the field forward

In order to have some perspectives on the needs to move the field forward, the following questions were asked as part of the questionnaire:

- How can countries and other entities work together to facilitate data sharing and other collaborative efforts?
- What types of data should be prioritised for data sharing, and what type of data should be prioritised for data generation?
- How can approaches to alternatives assessments be further harmonised across countries?

A summary of responses received to each question is given below.

How can countries and other entities work together to facilitate data sharing and other collaborative efforts?

The OECD SAAToolbox was mentioned by a number of respondents as a useful mechanism to facilitate sharing of information. In general the OECD Ad Hoc Group was seen as an important supportive framework. It was mentioned that the work could go a step further in collecting experience from OECD projects as well as other networks in order to draw practical guidance/good practices. There was a recommendation made that the focus of the Ad Hoc Group includes areas for collaboration, such as:

- Harmonization of criteria to identify a low concern/safer substance;
- Tools/guidance to support industry in alternatives assessment;
- Prioritising product-chemical combinations that would benefit from activities that support informed substitution.

A point that was raised by a number of respondents is the possibility that data associated to each chemical be provided in a harmonized format (e.g. by using the IUCLID tool based on the OECD Harmonised Templates (OHTs) format). This could help increase efficacy of data sharing and collaborative efforts and allow countries to apply their respective criteria on a comprehensive dataset.

A number of respondents noted that activities at the national level should aim to engage government and corporate management at higher level, for example through the organisation of workshops.

The link between substitution and innovation should be made stronger - this was emphasised at numerous occasion by respondents. Networks of stakeholders (industry, regulators, civil society, academia, policy) should aim at defining/prioritising R&D programmes and speed up innovation. Existing networks could be used to do so.

The importance of a sector specific approach when it comes to collaboration was highlighted, with initiatives to stimulate communication along the supply chain. These should establish mechanisms to engage specifically with SMEs.

What types of data should be prioritised for data sharing and what type of data should be prioritised for data generation?

Respondents highlighted that a wide range of useful data could be generated and shared:

- Data on availability of alternatives and alternatives assessment (e.g. examples of assessments, substitution, successful innovation);
- Hazard information, especially ecological hazards/ecotoxicity endpoints – not just aquatic, but also amphibian, avian, and other terrestrial impacts;
- Exposure data, especially emission rates for different use scenarios, worker exposure data, environmental monitoring data;
- Product ingredient and chemical quantity information;
- Life cycle inventory and impact assessment data;

- Experimental, read across, and new approach methodology (NAM) data;
- Public health and environmental costs data;
- Consistent data on chemical function and application – to know what alternatives could be used;
- Curated data for chemicals that have already been reviewed by a country for specific endpoints – including both chemicals that have been identified as needing to undergo risk evaluation and those that no further action is needed;
- Use data;
- Data that will allow ranking chemicals according to their environmental and health effects as well as their role in the circular economy;
- Information on the frameworks developed in different countries/regions and their success;
- Information on training and capacity building initiatives.

For the generation of data, data on alternatives could be characterised according to "safer" criteria, for example harmonised criteria that the OECD could help develop. The OECD Ad Hoc Group could also seek for opportunities to collaborate with other OECD groups in order to enhance data sharing efforts. More opportunity to engage with industry on the side of data sharing and generation would be of added value.

There was a comment that the database developed at ECHA is seen as very valuable tool for data sharing to support alternatives assessment and substitution and efforts could be made to make this database more users friendly so that it can be widely used.

How can approaches to alternatives assessments be further harmonised across countries?

Respondents highlighted that to harmonise approaches a key element is the sharing of relevant information across countries.

Some areas for harmonisation were suggested for possible further investigation:

- A minimum dataset requirement for alternatives analyses and possible criteria thresholds;
- Identify areas of priority with regard to uses of chemicals;
- Groups of chemicals where the need or possibility for substitution are strong;
- Socio-economic analysis;
- Criteria of performance for the alternatives;
- The development of green metrics (associated, for example, with major issues such as climate change and resource scarcity).

There could also be opportunities for incorporating relative hazard/relative risk rankings into assessments for groups of chemicals - and harmonize approaches across countries in this area. Developing and communicating harmonized approaches to alternatives assessment that could be used by industry and supported by government agencies, could also be an area to explore.

It was also highlighted that regulatory differences and requirements can make harmonisation challenging across countries, but having a consistent set of steps, data sources that must be reviewed, and a minimal set of required endpoints that need to be assessed could be of value.

Existing international frameworks, such as the Stockholm, Rotterdam, and Minamata Conventions, the Sustainable Development Goals, processes like the Strategic Approach to International Chemicals Management (SAICM) and areas where OECD is active in chemicals policy could be starting points for identifying priority areas for further alignment or harmonisation.

Annex A: Approaches to Support Alternatives Assessment and Substitution

DENMARK									
Name of the programme/ initiative	**Goal of the programme/ initiative**	**Corresponding policy, legislation, or international framework, if applicable**	**What factors or considerations led to the development of the programme/ initiative?**	**Year(s) of Implementation**	**Type of approach (voluntary or regulatory), including roles and responsibilities**	**Life cycle stage(s) addressed**	**Which of the following elements does the programme typically consider: hazard, exposure, risk , socio-economic aspects, life-cycle considerations**	**Chemicals addressed, specific projects or tools that have been developed or are underway. Provide link(s) to additional information.**	**Additional information/details of the programme, including if there is a focus on specific sectors/uses**
Partnership for substitution "Kemi i Kredsløb" (circular chemistry)	The aim of the partnership is to provide practical tools for companies on alternatives assessment as well as tools for assessing the technical and economic aspects of substitution. In addition, the partnership supports substitution projects in a number of Danish companies	The partnership is part of the national "Action plan for chemicals, 2014-17" and is funded by the Danish Eco-innovation programme http://eng.ecoinnovation.dk/the-danish-eco-innovation-program/ecoinnovation-subsidy-scheme/	A general need for support for substitution was identified, and the partnership model was considered suitable. The partnership had the aim of focussing on chemicals that act as barriers for circular economy, however these are difficult to identify	2014-2018	The funding for the partnership is part of national action plan. The participation is voluntary	All. It is an aim to focus on substitution needed to enable circular economy	all	Bispenol A organic solvents tincompounds Octical brightener Methylpyrrilidone Cobalt	http://www.kemiikredsloeb.com/ The partnership addresses all companies in all sectors where substitution would benefit environment, health or circular economy.

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.	Consolidated Act on the Environmental Technology Development and Demonstration Programme Statutory Order on the Environmental Technology Development and Demonstration Programme	Government action plan to support growth and environmental technologies	2007	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.	For chemical substitution projects there is a focus on reducing the use of hazardous substances, but also on creating growth and new jobs in Danish companies through innovation	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 health legislation to choose safer alternative if available		Workers health considerations	2003 or before	Regulatory, generic	Production- workplace	Exposure and risk	CMR + stot	http://engelsk.arbejdstilsynet.dk/en/regulations/acts/working-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.	https://www.ecolabel.dk/~/media/Ecolabel/Files/Virksomheder/Regler-for-markedsføring/Statutory-order-from-the-Ministry-of-Environment-No-274.ashx?la=da http://eur-lex.europa.eu/legal-content/EN/TXT/?	Considerations for the environment		Voluntary	All. Mainly from environment considerations but also health	Environment exposure	Various, depending on product	https://www.ecolabel.dk/da/in-english http://www.nordic-ecolabel.org/ http://ec.europa.eu/environment/ecolabel/

		uri=CELEX:32010R0066							
GERMANY									
Name of the programme/ initiative	**Goal of the programme/ initiative**	**Corresponding policy, legislation, or international framework, if applicable**	**What factors or considerations led to the development of the programme/ initiative?**	**Year(s) of Implementation**	**Type of approach (voluntary or regulatory), including roles and responsibilities**	**Life cycle stage(s) addressed**	**Which of the following elements does the programme typically consider: hazard, exposure, risk , socio-economic aspects, life-cycle considerations**	**Chemicals addressed, specific projects or tools that have been developed or are underway. Provide link(s) to additional information.**	**Additional information/details of the programme, including if there is a focus on specific sectors/uses**
IT-Tool SubSelect and guideline "Criteria for Sustainable Chemicals"	Tools for producers and operators evaluating sustainability through a set of criteria applicable to substances and mixtures. The assessment criteria encompass e.g. greenhouse gas potential, resource demand, (eco-) toxicity, mobility and persistence in the environment as well as responsibility in the value chain. The guideline helps producers and operators to green their chemical portfolio as well as their internal processes.	N/A	Realizing and fostering sustainable chemistry in practice	First release in 2010; update and SubSelect in 2016	voluntary	design and production	Hazard, exposure, risk , socio-economic aspects, analysis of alternatives and, when relevant, life-cycle considerations	All chemicals	https://www.umweltbundesamt.de/publikationen/guide-on-sustainable-chemicals?anfrage=Kennummer&Suchwort=4169 Supporting material: https://www.umweltbundesamt.de/en/document/subselect-guide-for-the-selection-of-sustainable

THE NETHERLANDS									
Name of the programme/ initiative	**Goal of the programme/ initiative**	**Corresponding policy, legislation, or international framework, if applicable**	**What factors or considerations led to the development of the programme/ initiative?**	**Year(s) of Implementation**	**Type of approach (voluntary or regulatory), including roles and responsibilities**	**Life cycle stage(s) addressed**	**Which of the following elements does the programme typically consider: hazard, exposure, risk , socio-economic aspects, life-cycle considerations**	**Chemicals addressed, specific projects or tools that have been developed or are underway. Provide link(s) to additional information.**	**Additional information/details of the programme, including if there is a focus on specific sectors/uses**
Safe Chemicals Innovation Agenda	Develop an agenda for R&D for safe chemicals, materials and products as input for EU and national R&D policy	Horizon 2020, 9th Framework Programme, national R&D policies	Two observations: 1. we need innovation at a more fundamental level than legislation alone is unable to stimulate 2. there is relatively little attention to safety of chemicals in R&D programmes	2018	Input for innovation policy	Design stage of chemicals, materials and products (take all stages into account)	Relevance for health and environment, impact on EU competitiveness, scientific challenge, type of substitution, contribution to other sustainability aspects, maturity level	All types of chemicals Website with workshop results to be available later	Workshop on draft agenda 28 March 2018. Report available mid-2018. Details: Jochem.vander.waals@minienm.nl
Stakeholder dialogue antifouling	Stimulate safe alternatives to antifouling paints with risks to aquatic environment. Learn from this example how to	Link with Biocidal Products Regulation	There are several potential alternative products with small market share. Need to discuss what is needed for scale up	Kick off with workshop 5 October 2018 at Innovation Expo in Rotterdam	Voluntary	Design stage of chemicals, materials and products (take all stages into account)	Hazard, exposure, risk, , socio-economic aspects, life-cycle considerations	Alternatives to antifoulant paints with copper/zinc Website with workshop results to be available later	Available later

	set up stakeholder dialogue in supply chains								
Website about substitution	Give some guidance for companies		Need to ease access to information		Voluntary	All		https://www.chemischestoffengoedgeregeld.nl/content/vervanging-gevaarlijke-stoffen	
Green Deal plant protection products sports and recreational fields	By 2020 end the use of chemical plant protection products at sports and recreation fields, unless in exceptional cases		Total ban has not been possible thus far, because of other safety aspects. Need for pilots and innovation.	2015-2020	Voluntary	Design stage of chemicals, materials and products (take all stages into account)	Hazard, exposure, risk, , socio-economic aspects, life-cycle considerations	http://www.greendeals.nl/gd-189-sport/	
National Policy on 'Zeer Zorgwekkende Stoffen' (ZZS≈SVHC)	Reduction and prevention of ZZS emissions, substitution of ZZS	National policy, link to REACH		Ongoing	Regulation	Potentially all life cycle stages, however, effect often in production stage.	Hazard, exposure, risk	All ZZS substances, http://www.rivm.nl/rvs/Stoffenlijsten/Zeer_Zorgwekkende_Stoffen (in Dutch)	Further explanation can be found below
SafeBBE	Support safe and sustainable design of (bio based) chemicals (and products). Provide an overview of applicable sustainability assessments and identify safety and sustainability indicators for R&D stages.	Strategic Programme (SPR) Dutch National Institute for Public health and the Enviroment (RIVM)	Need for early stage indicators during chemical (product) innovation/ R&D that reflect the safety indicators used for international (EU) legislation (e.g.REACH) and can be integrated in sustainability assessments.	2015-2018	Voluntary, research project	Cradle to grave/ cradle	Hazard, (exposure, risk), socio-economic aspects, life-cycle considerations (overview of existing sustainability and safety themes used in sustainability and risk assessments)	All open access tools/ publications: http://www.sustainabilitymethod.com/ Method selection for sustainability assessments: The case of recovery of resources from waste water https://www.sciencedirect.com/science/article/pii/S0301479717303274?via%3Dihub	http://www.rivm.nl/en/Topics/B/Biobased_economy/Safe_and_sustainable_bioeconomy_Safe_BBE

								Environmental assessment of bio-based chemicals in early-stage development: a review of methods and indicators: http://onlinelibrary.wiley.com/doi/10.1002/bbb.1772/full	
Biobased alternatives aprotic solvents	Generate information on substitution of specific substances of concern, stimulate substitution, stimulate biobased alternatives	National Policy on ZZS; link to REACH regulation	Interest in biobased replacement potential for substances of very high concern. Difficulty of replacement of this specific group of chemicals	2017	Research project	Design stage of chemicals/processes	Technical feasibility of alternatives, economic/market considerations, availability	Polar aprotic solvents: NMP, DMAc and DMF	https://www.wur.nl/en/news-wur/Show/Promising-biobased-alternatives-to-polar-aprotic-solvents.htm Report of the prior project: https://www.wur.nl/upload_mm/d/a/d/027cf799-0ba9-4496-85bf-d53bd6cd6d64_WUR-FBR%20report%201506%20RIVM%20ZZS-2-BIO%20project_v2.pdf Continuing project: http://resolve-bbi.eu/
Initial screening alternatives for biocides with formaldehyde or formaldehyde releasers	First investigation on availability of alternatives	Link with CLP and Biocidal Products Regulation	Change in classification may imply that formaldehyde containing products will be no longer authorized. This initial screening looks at the availability of alternatives for various applications as disinfectant or preservative (biocides).	2016	Research project	Use phase	Technical feasibility, hazard	Formaldehyde (releasers) in biocide applications	http://www.rivm.nl/bibliotheek/rapporten/2015-0186.html

Analysis of alternatives for BPA in thermal paper	Assessment in preparation of a potential EU REACH restriction on BPA in thermal paper	Link with REACH restriction	Extra input for the assessment of technical feasibility of alternatives and investigation of potential biobased alternatives	2015	Research project	Design, production and use	Availability, technical and economic feasibility	BPA in thermal paper	http://www.rivm.nl/en/Documents_and_publications/Common_and_Present/Newsmessages/2015/Biobased_alternatives_to_hormone_disrupting_substance_in_cash_register_receipts
Analysis of alternatives for a group of phthalates	Assessment in preparation of the REACH authorisation process for a selection of phthalates	Link with REACH Authorisation	Difficulty in evaluating (technical) feasibility of alternatives for (SEAC) experts, wish to prepare for the upcoming applications for authorisation	2014	Research project	Design, production and use	Hazard, technical and economic feasibility, availability and timing, R&D and suitability	Four phthalates (DEHP, BBP, DBP and DIBP) in six applications	http://www.rivm.nl/Documenten_en_publicaties/Algemeen_Actueel/Nieuwsberichten/2014/Onderzoek_naar_alternatieven_voor_ftalaten
UNITED STATES									
Name of the programme/ initiative	**Goal of the programme/ initiative**	**Corresponding policy, legislation, or international framework, if applicable**	**What factors or considerations led to the development of the programme/ initiative?**	**Year(s) of Implementation**	**Type of approach (voluntary or regulatory), including roles and responsibilities**	**Life cycle stage(s) addressed**	**Which of the following elements does the programme typically consider: hazard, exposure, risk , socio-economic aspects, life-cycle considerations**	**Chemicals addressed, specific projects or tools that have been developed or are underway. Provide link(s) to additional information.**	**Additional information/details of the programme, including if there is a focus on specific sectors/uses**
EPA DfE Chemical Alternatives Assessment Program	Identify and evaluate the safety of alternative chemicals	Toxic Substances Control Act (TSCA)	DfE AAs are conducted to inform risk management actions under TSCA, and may also serve as a complement to regulatory approaches.	2005-2015	Voluntary, multi-stakeholder partnership program of industry, research/academic community, NGOs, government, and public	DfE alternative assessments consider lifecycle stages from production to end-of-life.	Primary focus is on chemical hazard assessment, but exposure, technical feasibility, cost/benefits and availability, lifecycle impacts, and social impacts are also considered.	• BPA in Thermal Paper • Alternatives to DecaBDE • Alternatives to HBCD • Flame Retardants in Flexible Polyurethane Foam • Flame Retardants in Printed Circuit Boards • Nonylphenol Ethoxylates https://www.epa.gov/saferchoice/design-environment-alternatives-assessments	DfE criteria for designating chemical hazards: https://www.epa.gov/saferchoice/alternatives-assessment-criteria-hazard-evaluation

US EPA Safer Choice program	Help consumers, businesses, and purchasers find products that perform and are safer for human health and the environment	Voluntary program with authority from the Pollution Prevention Act and TSCA.	Response to stakeholders, industry, NGOs, and retailers, to encourage green chemistry up and down the value chain.	2002-present Renamed to Safer Choice (from Design for the Environment) in 2015	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	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	Focus on hazard assessment, with components of exposure (i.e. use limits based on residuals of concern in products) and life-cycle considerations (product packaging sustainability)	Safer Chemical Ingredients List-a list of chemical ingredients, that may be used to formulate products with the Safer Choice label (arranged by functional-use), that the Safer Choice program has evaluated and determined to be safer than traditional chemical ingredients: https://www.epa.gov/saferchoice/safer-ingredients#searchList	Safer Choice program Standard and Criteria: https://www.epa.gov/saferchoice/standard
UNITED STATES - STATE OF CALIFORNIA									
Name of the programme/ initiative	**Goal of the programme/ initiative**	**Corresponding policy, legislation, or international framework, if applicable**	**What factors or considerations led to the development of the programme/ initiative?**	**Year(s) of Implementation**	**Type of approach (voluntary or regulatory), including roles and responsibilities**	**Life cycle stage(s) addressed**	**Which of the following elements does the programme typically consider: hazard, exposure, risk , socio-economic aspects, life-cycle considerations**	**Chemicals addressed, specific projects or tools that have been developed or are underway. Provide link(s) to additional information.**	**Additional information/details of the programme, including if there is a focus on specific sectors/uses**
California Safer Consumer Products (SCP) Regulations	• Reduce toxic chemicals in consumer products • Create new business opportunities in the emerging	California's Green Chemistry Law (California Health and Safety Code (HSC), Division 20,	• Statutory and regulatory requirement to avoid regrettable substitution. • It provides a mechanism to	Since 2013	Regulatory. Roles and responsibilities of stakeholders are defined clearly by the SCP Regulations.	Regulations require considering entire life cycle span of the consumer product: from raw materials extraction to end-of-life.	Performance, function, hazard, exposure, life cycle multimedia impacts, and economic impacts including external and internal costs, when relevant.	• Children's foam-padded sleeping products with TDCPP or TCEP • Spray polyurethane foam with unreacted MDI (underway) • Paint stripper with	Alternatives Analysis Guide (Version 1.0) and other resources are available at: http://www.dtsc.ca.gov/SCP/AlternativesAnalysis.cfm

	safer consumer products industry • Help consumers and businesses identify what is in the products they buy for their families and customers	Chapter 6.5, Article 14) and Safer Consumer Products (SCP) Regulations (Title 22, California Code of Regulations (CCR), §69505). AB 1879 SB 509	address hazardous chemicals in products and reduce the number of legislative bills introduced on individual problematic chemicals. • It aims to provide a regulatory structure that incentivizes innovation and green chemistry					methylene chloride (underway) • Per- and poly-fluorinated alkyl substances on carpeting (underway) More information: http://www.dtsc.ca.gov/SCP/PriorityProducts.cfm	

CANADA

The Canadian Chemicals Management Plan (CMP) doesn't have a program specific to alternatives assessment or substitution; however this is an area being explored as part of program renewal in 2020. Under the current program, we have grouped substances for risk assessment to help inform substitution (e.g. flame retardants) and have prioritized 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 also 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. Stakeholder engagement is currently underway on topics related to informed substitution to inform program renewal in 2020.

Action by industry to phase out or reduce harmful substances and presumably find alternatives has been observed to be triggered by strong public concern, clear identification of risks and/or clear intention to take action, as seen in several cases under the CMP[5, 6].

LUXEMBOURG

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 for Sustainable Development and Infrastructure (MDDI) and the Ministry for the Economy (ME) promotes the substitution of hazardous substances by information and awareness raising via dedicated events, trainings and a website section on substitution. In addition, companies are supported specifically in their questions and request related to substitution.

EUROPEAN UNION

REACH

Name of the programme/ initiative	Goal of the programme/ initiative	Corresponding policy, legislation, or international framework, if applicable	What factors or considerations led to the development of the programme/ initiative?	Year(s) of Implementation	Type of approach (voluntary or regulatory), including roles and responsibilities	Life cycle stage(s) addressed	Which of the following elements does the programme typically consider: hazard, exposure, risk , socio-economic aspects, life-cycle considerations	Chemicals addressed, specific projects or tools that have been developed or are underway. Provide link(s) to additional information.	Additional information/details of the programme, including if there is a focus on specific sectors/uses
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	REACH Regulation (Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation,	Revision of previous EU legislations on manufacture and use of chemicals	2007	Regulatory approach. Type and role of stakeholders depending on the procedure stage: 1. SVHC identification: EU Member State or ECHA, at the request	No specific life-cycle stage addressed. The manufacturing stage is exempted.	SVHC identification is hazard-based only. Recommendation for inclusion in Annex XIV is mainly based on intrinsic properties, wide dispersiveness of the use(s) and volumes that fall within the scope of the authorisation requirement but can take	List of SVHCs included in the Candidate List: https://echa.europa.eu/candidate-list-table Recommendation for inclusion in Authorisation List	Info on SVHC identification: https://echa.europa.eu/substances-of-very-high-concern-identification-explained Inclusion in the Candidate List leads to

[5] Discontinued and reduced uses of DTBSBP. See section 3.1 Current Uses in: https://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=0D0BCDA2-1

[6] Reduced industrial uses and releases of BPA, per comment and response on the Risk Management Approach: http://ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=E0A2242D-1

	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 which ones should be included in the Authorisation List (Annex XIV of REACH) as a priority The next step is application for authorisation (see above)	Authorisation and Restriction of Chemicals (REACH))			of the Commission, proposes a substance to be identified as an SVHC. Stakeholders are invited to comment on the identification during a public 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 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		further considerations into account (e.g. grouping of substances due to similar uses, other regulatory measures).	https://echa.europa.eu/previous-recommendations	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 Both steps, and the next step (application for authorisation) have been recognised as providing strong incentives for substitution. See Impacts of REACH Authorisation study

					the recommendation during a public consultation. The Member State Committee then prepares its opinion on the draft recommendation taking into account the comments received during the public 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 alternatives to the	REACH Regulation (Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH))	Revision of previous EU legislations on manufacture and use of chemicals	2007	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, Committee for Risk Assessment and	Stage of the use of the substance and, when relevant, assessment of risks arising from the use of articles made with the substance	Hazard, exposure, risk , socio-economic aspects, analysis of alternatives and, when relevant, life-cycle considerations	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) phthalate (DEHP) • Lead chromate molybdate sulfate red and Lead sulfochromate yellow	Support material including Guidance on how to apply for an authorisation (which includes how to prepare an analysis of alternatives) and Guidance on socio-economic analysis as part of an application for authorisation are available here: https://echa.europa.eu/applying-for-authorisation/start-preparing-your-application The application for

	substance applied for continued use.				Committee for Socio-economic analysis): opinion-making process. European Commission and Member States Competent Authorities for REACH and CLP: decision-making process			• Chromium trioxide • Trichloroethylene • Anthracene oil • Pitch, coal tar, high-temp.	authorisation process, as well as the preceding steps (identification as substances of very high concern and recommendation for inclusion in Authorisation List) have been recognised as providing strong incentives for substitution. See Impacts of REACH Authorisation study
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 the substance	REACH Regulation (Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH))	Revision of previous EU legislations on manufacture and use of chemicals	2007	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 (secretariat, Committee for Risk Assessment and Committee for Socio-economic analysis): opinion-making process. All stakeholders (e.g.	The restriction targets the stage(s) where the substance causes a concern but the analysis can be broader.	Hazard, exposure, risk , socio-economic aspects, analysis of alternatives and, when relevant, life-cycle considerations	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): • 1,4-Dichlorobenzene in air freshener or deodoriser • Bisphenol A in thermal paper • Nonylphenol and Nonylphenol ethoxylates in various applications • DEHP, DBP and BBP in in toys and childcare articles • decaBDE	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 https://echa.europa.eu/fr/support/socio-economic-analysis-in-reach

	considered for the restriction.				commenting on opinions from RAC and SEAC). European Commission and Member States Competent Authorities for REACH and CLP: decision-making process.			(manufacture and placing on the market)	
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 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	CLP: Regulation (EC) no 1272/2008 of the European parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures	Revision of previous EU legislations on classification and labelling of substances and mixtures (Dangerous Substances Directive and Dangerous Preparations Directive), now based on the United Nations' Globally Harmonised System (GHS)	2009	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 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 holds the C&L inventory and provides Member States and the institutions of the	No specific life-cycle stage addressed.	Hazard only	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	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 Regulations and Directives. The classification of a substance as hazardous can be an important incentive for its substitution by safer alternatives.

	certain hazardous chemicals is harmonised to ensure adequate risk management throughout the EU.				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.				
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	BPR: Regulation (EU) no 528/2012 of the European parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products	Revision of previous EU legislation on the placing on the market and use of biocidal products (Directive 98/8/EC from 1998)	2013	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 an 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.	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.	Hazard, exposure, risk , socio-economic aspects Hazard assessment takes place to determine whether a substance meets the criteria for exclusion. Both at active substance approval stage and biocidal product authorisation stage, risks assessments are performed. An assessment of whether derogation criteria are met is also performed, i.e. negligible risk, essentiality to control a serious dangers to human/animal health or the environment, impact of a ban for society (ex: socio-economic element for the EU society, not the company asking the approval/authorisation). If derogation criteria are met, a comparative assessment (Article 23 of the BPR) before delivering	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.	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-

	substances of very high concern, covering CMR 1A and 1B, 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				- 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 conditions for derogation to exclusion are fulfilled, during the final stages of the decision-making process **For the authorisation process of biocidal**		an authorisation on a product to determine if alternatives present significantly lower risks and do not present significant economic or practical disadvantages, and if the available chemical diversity is adequate to control the development of resistance		cc3a8add38cb

	than for approvals/authorisations in general. .				**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) – Substitution provisions	The BPR also provides for s**ubstitution criteria** with the 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	BPR: Regulation (EU) no 528/2012 of the European parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products	Revision of previous EU legislation on the placing on the market and use of biocidal products (Directive 98/8/EC from 1998)	2013	Same process as above for substances subject to 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 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. A comparative assessment with potential alternative has also to be performed by	Both at active substance approval stage and biocidal product authorisation stage, risks assessment are performed. A comparative assessment (Article 23 of the BPR) is performed by the receiving Member State before delivering an authorisation on a product to determine if alternatives present significantly lower risks and do not present significant economic or practical disadvantages, and if the available chemical diversity is adequate to control the development of resistance	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 : spinosad, glutaraldehyde, imidacloprid, PHMB etc.	Additional information on approval of active 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

	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.					Member States when considering applications for authorisation of products containing substances that are candidates for substitution.			
EU Plant Protection Products Regulation (PPPR) – Exclusion provisions	Regulating the placing on the market and use of plant protection products, which are used to protect plants or plant products against harmful organisms by the action of the active substances contained in the plant protection product. This Regulation aims to improve the functioning of the internal market in the EU, while ensuring a high level of protection for humans,	PPPPR: Regulation (EC) No 1107/2009 of the European parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market	Revision of previous EU legislation on the placing on the market of plant protection products (Directive 91/414/EEC from 1991)	2011	Regulatory approach. Type and role of stakeholders depending on the stage of PPPR process for approval of an active substance, or for authorisation of a plant protection product. **For the approval process of an active substance** : - industry submit an application for approval to a Rapporteur Member State - the Rapporteur Member State performs an hazard/risk/efficacy assessment, and	The manufacturing stage is not assessed, but the risks linked to use of plant protection products are assessed in all phases and consequences: primary exposures, secondary exposures, fate and behaviour in the environment. Derogation possibilities are assessed before deciding on an approval of active substances subject to the exclusion criteria, and by	Hazard, exposure, risk , but NO consideration of socio-economic aspects Both at active substance approval stage and plant protection product authorisation stage, hazard and risks assessments are performed. Hazard assessment takes place in particular to determine whether a substance meets the criteria for exclusion. An assessment of whether derogation criteria are met is also performed, i.e. negligible exposure, absence of other means to contain a serious danger.	List of Active Substances under the PPPR process: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN	Additional information on the processes under the PPP Regulation: https://ec.europa.eu/food/plant/pesticides_en EFSA website on plant protection products: https://www.efsa.europa.eu/en/topics/topic/pesticides

	animals and the environment. The PPPR provides for **exclusion criteria** (Annex II, points 3.6.2 -3.6.5 and points 3.7.1-3.7.3 and 3.8.2) for active substances of very high concern, covering CMR 1A and 1B, endocrine disruptors, and POPs, PBT/vPvB substances. These active substances and plant protection products containing them should normally not be approved or authorised. Derogations are possible for C1B (with threshold), R1B substances and EDs in case of negligible exposure, or if they are essential to control a serious danger to plant health that cannot be contained by other means. For such substances, approvals are				submits its draft assessment to the European Food Safety Authority (EFSA) - a peer review with all EU Member States is organised by EFSA. - EFSA delivers conclusions to the European Commission on whether or not the active substance meets the approval criteria. - the European Commission, after consultation of the Standing Committee on Plants, Animals Food and Feed (composed of EU Member States' representatives) decides on the approval or non-approval of the substances at EU level. **For the authorisation process of plant protection products containing active substances**: - industry submits an application for authorisation to (at least one) Member State	each Member State before delivering an authorisation on a product containing a substance subject to exclusion.			

	more limited in time, and authorisation of products containing them are also more limited in time than for approvals/authorisations in general.				- the EU Member State receiving the application assesses the application, and decides on the authorisation of the plant protection products on its territory. - industry can then submit applications for mutual recognition of authorisations in other Member States				
EU Plant Protection Products Regulation (PPPR) – Substitution and low risk provisions	The PPPR also foresees that active substances meeting the criteria in Annex II, point 4, are are approved as candidates for substitution: e.g. 2 out of 3 PBT criteria are met, ADI, ARfD or AOEL is significantly lower than those of the majority of the approved active substances in a group or use category, etc.. Products containing active substances that are candidates for substitution are subject to a	PPPPR: Regulation (EC) No 1107/2009 of the European parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market, in particular Articles 24 and 50	Revision of previous EU legislation on the placing on the market of plant protection products (Directive 91/414/EEC from 1991)	2011	Same process as above for substances subject to exclusion, and products containing them. In the product authorisation process, Member States must conduct a comparative assessment to establish whether more favourable alternatives to using the plant protection product exist, including non-chemical methods. Applications for authorisation of products containing only low-risk substances must be treated within a shorter timeframe than others.	The manufacturing stage is not assessed, but the risks linked to use of the plant protection products are assessed in all its phases and consequences: primary exposures, secondary exposures, fate and behaviour in the environment. A comparative assessment weighing up the risks and benfits of potential alternative has also to be performed by Member States	Hazard, exposure, risk , and also practical and economic disadvantages. Both at active substance approval stage and plant protection product authorisation stage, hazard and risks assessments are performed. Hazard assessment takes place in particular to determine whether a substance meets the criteria for being designated as candidate for substitution.	List of Active Substances approved as candidates for substitution under the PPPR : Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 (available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R0408	Additional information on the processes under the PPP Regulation: https://ec.europa.eu/food/plant/pesticides_en Questions and answers on candidates for substitution: https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_cfs_qas.pdf More information on low-risk substances: https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_sup_low-risk-ppps.pdf

	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. Furthermore, the Regulation foresees that active substances meeting the criteria set out in Annex II, part 5, can be approved as low-risk substances. For such substances, initial approval periods are longer.					when considering applications for authorisation of products containing substances that are 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	Support and complement to the stimulus provided by the EU chemicals legislation comprising REACH, CLP and the Biocidal	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	No specific life-cycle stage	Four main action areas identified: 1. Capacity building; 2. Facilitating access to funding and technical support;	**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	Support and complement to the stimulus provided by the EU chemicals legislation comprising REACH, CLP and the Biocidal Products regulations. This strategy is also linked to the current

	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	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.		four main action areas.		3. Facilitating the use of registration, classification and risk management data for sustainable substitution; 4. Development of networks related to substitution of chemicals of concern.		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	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
EUROPEAN ENVIRONMENTAL BUREAU									
Name of the programme/ initiative	**Goal of the programme/ initiative**	**Corresponding policy, legislation, or international framework, if applicable**	**What factors or considerations led to the development of the programme/ initiative?**	**Year(s) of Implementation**	**Type of approach (voluntary or regulatory), including roles and responsibilities**	**Life cycle stage(s) addressed**	**Which of the following elements does the programme typically consider: hazard, exposure, risk , socio-economic aspects, life-cycle considerations**	**Chemicals addressed, specific projects or tools that have been developed or are underway. Provide link(s) to additional information.**	**Additional information/details of the programme, including if there is a focus on specific sectors/uses**
Pesticide Free Towns	Avoid pesticide use in public areas of European cities.	European Union Directive 2009/128/EC of the 21 October 2009 on Sustainable Use of Pesticides (SUDP)	The environment: reduced pollution (air, ground and water). Herbicide use in urban areas, and more specifically on impermeable surfaces, is actually a major source of water	Since 2009	Voluntary Bring together a critical mass of towns committed to phasing out pesticide use and provide a European platform of experience, practice and knowledge	Use	Hazard Exposure	Pesticides Provide information on alternative methods and techniques as well as case studies http://www.pesticide-free-towns.info/methods-techniques#term-6	http://www.pesticide-free-towns.info/ Although this programme tackles pesticides which may be out of the scope of the OECD Ad Hoc Group

			pollution, which generates significant costs for local authorities. Biodiversity: pollinating insects and other beneficial insects, soil micro-organisms, birds, amphibians, pets and so on. Citizens: protection for the most vulnerable groups, quality of life for residents and those entering the city and its green areas. Civil workers in parks and public spaces: short- and long-term health consequences		sharing, and mutual support				on the Substitution of Harmful Chemical, this approach my be useful for tackling other uses of chemicals
Substitution of hazardous chemicals through worker reps initiative	Substitute hazardous substances at workplaces in Spain	European OSHA legislation, including the Chemical Agents Directive, the Carcinogens and Mutagens Directive and other	Need to reduce worker exposure to hazardous substances. Need to increase workers knowledge on chemical risk Take advantage of worker representatives capacity to dialogue and negotiate with management	2004-2013	Voluntary This programme was carried out by the Trade Union CCOO and included: - Development of tools (Risctox database , guidance, etc) - Training of worker representatives on chemical risk and on substitution. - Advisory to worker reps on substitution cases. - Exchange of experiences	Use	Hazard Exposure	Industrial chemicals, pesticides, biocides risxtox database: http://www.istas.net/risctox/dn_risctox_buscador.asp	The programme is not in place any more however we consider this experience very interesting and we could provide further materials and publications used for this programme.

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ChemSec Marketplace Marketplace.chemsec.org	The idea behind the Marketplace is to achieve two goals: to provide a unique marketing opportunity for producers of safer alternatives, and to become a one-stop shop for downstream user companies looking to substitute hazardous chemicals in their products. Using the Marketplace is free of charge and no financial transactions between buyers and sellers will be facilitated by the website. Each ad includes contact details that allow users to carry on further discussions outside the	Global	In recent years there has been a drive by companies to substitute the hazardous chemicals in their products and supply chains with safer alternatives. Sadly, however, these alternatives are often hard to find. The Marketplace resembles other user-created content websites. Just like eBay, craigslist or Airbnb, you create your own ads – showing everybody that you either have an alternative to sell or that you are looking to buy one.	Implemented May 2017	voluntary	every	hazard	Aims at marketing products which can be used to replace chemicals fulfilling REACH SVHC criteria	Targets all sectors

	Marketplace. The Marketplace merely provides a meeting point.								
Lowell Centre for Sustainable Production, University of Massachusetts Lowell									
Name of the programme/ initiative	**Goal of the programme/ initiative**	**Corresponding policy, legislation, or international framework, if applicable**	**What factors or considerations led to the development of the programme/ initiative?**	**Year(s) of Implementation**	**Type of approach (voluntary or regulatory), including roles and responsibilities**	**Life cycle stage(s) addressed**	**Which of the following elements does the programme typically consider: hazard, exposure, risk , socio-economic aspects, life-cycle considerations**	**Chemicals addressed, specific projects or tools that have been developed or are underway. Provide link(s) to additional information.**	**Additional information/details of the programme, including if there is a focus on specific sectors/uses**
Lowell Center for Sustainable Production	Provide leadership and technical expertise to government, businesses and the advocacy community to advance the methods and practice of alternatives assessment to support the adoption of safer alternatives.	The Lowell Center's Alternatives Assessment Framework has been a critical resource for the development of the alternatives assessment field – published in 2016. Our work now follows the 2014 National Academies Framework to Guide Selection of Safer Alternatives and also uses the IC2 guide.	- A vision a moving towards a material economy that fosters use of safer chemicals and production processes. - Realization that a focus on problem assessment (i.e. chemical risk assessment)without asking a more solutions-oriented question "is there something safer that can achieve the same function" keeps us stuck in accepting risks when safer alternatives are available or need to be developed. -A focus on the need for innovation that meets the dual goals of economic/ business development AND prevention		Voluntary/ Programmatic. Roles: -Strategic consultation for government programs to enhance their substitution efforts and use of alternatives assessment -Method development -Alternatives assessment curriculum development/training -Supporting/ facilitating an AA community of practice – professional networks/dialogs	Determined in the scoping phase of the alternatives assessment. Primary life cycle stages are production, use and end of life stages. Always need to be open to LCA if the scoping phase of an AA suggests that using LCA to address lifecycle impacts is the more appropriate tool for some life cycle stages.	Hazard, exposure characteristics, economic assessment, performance and relevant/key life cycle impacts as determined by the scoping phase	AA Community of Practice Symposium There are a number of AA assessments that TURI has conducted (all in the OECD toolbox). TURI has just launched an updated version of its P2OASys tool https://www.turi.org/Our_Work/Research/Alternatives_Assessment/Tools_and_Methods/P2OASys_Tool_to_Compare_Materials	Links to work of the Green Chemistry and Commerce Council that is working to mainstream green chemistry. Fostering more work on the innovation front.

IUPAC, Interdivisional Committee on Green Chemistry, ICGCSD
IUPAC is "The International Union of Pure and Applied Chemistry" and provides objective scientific expertise and develops the essential tools for the application and communication of chemical knowledge for the benefit of humankind and the world." (IUPAC Mission from the IUPAC Strategic Plan developed 2014/5 and accessible from https://www.iupac.org/cms/wp-content/uploads/2015/07/Mission.pdf). On September 2015 the UN Summit adopted the 17 Sustainable Development Goals (SDGs) of the 2030 Agenda for Sustainable Development that applies to all countries in order to mobilize efforts to end all forms of poverty, inequalities and protect the planet, and ensure prosperity for all as part of a new sustainable development agenda. In May 2017 ICGCSD participated with two important contributions in the framework of the UN Technology Facilitation Mechanism and the upcoming Science, Technology and Innovation Forum for the Sustainable Development Goals around the following topics: (https://sustainabledevelopment.un.org/TFM/STIForum2017/OnlineDiscussion) TOPIC 1: Science, technology and innovation for the SDGs 1, 2, 3, 5, 9 and 14 https://sustainabledevelopment.un.org/forum/?forum=88c TOPIC 2: STI plans, policies and capacity building https://sustainabledevelopment.un.org/forum/?forum=89 The discussion aims to mobilise all stakeholders to share information on trends in the deployment of science, technology and innovation for the Sustainable Development Goals, specific solutions and achievements, state of the art expertise on specific issues and practice areas, emerging priorities, critical knowledge and innovation gaps, as well as their views on ways of mobilizing science, technology and innovation responses to address these gaps. In June 2017, ICGCSD contributed to UNEP's call to submit best practices and initiatives in the area of sustainable chemistry pursuant to Resolution 2/7 on the sound management chemicals and waste, which was adopted in 2016 at the second session of the UN Environment Assembly http://www.unep.org/chemicalsandwaste/sustainablechemistry- inputs-stakeholders. Further, IUPAC's mission statement describes the organisation's commitment to Sustainable Development in the statement "IUPAC accomplishes its mission by fostering sustainable development, providing a common language for chemistry, and advocating the free exchange of scientific information." (IUPAC Mission Statement, ibid). The focus of the ICGCSD is "To assist in advancing the objectives set out in the Strategic Plan adopted by IUPAC in 2015, this Interdivisional Committee will initiate, promote, and coordinate the work of the Union in the area of green and sustainable chemistry.", where green and sustainable chemistry includes Substitution of Chemicals of Concern.