

Strategy to promote substitution to safer chemicals through innovation

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Table of contents

1. Purpose	4
2. Background	4
3. Action areas	6
3.1. Capacity building.....	6
3.2. Facilitating access to funding and technical support	8
3.3. Facilitating the use of registration, classification and risk management data for sustainable substitution.....	9
3.4. Development of networks related to substitution of chemicals of concern	11
4. ECHA's role and resources	12
4.1. Role in the implementation of the strategy	12
4.2. Resources	13
5. Implementation and follow-up	14
6. Communication	14
Annexes	14
Annex 1: How REACH, CLP and the Biocidal Products regulations promote substitution.....	15
Annex 2: Possible elements of supply chain workshops on alternatives assessment and substitution	18

Strategy to promote substitution to safer chemicals through innovation

1. Purpose

Substitution contributes to the overarching EU objectives for a non-toxic environment and a circular economy, wherein innovation and sustainable production and consumption are key elements. The progressive substitution of substances of very high concern by suitable alternatives is also one of the aims of REACH authorisation.

The overall purpose of ECHA's substitution strategy is to 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. In sum, the purpose of ECHA's strategy is to accelerate substitution, supporting and complementing the stimulus provided by the chemicals regulations.

2. Background

The EU chemicals policy is aimed at ensuring a high level of protection of human health and the environment both for present and future generations while also ensuring the efficient functioning of the internal market and the competitiveness of the European chemicals industry. REACH, CLP and the Biocidal Products regulations have been designed to put pressure on and provide incentives for industry to try to replace hazardous substances with less hazardous ones. By ensuring that these regulations are implemented successfully, ECHA supports substitution both directly and indirectly (see Annex 1).

This strategy presents how to promote substitution as a measure towards safer chemicals and products, as a support and complement to the stimulus provided by the EU chemicals legislation comprising REACH, CLP and the Biocidal Products regulations. Substitution is underpinned by research and development (R&D) and innovation, and ECHA's strategy seeks to find useful drivers for substitution linked to these efforts.

The strategy is 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. This context stresses the importance of an EU-wide coordinated action to support substitution and the need to consider, where relevant, the products' life cycle, and to establish links with the initiatives related to substances in articles.

One of the proposed strategic priorities in ECHA's draft Strategic Plan for 2019-23 focuses on the safe and sustainable use of chemicals by industry. Knowing the properties and uses of substances is essential for companies to understand the long-term viability of their chemicals portfolio. With this knowledge, companies can better integrate substitution as part of their business model. Being proactive and staying at the forefront of technological developments will help European businesses in becoming more competitive. Furthermore, investors start to include sustainable chemistry as an integral part of their risk assessment and business planning, and retailers and consumers increasingly demand safer products¹ along with their willingness to pay a premium for them.

*In this strategy, the term "substitution" is understood in a broad way and can be defined as "the replacement or reduction of hazardous substances in products or processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organisational measures." *) In this context, consideration of the (technical) function of the substance rather than focusing on its chemical structure and associated risk is key to allow a wider range of substitution solutions. This approach called 'functional substitution' helps in avoiding regrettable substitution, moving away from focusing on similar chemical drop-in substitutes which may lead to substitution with alternatives that have similar toxicology profiles. **)*

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

**) Tickner J. et al. *Advancing Safer Alternatives Through Functional Substitution*, 2015. Available at <http://pubs.acs.org/doi/abs/10.1021/es503328m>.

In the Strategic Plan for 2019-23, ECHA has identified several themes which are relevant for substitution, including:

- promoting best practice examples of increased substitution of hazardous substances, green chemistry and sustainability in the supply chain;
- promoting a mindset and behavioural change within industry towards sustainable and safer chemicals;
- collaborating with industry associations in raising awareness in developing and providing tools for sustainability assessments of chemical supplies.

ECHA already has been promoting substitution within the EU and more internationally. ECHA co-chairs the Ad Hoc Group on Substitution of Hazardous Chemicals of the OECD and plans to collaborate with several institutions and Member States to advance substitution. These institutions comprise, for instance, the International Sustainable Chemistry Collaborative Centre (ISC3) in Germany, the proposed centre to promote substitution in Sweden, the INERIS Helpdesk on substitution in France, the ChemSec's Marketplace for safer alternatives and the COSME project on substitution of the Commission (DG GROW). The latter project puts emphasis on the innovative and competitiveness driven approaches for SMEs to find alternatives. These external activities will need to be considered as part of a strategy on substitution to ensure that synergies are realised and that ECHA's activities add value. The use of the European Enterprise Network (more than 400 institutions in the EU) could also be considered for dissemination of best practices examples.

¹ [TÜV SÜD Safety Gauge: Tracking business and consumer sentiment](#), TÜV SÜD, 2017.

Substitution is a business-critical consideration. Changing the mindset of industry along the whole value chain (i.e. including product end users and retailers, which do not necessarily use the substances of concern themselves but can trigger substitution initiatives) and of government agencies is essential to building a stronger cultural foundation for substitution in the EU. The mindset change embraces the view that substitution is part of an innovation activity that creates business opportunities and has environmental and health benefits. Substitution can therefore be seen as an essential building block for reaching the UN 2020 and 2030 Sustainable Development Goals.

3. Action areas

Based on a background report developed by the Lowell Centre for Sustainable Production² – a ‘thought starter’ for a substitution strategy that was presented to CARACAL and further discussions with the Commission, Member States, industry and NGO stakeholders, amongst others at the 9-10 October 2017 Substitution workshop³ – the following four action areas have been identified to underpin ECHA’s substitution strategy:

1. Capacity building;
2. Facilitating access to funding and technical support;
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.

Each of these action areas are described in more detail below. Based on feedback and further analysis, each action area needs to be further characterised in ECHA’s annual workplans describing the implementation of the strategy. Some elements pertaining to the proposed action areas are already being implemented, in particular in the action area related to “facilitating the use of data. Other action areas are new, at least with respect to their substitution focus.

3.1. Capacity building

Supply chain workshops to initiate collaboration

Supply chain collaboration is a critical prerequisite for advancing the development and adoption of safer alternatives. Yet there are a number of challenges to substitution, including achieving performance and cost requirements, understanding available options, and evaluation of these. As such, successful supply chain collaboration – collaboration that supports innovation in research, development and use of safer alternatives to hazardous chemicals – requires capacity building along the whole supply chain.

Knowledge on the options for substitution of hazardous substances is not equally shared throughout the supply chain. On the one hand, substance-level technical knowledge is often greater among upstream manufacturers and formulators of chemicals than it is among downstream users and product manufacturers. In addition, downstream users often have much less technical knowledge about the hazard profile of specific substances.

On the other hand, downstream users are likely to know the different technological possibilities to innovate and substitute the hazardous chemicals. They also have the possibility to work with their clients, who might not use the chemical but rather buy and use the articles produced by the downstream users. The specifications made by the clients can help or hinder technical progress and innovation to substitute towards less hazardous chemicals. Similarly, the final consumers (either directly or through consumer organisations) can drive the demand for less hazardous products. For these reasons, an opportunity to exchange views from the clients of the end users all the way to the manufacturers and importers of the chemicals is likely to be beneficial and representatives of these actors should be present at the workshops. Involvement of companies from other sectors also helps in sharing experiences on substitution activities

² Tickner J. et al. *Approaches for Accelerating Substitution under REACH and Beyond: Strategic Options Assessment*, July 2017. Available at: https://echa.europa.eu/documents/10162/13630/lcsp_strategic_options_July_2017_en.pdf/f47e53e4-a9e8-28b8-037c-779cbbbed2e23.

³ <https://echa.europa.eu/-/workshop-on-substitution-strategy-9-10-october-2017-echa>

(“cross-sectoral fertilisation”).

For some substances of concern, in some sectors, safer and feasible alternatives may not be currently viable. Understanding these current challenges and connecting these industries with the R&D and technical support communities are necessary steps for advancing the technological innovations needed to transition away from the use of hazardous chemicals.

The concept

During the preparation of this strategy, it became evident that capacity in companies and authorities concerning analysis of alternatives, innovation and substitution should improve. However, traditional “classroom”-type training may not be a very productive, engaging or effective approach to increase this capacity. Instead, ECHA will collaborate with Member State and EU-level authorities, industry associations and, possibly, with NGOs working on substitution to organise workshops on specific substitution challenges⁴. These supply chain collaboration workshops would normally be held at Member State level and be held in the language of the country. The workshops can be held at EU level, too, when deemed appropriate. Annex 2 gives the possible elements of such workshops.

The workshops would be used to initiate dialogue among the various concerned actors across the supply chain (from top to bottom, and with special emphasis on downstream users, SMEs and their customers/final consumers) about the opportunities and challenges of substitution. The purpose is to better understand needs and to make progress on the targeted substitution issues, ideally resulting in concrete innovation projects. More specifically, the workshops seek to achieve the following goals:

1. Better understanding and inclusion of substitution thinking into innovation practices among enterprises throughout the sectors and supply chains of specific substances or chemical functions of concern; and
2. To build sectoral and supply chain collaborations that advance research, evaluation and adoption of safer alternatives to substances of concern.

These events would be an opportunity to learn about the technological and functional needs for capacity building and training at the operational level of companies.

A European or national industry association, a Member State competent authority (MSCA), or possibly an interested NGO or academic/technical research organisation would normally take the lead in initiating and organising workshops on substitution. ECHA will give advice and support for organising the workshops, as appropriate. It is likely that the workshops would be organised at a sectoral or chemical’s functionality level⁵, gathering companies operating at different levels of a particular supply chain or from other sectors confronted with a similar issue, specialised R&D institutions (including academics), technical support centres and (private and public) fund providers, MSCAs and other relevant stakeholders. Gathering these stakeholders would provide a more holistic view of the substitution issue at stake, including technical, economic, market and intellectual property aspects as well as product life cycle considerations, in order to identify the most appropriate further actions to initiate.

The benefit of this approach is that such workshops can be tailored directly to the needs of those companies and authorities that hold the key to substitution. ECHA will develop a standard package of methods and content, which would be used as a basis for the organisation of the workshops. The material could be translated into different languages.

Next steps

Several Member States and stakeholder organisations have indicated their interest to organise substitution supply chain workshops in 2018. The workshops of early 2018 would provide an opportunity to further refine the approach.

The workshops will not only increase the capacity of the participants. They will also allow ECHA

⁴ For example, in January 2017, ECHA facilitated a pilot workshop of this kind together with the Finnish Galvanisation Association and the Aalto University Design Factory and participants found the event very useful. See the report at https://echa.europa.eu/documents/10162/13630/finnish_crvi_workshop_en.pdf/e55d3063-00c2-c69c-004c-48d584257110.

⁵ Examples of topics are alternatives to chrome VI plating in a particular Member State, alternatives to perfluorinated substances in the textile industry, substitution issues in car industry at the EU level, etc.

and other interested parties to gain experience and learn how different skills (e.g. organisational, managerial, technical, economic, and health-, safety- and environment-related skills) are fostered in companies and Member State competent authorities to identify and analyse alternatives.

Since the insights and learnings from workshops are helpful also to people who did not participate in them, special attention will be paid to establishing an effective way of communicating the aggregated learnings of these workshops to interested stakeholders to create replicable collaborative models. ECHA plans to publish on its website the presentations and main outcomes of these workshops and share the information via its communication channels.

Another capacity building need is in the skills of carrying out analysis of alternatives. The Network of REACH SEA and Analysis of Alternatives Practitioners (NeRSAP) will continue to be used to improve the capacities in Member States and industry to carry out analysis of alternatives. The learnings of this capacity building can be shared in innovation and substitution network (see Section 3.4).

3.2. Facilitating access to funding and technical support

Some funding for sustainable chemistry projects at EU and Member State level is available both from public and private funding organisations. However, funding targeted to the substitution of hazardous chemicals as such is scarce. Technical support is available from research and technical institutions as well as from the suppliers of alternative substances or technologies. However, this support is not always known or connected to the companies confronted with a substitution issue. The purpose of facilitating the access to technical support and additional funding is to boost substitution away from hazardous chemicals. The increased funding would be helpful to both innovation-driven R&D as well as for adapting existing substitution solutions in companies. The purpose of this activity is also to improve the links between industry's R&D needs and funding.

In order to expand opportunities for research funding necessary to replace chemicals of concern, ECHA will first – with help of Member States, the Commission and stakeholders – map the available funding mechanisms and institutions which can be relevant for supporting substitution-related projects and disseminate the collected information and facilitate the involvement of these institutions in projects. ECHA would discuss with both public and private funding institutions the drivers and needs for support on substitution.

Therefore, in addition to being an “information gatherer” on funding possibilities, ECHA will in part seek ways to have substitution financed through existing funding opportunities or programmes (i.e. using “old money” more effectively). Another possibility would be to promote or advocate to funds providers towards the creation of new opportunities or funding mechanisms (“new money”) for R&D or adapting technologies for substituting away from chemicals of concern. Ideally, innovation fund providers would ensure that the innovative solutions they support are based on sustainable chemistry. Substitution away from hazardous substances should feature more prominently in their award criteria.

The supply chain workshops (see Action area 1) provide good opportunities to see to what extent (a lack of) R&D funding might support (or impede) innovation and thus substitution. Likewise, the REACH authorisation and restriction processes can help to identify priority areas (e.g. use of specific hazardous substances) for support.

ECHA also recognises the importance of providing technical support to companies, including SMEs, in testing the identified potential alternatives to the chemicals of concern before these can be adopted and a new product may enter the market. However, this support is often highly technical and would require knowledge of the companies' circumstances. Thus, it is likely that such technical support is better organised at national, regional or even local level. Recognising that ECHA's own technical knowledge in industrial uses is very limited, it could still help Member States and stakeholders in mapping relevant R&D and technical institutions and disseminate the collected information and facilitate the involvement of these institutions in substitution projects (to the extent confidential business information remain preserved).

Overall, it is important to recognise that facilitating funding and technical support do not belong to ECHA's core activities. However, if ECHA can help, the leveraging effect could be substantial. Through further discussion and interaction with stakeholders, ECHA will gradually further develop

the scope and extent of its actions to ensure the leveraging effect is optimal.

3.3. Facilitating the use of registration, classification and risk management data for sustainable substitution

REACH and CLP data as a basis for hazard and risk assessment of alternatives

Registrants under REACH are responsible for providing relevant information on the substances

Information of registrants and downstream users

From December 2017 onwards, ECHA will send letters to registrants of those substances identified to be part of groups of structurally similar substances, which will be manually screened for potential further regulatory action.

In addition to informing individual registrants, ECHA envisages disseminating on its website additional information on the groups of substances identified under the screening process. This is useful for downstream users who are considering substituting away from hazardous substances – as similar substances are likely to have similar hazardous properties.

The QSAR toolbox

ECHA has invested in the OECD QSAR Toolbox, which is a software intended to fill gaps in (eco)toxicity data needed for assessing the hazards of chemicals. The QSAR Toolbox incorporates information and tools from various sources into a logical workflow. Experts in industry use QSAR Toolbox in the development of new products and chemicals to avoid regrettable substitution.

they manufacture and import. ECHA may perform compliance checks to ensure that the REACH information requirements are fulfilled. In addition, substance evaluation may be used to ask information which is beyond the REACH standard information requirements, to clarify any concern a specific substance or group of substances may pose. More specific information on uses, exposure/emissions, risks and alternatives is available through the restriction and application for authorisation processes. Thus, ECHA's processes form a core information set for a safe and sustainable use of chemicals and substitution activities.

Indeed, sustainable substitution requires a proper understanding of the hazards and risks associated with the substances to be substituted and, when a chemical is substituted by another, of the hazards and risks of the alternatives. ECHA has worked for many years to both improve the quality of incoming registration dossiers and make the data available. As a consequence, a wealth of information from the registration dossiers and classification and labelling (C&L) notifications is disseminated through ECHA's website and directly accessible to authorities, providing today much more information than was available before REACH.

Structural similarity and grouping approach to avoid regrettable substitution

Information on registrations of single substances enables their grouping based on their chemical structures. ECHA will continue to make the data available and strives to do so in a way that facilitates substitution away from chemicals of concern and, at the same time, avoids regrettable substitution.

ECHA and Member States are working more and more on groups of substances rather than taking action on individual ones. Grouping approaches have been used for some years now when proposing substances for further regulatory risk management actions or in the context of substance evaluation. ECHA has also started to use these approaches in the early stages of assessment such as for the screening and identification of substances of potential concern but

also to avoid regrettable substitution⁶. Thus, it is possible to use grouping approaches to raise awareness of the potential need for substitution, too. Two examples of how structural similarity information can be used to support substitution are detailed below.

Next steps

To further support industry in their substitution work, ECHA could prioritise the enhancement of dissemination or facilitate access to certain pieces of information collected from REACH processes managed by ECHA (e.g. registration, authorisation) or generated by Member States (e.g. through the common screening). Also, tools such as the QSAR Toolbox will be further promoted to industry. The purpose is that relevant stakeholders can make timely and well-informed decisions about the manufacture and use of new substances. Depending on the availability of resources, ECHA will consider to develop different projects:

- For registration data, it might be possible to search by uses as well as sectors of use, if companies and stakeholders would consider such information useful. However, the use descriptions may be very general in the registration dossiers. ECHA will investigate how it can motivate registrants to provide in their registration dossier complementary information which would be useful for downstream users in assessing potential alternatives (e.g. more precise descriptions of uses and technical functions, ranges of technical applications, etc.).
- For data in applications for authorisation and for restrictions, it would be possible to display on ECHA's website information on the analysis of alternatives from the dossiers as well as the key information on alternatives obtained during public consultation in a searchable format. Inclusion of life cycle considerations on alternatives in these two regulatory processes would be encouraged, too.
- ECHA could also set up an open-ended public web form for the submission of information on alternatives, outside any REACH regulatory process, to constitute a database on potential alternatives. However, ECHA would not have the technical expertise to assess the correctness of such information. Thus, it would not examine or approve the correctness of the information and this remains the responsibility of the submitters and users. The challenges related to resource, logistics and ICT needs would need to be analysed should there be a genuine need for such an information database in addition to the already existing similar initiatives (e.g. SUBSPORT, ChemSec Marketplace).
- ECHA could monitor activities and options for substitution of substances on the market by analysing submission data. Among the relevant sources of information there are the product and process orientated research and development (PPORD) notifications submitted by companies undertaking scientific developments with substances in quantities exceeding 1 tonne annually. Concerning PPORD notifications, ECHA has the responsibility to address any concern with the safe use of substances to the notifiers while keeping the submitted information in the notifications confidential. Should there be indications of regrettable substitution, ECHA could engage in a preventive dialogue directly with the submitters.
- ECHA, together with Member States, will investigate the most appropriate way to communicate earlier and more clearly and visibly about the outcome of the work on groups of substances to help stakeholders make more informed decisions on potential alternatives.

ECHA will discuss with Member States and stakeholders what additional data would be most useful for them. ECHA will also discuss with them what existing information should be disseminated in a more helpful manner on its website. In addition, the technical feasibility and costs of implementation of the IT services outlined in this section will need to be appraised before further decisions can be taken.

⁶ This is carried out, for instance, by including in the group under assessment those substances for which only C&L notifications are available but which are structurally similar to substances on the Candidate List.

3.4. Development of networks related to substitution of chemicals of concern

The role of networks to support substitution

Implementing ECHA's substitution strategy will require coordination and collaboration among many stakeholders. Currently, no specific network exists to support substitution among EU Member States, the Commission and stakeholders. In other words, there is no systematic way to routinely and effectively connect and collaborate on substitution challenges and opportunities.

Collaborative networks for innovation and substitution can play an important role in coordinating and advancing the practice of informed substitution. They can also support innovation through the development, evaluation and adoption of safer alternatives.

Networks to support substitution can improve effective collaboration by:

1. **improving coordination** among multiple programmes across the Commission, ECHA, Member States and industry in order to leverage and expand on existing efforts rather than duplicating them;
2. **connecting often disconnected** knowledge, expertise, programmes, and other resources;
3. **increasing capacity** through collaborative learning, and advancing opportunities for embedding substitution in the culture of organisations through sharing of challenges and experiences;
4. **implementing specific new collaborative initiatives** to overcome barriers and improve substitution practice.

Key elements in a successful network are:

1. a clear mission;
2. a clear goal for the network;
3. building trust in the process
4. continuous facilitation;
5. follow-up so that the network operations evolve.

Networks can be (i) authorities-centred (e.g. be between Member State authorities and their EU counterparts), (ii) sector-specific or (iii) supply chain-specific. They can also be (iv) multi-stakeholder networks, consisting of different sectors, different actors in the supply chain as well as different authorities at Member State and EU level. It is unlikely that there is a "one size fits all" network that meets the needs of the wide range of stakeholders involved in driving the evaluation and adoption of safer alternatives in the EU. For instance, in the US there are different types of networks to support substitution⁷. There are important reasons for having stakeholder-specific networks and fora (e.g. internal industry dialogues or internal government authority dialogues) as well as multi-stakeholder collaborations.

During the preparation of ECHA's strategy, efforts were made to identify an existing network that could be expanded to cover substitution-related issues. The only one that was identified to partially address this topic is NeRSAP. It considered expansion of its activities related to substitution in its 2017 meeting. It concluded that while it would continue to build capacity and serve as a network on analysis of alternatives, it would not be a suitable network to cover many of the other substitution-related issues.

Finally, it is worth noting that as part of its work on substances in articles, ECHA has identified a possibility of working together with the companies who wish to exploit the market opportunities of providing articles that do not contain (certain) chemicals of concern. This possibility needs to be explored further.

⁷ E.g. Interstate Chemicals Clearinghouse, Green Chemistry and Commerce Council, BizNGO, Interagency Alternatives Assessment Working Group. See https://echa.europa.eu/documents/10162/23500833/networks_support_substitution_molly_en.pdf/b4f5ae5c-3a06-ee8d-c1c9-e6631bcfae6e.

Next steps

Based, among other factors, on the conclusions of the substitution workshop of 9-10 October 2017, the following can be concluded in terms of the different types of networks that could be considered:

- At this stage, it would be most important to set up a new multi-stakeholders network to support innovation and substitution. This network would comprise ECHA, the Commission, MSCAs, industry organisations and certain individual companies, NGOs, research organisations (including academics) and consumers' associations interested in substitution. The precise mission and goal would need to be established; however, the primary objective would be to inform, exchange and coordinate the various substitution-related activities.
- NeRSAP⁸ meetings – gathering experts from industry, consultancy, Member States, the Commission, ECHA and NGOs – on socio-economic analysis and analysis of alternatives would continue to be used to exchange experiences and to build on capacity on the methodologies, cases studies and best practices of analysis of alternatives under REACH.
- ECHA, some Member States and stakeholders are involved in the OECD Ad Hoc Group on Substitution of Harmful Chemicals. The above-mentioned EU-wide substitution network would need to support the work carried out in the OECD, and *vice versa*.

A specific network consisting only of EU and Member States authorities was considered at this stage to be of lower importance. This is rational, as it would seem wise to concentrate the relatively limited staff resources to the successful creation of one network where all interested parties would be involved.

It was noted that the Forum (network of national enforcement authorities for REACH/CLP/BPR) and the HelpNet (network of national helpdesks) could potentially play a role in supporting companies – in particular SMEs – in their substitution efforts⁹. During the implementation of the innovation and substitution strategy, the potential roles of the national enforcement authorities as well as the helpdesks in actively supporting substitution will need to be further explored.

4. ECHA's role and resources

4.1. Role in the implementation of the strategy

The role of ECHA in the implementation of this strategy depends on the action areas.

In action area 1 (Capacity building), ECHA's role would be to assist Member States or organisations in preparing the programme, to suggest speakers, possibly to facilitate part of the discussion, and to be a repository of the presentations, conclusions and other possible material made available during the workshops. An important task will be to synthesise the lessons learnt thus enabling ECHA to assist in the preparation of subsequent workshops. As relevant, ECHA will also have some of the core material (e.g. conclusions) translated to English, and if possible in other official EU languages, so that the lessons learnt from the workshops would be disseminated to interested people in other Member States.

Obviously, concrete ideas for substitution should emerge from the workshop participants. ECHA will provide its services to disseminate these ideas so that companies in other sectors or Member States could learn and possibly also implement the ideas generated.

In action area 2 (Funding and other support), ECHA would have a small, catalytic role. It would seek collaboration with the Commission services to ensure increased possibilities for funding and other support at the EU level. To the extent possible, ECHA would do the same with MSCAs. However, given the differences in operations of the national institutions, this collaboration needs to be established with realistic expectations. The supply chain workshops are envisaged to identify specific needs that need to be addressed, and thus the role of ECHA would need to adapt accordingly.

⁸ NeRSAP: Network of REACH SEA and Analysis of Alternatives practitioners, see <https://echa.europa.eu/support/socio-economic-analysis-in-reach/network-of-reach-sea-and-analysis-of-alternatives-practitioners>.

⁹ This possibility still needs to be discussed with the FORUM and HelpNet.

In action area 3 (Facilitating access to data from REACH and CLP), ECHA will have a central role. However, while the aim is to provide further help to avoid regrettable substitution, it is important to recognise that any new activity (e.g. improvement of dissemination/accessibility of specific data fields) can potentially require significant extra resources, which are currently not foreseen in the multi-annual planning.

In action area 4 (Networks), ECHA's initial role would be that of a facilitator or coordinator of the network by providing administrative and technical services. The network will also be the source of learning from the different workshops and thus the network, and consequently ECHA's role, would evolve. ECHA will continue its coordinating role in the Steering Group of NeRSAP and will continue as co-chair of the OECD Ad Hoc Group on Substitution of Hazardous Chemicals.

The four action areas of ECHA's substitution strategy have linkages (Figure 1). The main connection between the activities is expected to take place through the substitution network. The workshops will naturally draw upon any suggestions or lessons learnt from the activities related to technical support and funding, as well as on ECHA's activities to use its data to more effectively promote substitution. The workshops can also give feedback and ideas to these two activity areas.

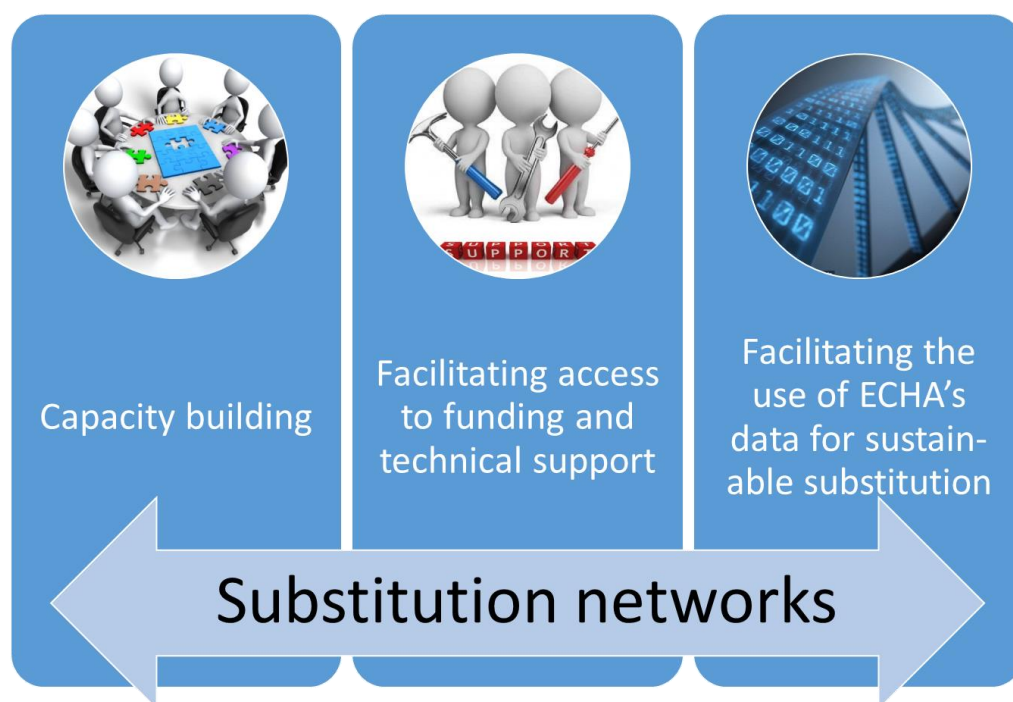


Figure 1: Linkages between the four action areas of ECHA's substitution strategy

4.2. Resources

The resource implications for the implementation of the strategy in the years to come will naturally depend on the scale of ECHA's involvement in the different activities and on the success of these activities. ECHA has allocated approximately three full time equivalents (FTE) for 2018 for the implementation of the strategy, consisting the required number of staff members, depending on the number of workshops. Depending on the development of the activities, the future staff and other resources will be planned in the latter part of 2018. Further implications for IT need to be carefully checked, in particular in the area of data management.

ECHA will be able to plan the activities from 2019 onwards in a more informed manner based on the experience gained in 2018.

5. Implementation and follow-up

ECHA envisages to plan the details of the implementation of the substitution strategy as part of its annual work plan. Activity 4 (Network) between Member States, the Commission, industry or NGO stakeholders as well as other active parties in the network need to be planned in a “fit for purpose” manner. The learnings from the supply chain collaboration workshops will help in further developing the substitution strategy from 2019 onwards. By the end of 2018 ECHA will elaborate the activities on substitution for 2019 in its annual work plan.

ECHA also envisages to prepare a concise annual report to document what progress has been made in the implementation of its substitution strategy. The report would also highlight how the implementation of the strategy would need to be changed in the following years. The report, as well as the plan, will be made available on ECHA’s substitution web pages.

ECHA will explore the possibilities for developing indicators (quantitative or qualitative) for the four action areas that could help in analysing the success of the strategy (e.g. number of workshops organised, participants’ satisfaction scores, amount of R&D funding supporting substitution, number of network teleconferences, etc.). After a few years, surveys or studies could be conducted to obtain a more accurate picture of how the implementation of the present strategy contributes to support substitution.

6. Communication

Communication between ECHA and the respective audiences to promote and exchange information on substitution-related issues is a key and transversal element of all the action areas of this strategy.

ECHA will develop an annual communication plan and consider the whole set of communication means at its disposal to reach the relevant stakeholders in relation to the topics addressed (news, web pages, webinars, social media campaigns, animated videos, etc.). Communication activities will be built around the events, workshops and other milestones of this strategy.

Significant benefits in implementing the action areas described below would emerge if high-level leadership from ECHA, the Commission and Member State representatives was given to support substitution. It is important to highlight how innovation is intrinsically linked with substitution in the context of a circular economy and the sustainable use of chemicals. This could take place in events in which decision makers of companies participate, where a clear and understandable message on a modern approach to use chemicals sustainably would be delivered. For this, ECHA would develop the content, in the form of supporting documents and presentations, which can be used to spread the message to downstream industry, formulators as well as the suppliers of chemicals, adaptable to the needs of different audiences. These presentations would link to efforts to promote sustainable chemistry throughout the EU.

Annexes

Annex 1: How REACH, CLP and the Biocidal Products regulations promote substitution

Annex 2: Possible elements of supply chain workshops on alternatives assessment and substitution

Annex 1: How REACH, CLP and the Biocidal Products regulations promote substitution

1. Background

The EU chemicals policy is aimed at ensuring a high level of protection of human health and the environment both for present and future generations while also ensuring the efficient functioning of the internal market and the competitiveness of the European chemicals industry. One of the important objectives within that policy is to encourage the substitution of dangerous substances by less dangerous ones where suitable alternatives are available. The increased accountability of downstream users and better public information will create a strong demand for substitute chemicals that have been tested sufficiently and that are safe for the envisaged use. Developing new and safer chemicals will also stimulate innovation and will hence support the competitiveness of the European industry.

Within REACH, substitution is often referred to in the context of authorisation of substances of very high concern (SVHCs), where the long-term goal is to replace these substances with safer alternatives or techniques. This is an important objective for which much effort is made to have it work in practice. However, the legislative systems in place for chemicals and biocides – REACH¹⁰, CLP¹¹ and the Biocidal Products Regulation¹² – have a much broader perspective than SVHCs only and have in general been designed to place pressure on and provide incentives for industry to try to replace hazardous substances with less hazardous ones.

This document describes how REACH, CLP and Biocidal Products regulations as such contribute to substitution of hazardous substances.

2. REACH and CLP regulations as drivers for substitution

In general, the health and environment objective of REACH is expected to be achieved through (1) better knowledge on the properties and uses of chemicals, which results in better safety and control measures, reducing exposure and hence the negative impacts on human health and the environment; and (2) the use of less dangerous alternatives to those substances of very high concern. The key drivers are registration, requirements concerning information through the supply chain, authorisation and restrictions.

Registration under REACH requires the collection, generation and assessment of hazard and exposure data, risk assessment and the identification of risk management measures to ensure the safe use of chemicals. This is further reinforced by compliance checks and substance evaluation processes. The preparation of chemical safety assessments (CSAs), the systematic collection of data and, where necessary, the generation of new (test) data will all lead to improved information on safe use and handling. In general, the requirement of manufacturers and importers to register substances will create situations where a substance is no longer supported by registrants due to its hazardous properties as well as the availability of suitable alternatives, and is therefore withdrawn from the market.

The communication of information through safety data sheets (SDSs) and extended safety data sheets (eSDSs) enables downstream users to check their handling and use of chemicals and, if necessary, to implement further risk management measures or in some case even to decide to no longer use certain substances. Here, in particular the substantially increased and improved information on the classification and labelling of all substances on the market will help companies, for instance, in making better informed choices, whether there are possibilities to change to other, safer substances. The requirement to communicate information upstream on operating conditions or risk management measures (RMMs) will as well improve the quality of the safety assessments and ultimately the overall quality of SDSs. Finally, the need for article producers to communicate on whether their articles contain SVHCs included in the Candidate List under REACH may trigger requests from retailers for the phase-out of SVHCs in articles, and enables consumers to take the presence of an SVHC into account in their purchasing decisions.

¹⁰ Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.

¹¹ Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

¹² Regulation (EC) No 528/2012 concerning the making available on the market and use of biocidal products.

Thus, substitution is promoted here, too.

The authorisation provisions within REACH are aimed at ensuring that risks from SVHCs are properly controlled and that these substances are progressively replaced by safer alternative substances or technologies where these are economically and technically feasible. The authorisation title allows companies to apply for an authorisation for a continued (or new) use of an Annex XIV substance. However, the mandatory requirement for an analysis of alternatives and the public consultation on alternatives are clear additional mechanisms fostering the companies applying for authorisation to search for substitutes. Furthermore, the authorisations granted by the Commission are subject to time-limited review. This time limit ensures that industry needs to continue its efforts to search for substitutes, also in cases where transfer to alternatives is not possible in the short term. From several studies, including the review of the REACH Regulation carried out by the Commission in 2012¹³, the study "Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs" in 2015¹⁴ and the study "Impacts of REACH Authorisation" in 2017¹⁵, it is clear that – as a result of Annex XIV and candidate listings – substances have been and continue to be withdrawn from use and downstream users are moving to substitutes where possible.

The restrictions process as such is meant to introduce restrictions on the manufacture and import, placing on the market and/or on specific uses where these can be shown to pose an unacceptable risk to human health or the environment that should be addressed on an EU-wide basis. Obviously, if the use of a substance is banned (with possible derogations) by placing it on Annex XVII to REACH, substitution has to take place. Like in the previous legislation, the use of substances that are classified as CMRs¹⁶ (category 1A or 1B) as such or in mixtures by consumers will be restricted, and a specific simplified procedure has been introduced with REACH which can also be used to limit the use of such substances in articles. This procedure has been used for restricting the presence of polycyclic aromatic hydrocarbons (PAHs) in articles¹⁷ and CMRs in textiles¹⁸. Finally, after the sunset date for authorisation has passed, ECHA has to consider the need for restrictions on SVHCs used in articles. This requirement has been used for several substances and resulted in an opinion of ECHA to restrict the four classified phthalates (DIBP, DBP, BBP and DEHP) in articles¹⁹. This can contribute significantly to the promotion of substitution of these substances globally and also ensure that production and use of SVHCs is not simply moving outside the EU.

In addition to the direct link between the CLP Regulation and restrictions for CMRs under REACH, there are more than 20 EU regulations and directives which currently refer to the existing rules on classification and labelling – together covering wide policy areas such as consumer products, occupational health and safety, waste and end-of-life products and general legislation on control of dangerous or hazardous chemicals – such as Seveso, Prior Informed Consent (PIC) and air and water quality directives. Hence, it can be anticipated that as a result of more information becoming available through the registration process, a range of further risk management measures may be initiated in line with this downstream legislation. The Commission noted in the 2012 REACH review that the majority of the changes in classification that resulted from increased information becoming available through the introduction of REACH were more restrictive.

To summarise, through the registration, supply chain communication and regulatory risk management processes, REACH and CLP Regulations are expected to achieve substantial human health and environmental benefits because they promote substitution to safer alternatives. Their effectiveness is strongly dependent on evaluation, provision of guidance, inspections and enforcement activities. The authorisation process as such aims at the substitution of substances of very high concern in the longer term. The restriction process does this in a more direct manner. The complete legislative system provides strong incentives and direct as well as indirect mechanisms to substitute hazardous substances with less hazardous ones.

¹³ http://ec.europa.eu/environment/chemicals/reach/review_2012_en.htm

¹⁴ <https://ec.europa.eu/docsroom/documents/14581/attachments/1/translations/en/renditions/pdf>

¹⁵ Publication expected end of 2017.

¹⁶ Carcinogenic, Mutagenic or Toxic to Reproduction.

¹⁷ Restriction: <https://echa.europa.eu/documents/10162/176064a8-0896-4124-87e1-75cdf2008d59>.

¹⁸ Pending decision.

¹⁹ <https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/13919/term>

3. Substitution under the Biocidal Products Regulation

The Biocidal Products Regulation (BPR) is promoting substitution through two main mechanisms. Firstly, the BPR provides conditions for approval of active substances and for granting product authorisation. These conditions will guide both applicants when considering and preparing their application and authorities when assessing the application. Secondly, and more specifically, the BPR provides for exclusion criteria (covering CMR 1A and 1B, endocrine disruptors, and PBT/vPvB substances) and for the concept of candidates for substitution for approval of active substances. Candidates for substitution are identified during the approval of active substance stage, which is further reflected in the product authorisation stage, where candidates for substitution trigger a comparative assessment of biocidal products.

The concept of substitution criteria and comparative assessment did not exist under the earlier Biocidal Products Directive. In implementing these procedures, ECHA is active through its Biocidal Products Committee (BPC):

1. At the stage of approval of an active substance where the BPC gives an opinion on whether the criteria for substitution are met.
2. In the BPC's opinions on Union authorisation on comparative assessment where relevant. Following the comparative assessment, an authorisation may not be granted or may be restricted if another biocidal product is available showing a significantly lower risk while being sufficiently effective.

Annex 2: Possible elements of supply chain workshops on alternatives assessment and substitution

Below are possible elements of supply chain workshops on alternatives assessment and substitution. These workshops would also build the capacity of supply chain collaborations to enhance substitution possibilities.

Purpose

The overall purpose of the workshop is to provide a platform to learn about substitution possibilities, seen from the different market actors' points of view. The specific purposes of each workshop are:

1. to identify concrete innovation projects to stimulate and connect supply chains with necessary R&D resources and support, particularly where alternatives may not be currently available for a given application or use;
2. to provide workshop participants with foundational information about substitution and its links to innovation;
3. to understand the capacity development needs of actors across the supply chain regarding the identification, evaluation and adoption of alternatives to identified substances/chemical functions of concern.

Language

The workshops would be held in the language(s) of the Member State where the workshop is held. In this way, local SMEs could also take an active part in the discussions.

Organisers/facilitators

ECHA would assist a Member State competent authority, national or EU industry association or group of companies in organising and facilitating the workshop. ECHA would not take the lead in organising the workshops, but rather participate in the workshop organising committee to assist as needed in providing experience from previously hosted workshops, and in the sharing of resources that have been created for and used during prior events. ECHA could also facilitate part of the workshop, as relevant. ECHA would assign to this work a staff member who knows the language that would be spoken in the workshop (as long as it has such a staff member available).

Participants

Participants could comprise some of the following actors:

- suppliers of substances (chemicals manufacturers and importers) and mixtures (formulators) or their representatives (distributors)
- downstream users of the substances and mixtures
- suppliers of alternative substances or technologies
- clients of the downstream users (e.g. article manufacturers)
- staff members of the MSCA who have an interest in analysis of alternatives and substitution
- national organisations (including research institutions) providing technical assistance in technology development
- national funding organisations for innovation and R&D
- representatives of consumers
- other third parties having an interest in substitution.

Elements of the programme

The workshops are envisioned as one- or two-day events. Each workshop would focus on a particular industrial sector, chemical function or a use for which there is need to substitute (e.g. on the basis of the Candidate List, Authorisation List or Restriction List). The need can also be anticipatory. The programme would focus on the availability, performance and cost challenges to substitution. Possible examples include formaldehyde in wood products, hexavalent chromium in metal plating, and perfluorinated compounds in textiles.

Workshops would be designed to facilitate ongoing or future collaboration to address the chemical/functional challenge.

Possible topics to address during each workshop include:

- Setting the context for substitution – drivers, needs, and opportunities – what makes a successful supply chain collaboration.
- Part I: Substitution 101 – the basic steps for substitution planning, including the analysis of alternatives step-wise approach; examples of successful/innovative and problematic substitutions; substitution analysis tools.
- Part II: Core questions and strategies for engaging suppliers about alternatives – functional, technical, cost and safety requirements.
- Part III: Current alternative technology options: current landscape; opportunities for cooperative research and development in the value chain – engaging technical assistance and innovation R&D support centres and performance testing collaboration.
- Part IV: Establishing ongoing collaboration to address substitution needs – needs and next steps to continue the collaboration.

Each workshop would be tailored to the needs of those companies, organisations and authorities participating in the workshop. ECHA would support developing a standard package of materials to serve as a basis for the organisation of the workshops, drawing on the assistance by organisations that have developed materials for supply chain capacity building substitution programmes in the past. While ECHA has limited resources to provide translations itself, Member States could translate these materials to their national languages.

Drawing lessons and improving support to substitution

Lessons learnt from the workshops will be compiled in late 2018. These lessons learnt would help in further developing the substitution strategy from 2019 onwards. If the dialogues prove helpful to foster collaborations for substitution and if ECHA can add value to these, the Agency will continue to support such events in the years to come.

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