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EUROPEAN CHEMICALS AGENCY

Report on substitution-supporting activities in 2018-2019 and focus in 2020-21

Implementation of the Substitution Strategy

July 2020

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Summary

In January 2018, ECHA published its strategy to promote substitution to safer chemicals through innovation[1]. The main purpose of the ECHA's substitution strategy was *"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 strategy was seen as *"a support and complement to the stimulus provided by the EU chemicals legislation comprising REACH, CLP and the Biocidal Products regulations*". In so doing, ECHA's substitution strategy complemented the goals of these regulations, by supporting the substitution of harmful substances by suitable alternatives, whilst also contributing to the overarching EU objectives of the time for innovation and achieving a circular economy.

Support to informed substitution and sustainable use of chemicals is part of ECHA's strategic plan for 2019-23, under strategic priority 2 - Safe and sustainable use of chemicals by industry[2].

ECHA's substitution activities for 2020-21 re-emphasise the enabling role of REACH, CLP and the Biocidal Products regulation as the main continuous basis for substitution. This will be leveraged by additional activities to help stakeholders in advancing substitution through different means.

In 2020-21, ECHA will continue with the processing of a high number of REACH applications for authorisation and restriction proposals. The authorisation requirement for substances listed in Annex XIV has a direct impact on substitution, and so has the candidate list with identified substances of very high concern. Also, the continuing work on harmonised classification under CLP, on groups of substances and the further dissemination of information on chemicals plays an important role in supporting substitution of substances of concern, e.g. by the early identification of unwanted substitutes. Notably, the increased transparency of authorities' work through the dissemination of information on the Public Activities Coordination Tool (PACT) and via the Risk Management Options Analysis (RMOA) aims at increasing regulatory predictability, encouraging industry to look for alternatives as early as possible. In addition, the publication of the chemical universe[3] will also support industry in understanding in which regulatory priority pool their substances of interest belong. The newly released European Union Chemical Legislation Finder (EUCLEF) now enables companies to find out in an easier way how their substances are being regulated in the EU and what legal obligations they have.

Under the BPR, in addition to the strict limitations to approve substances which meet the exclusion criteria, the main driver for the substitution of hazardous substances is the requirement of a comparative assessment for biocidal products containing those substances[4]. The ability to perform comprehensive comparative assessments is linked to the progress of the Review Programme of active substances. This is also important for the aspect of prevention of the development of resistance and ensuring a sustainable approach to the substitution of hazardous substances in biocidal products, for which at least three chemical substances need to be available for a given use. Therefore, the progress of the Review Programme of existing active substances, which is the main priority of ECHA's efforts in the biocides area, is important for enabling effective substitution.

ECHA's substitution activities for 2020-21 build on lessons learnt from the implementation of its 2018 substitution strategy[5] and connects with the European Commission's priorities for 2019-

[1] https://echa.europa.eu/documents/10162/13630/250118_substitution_strategy_en.pdf/bce91d57-9dfc-2a46-4afd-5998dbb88500

[2] See https://echa.europa.eu/documents/10162/26075800/echa_strategic_plan_2019-2023_en.pdf/3457ccff-7240-2c1f-3a15-fa6e5e65ac56

[3] https://echa.europa.eu/universe-of-registered-substances

[4] Technical Guidance Note on comparative assessment of biocidal products, CA-May15-Doc.4.3.a – Final

[5] The annexes of this report summarise the achievements and lessons learnt from the implementation of the strategy in 2018-19

24. In particular, it links with the European Green Deal[6], with the forthcoming chemicals strategy for sustainability and the New Circular Economy Action Plan focusing on sustainable resource use. Similarly, ECHA's substitution activities contribute to the transition to a more sustainable economy, they connect well with the new Industrial Strategy for Europe and the SME Strategy for a sustainable and digital Europe.

In terms of stimulating research, ECHA's substitution activities connect with innovation through the concepts of safety-by-design and sustainability-by-design put forward in the Horizon Europe programme. Concerning the funding of other substitution-supporting projects, the Commission's LIFE programme will remain a key EU-wide instrument in the next years.

In addition to the continuous implementation of the regulatory processes supporting substitution, it is noticeable that since ECHA's substitution strategy was instituted in 2018, a number of dialogues, projects and resource hubs were initiated on substitution or safe-by-design by Member States, the European Commission and other stakeholders[7]. ECHA's activities stimulate substitution in helping to network and catalyse these activities. It also contributed to shift the discussion about substitution from a compliance-based focus on eliminating chemicals of concern (which can lead to regrettable substitutions) to one focused on innovation in safer, effective alternatives.

With a view to the substitution activities for 2020-21, ECHA has received feedback and suggestions for consideration from multiple stakeholders. Based on the experience, the feedback and the limited resources available, ECHA puts emphasis on substitution-support actions which are building on and leverage substitution related to its core regulatory activities under REACH (mainly Restriction and Authorisation) and the Biocidal Product Regulation.

For 2020-2021 the activities focus on substances of very high concern that are subject to authorisation, have been proposed for inclusion in Annex XIV, substances that may become subject to restriction or that require substitution under the BPR:

- Facilitation of access to relevant data to avoid regrettable substitution by dissemination
- Systematic work with groups of substances by authorities to allow the identification of substances in need for further regulatory risk management action, substances with low hazard and avoid regrettable substitution
- Capacity building on analysis of alternatives and informed substitution
- Development of networks related to informed substitution of chemicals of concern
- Accelerate the Review Programme of existing biocidal active substances.

ECHA will engage with industry, Member States, NGOs and other key stakeholders to ensure the successful implementation of these action areas.

In the longer term, ECHA will also continue its activity in the other action areas, namely:

- Facilitation of access to research funding and technical support
- Facilitation of the comparative assessment for the biocidal products

ECHA will follow closely the development of the Commission's activities under the Green Deal,

[6] https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

[7] For instance, the set-up of the Swedish substitution centre; the renewal of the SUBSPORT Substitution Support Portal; the study for the European Commission - DG Environment "*Chemicals Innovation Action Agenda: Transition to Safer Chemicals and Technologies*"; the Dutch non-paper on "*Safe-by-design for materials and chemicals*"

in particular the chemicals strategy for sustainability, the EU's broader circular economy package and zero-pollution ambition objectives, as well as the Industrial strategy and the SME strategy, and will see how its substitution activities can support these in a meaningful and practical way, provided that sufficient resources are made available.

1. REACH, CLP and BPR as drivers for substitution

REACH, CLP and BPR regulations have, amongst others, been designed to regulate hazardous substances. REACH and BPR provide incentives for industry to replace them with less hazardous ones. As such, the implementation of these regulatory processes will remain to be the core of ECHA's activities to support substitution in the coming years.

This section comprises the main components of these regulations that have an impact on substitution and describes how the developments planned for 2020-21 in the field of grouping of substances and dissemination of data will further contribute to the facilitation of access to relevant data to avoid regrettable substitution.

1.1 REACH and CLP

In general, the health and environment objectives of REACH are 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 (SVHC). The key drivers under REACH are registration, requirements concerning information through the supply chain, authorisation (including the Candidate List and application for authorisation processes) 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.

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, when searching whether there are possibilities to change to safer alternatives. The requirement to communicate information upstream on operating conditions or risk management measures (RMMs) will also improve the quality of the safety assessments and ultimately the overall quality of SDSs. Finally, the Candidate List plays an important role to foster these substitution activities and helps avoiding regrettable substitutions. It provides a common basis for actors and sends a clear signal to the market and R&D. 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. Similarly, it enables consumers to take the presence of an SVHC into account in their purchasing decisions, creating a market demand for safer substitutes.

The ***authorisation*** provisions within REACH are aimed at ensuring that risks from SVHCs are properly controlled and that the corresponding substances are progressively replaced by suitable alternative substances or technologies. The authorisation title allows companies to apply for an authorisation for a continued (or new) use of an Annex XIV substance. The mandatory requirement to analyse alternatives is an important mechanism fostering the possible applicants to search and analyse substitutes. This is emphasised by the stakeholder consultation to provide scrutiny and for third parties to come forward with alternatives. Furthermore, the authorisations granted by the Commission are subject to time-limited review. This time limit ensures that industry continuously searches for substitutes.

Several studies have shown that the inclusion of substances on the PACT[8], the Community Rolling Action Plan (CoRAP), the Candidate List and the Authorisation List (Annex XIV) has helped to increase the level of activity as regards substitution, withdrawal and replacement of hazardous substances in the EU[9].

The ***restriction*** 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 CMRs[10] (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 articles[11] and CMRs in textiles[12]. 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 articles[13]. This can contribute significantly to the promotion of substitution of these substances globally and also ensures 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, as referred to in the paragraph above, there are more than 20 EU regulations and directives which make (direct or indirect) use of the existing rules on classification and labelling. These cover a wide range of policy areas such as consumer products, occupational health and safety, waste and end-of-life products as well as general legislation on the control of dangerous or hazardous chemicals or major-accident hazards involving dangerous substances – such as Seveso, Prior Informed Consent (PIC), Industrial Emissions (IED). 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 the above-mentioned pieces of legislation. In addition to the available information from registration dossiers, the implementation of the Integrated Regulatory Strategy (IRS)[14] contributes to support authorities in identifying substances of concern and progress them to the appropriate risk management measures under REACH, CLP or other legislation. The impact of the IRS can be seen by an increased number of substances going through a harmonised classification and labelling process under CLP over the last years.

Facilitation of access to relevant data to avoid regrettable substitution by dissemination

In line with the objectives of ECHA's Programming Document(s) 2020-2023, ECHA plans to work on building a multi-annual Dissemination Roadmap. The goal of this activity is to support ECHA's priorities, to continue increasing transparency, to improve the clarity and usefulness of disseminated data, and to enhance the visibility of the work carried out by the Agency. At the

[8] The public activities coordination tool (PACT) provides an overview of the substance-specific activities that authorities are working on under REACH and the CLP Regulation. These activities are being carried out in line with ECHA's Integrated Regulatory Strategy.

[9] Review of the REACH Regulation carried out by the Commission in 2012, the study "Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs" in 2015 , the study "Impacts of REACH Authorisation" in 2017

[10] Carcinogenic, Mutagenic or Toxic to Reproduction.

[11] Restriction: https://echa.europa.eu/documents/10162/176064a8-0896-4124-87e1-75cdf2008d59.

[12] https://echa.europa.eu/documents/10162/176064a8-0896-4124-87e1-75cdf2008d59

[13] https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/13919/term

[14] https://echa.europa.eu/substances-of-potential-concern; Integrated Regulatory Strategy Annual Report (May 2020) https://echa.europa.eu/documents/10162/27467748/irs_annual_report_2019_en.pdf/bd23e8cb-a55a-24af-4be3-7a29828ebb09

same time it calls for a well-discussed and organised approach regarding the developments in the dissemination domain, involving external stakeholders' consultation.

Enhancing the breadth of information that is published together with better ways to access the information to facilitate its processing will support substitution activities in industry when identifying and assessing potential substitutes taking into account their potential properties. As part of the Roadmap discussions, ECHA intends to consult stakeholders to ascertain their interest and the usefulness of the different actions under the Roadmap. The analysis and stakeholder engagement for this activity is planned to be carried out in 2020.

The dissemination of information on PACT and in particular RMOA will lead to an increased regulatory predictability, supporting industry at an early stage in looking for alternatives. The publication of the chemical universe[15] will also support industry in understanding in which regulatory priority pool their substances of interest belong.

Authorities' work on groups of substances

ECHA, together with Member States will continue addressing groups of substances which are structurally similar. ECHA implements this approach to ensure a more effective use of all available information on the substances and an enhanced consistency of authorities' regulatory work. In addition, grouping of substances will support the identification of substances in need for further regulatory risk management action and substances with low hazard, supporting informed substitution and minimising the instances of regrettable substitution. The outcome of the work of authorities on those groups of substances will be disseminated via ECHA website as any other regulatory action via PACT (e.g. RMOA).

1.2 Biocidal Products Regulation

General approach to substitution under the BPR

The Biocidal Products Regulation (BPR) is promoting substitution through two main mechanisms.

Firstly, the BPR provides conditions for approval of active substances. Active substances meeting the exclusion criteria[16] may only be approved when the active substance is essential in protecting environment or human health or when non-approval would have disproportionate effects on society.

Before approving active substances meeting the substitution[17] or the exclusion criteria, ECHA launches consultations to gather relevant information on the availability and suitability of substitutes or alternatives (either chemical or non-chemical). This information on the availability of possible alternatives is taken into account when deciding on the approval of the active substance and is also highly important to support the comparative assessment that is required for the authorisation of biocidal products. Besides this, ECHA runs on behalf of the Commission the consultations on Article 5(2) of the BPR on the potential derogation for non-approval of exclusion substances. Such derogations maybe granted on the grounds of negligible risk, essentiality of the substance or disproportionate effects on society. The information collected here is currently mainly received from industry or stakeholders associations.

[15] https://echa.europa.eu/universe-of-registered-substances

[16] i.e. classified as CMR 1a or 1b under CLP, identified as endocrine disruptors, PBT or vPvB substances

[17] The substitution criteria are based on the intrinsic hazardous properties in combination with the use. An active substance will be considered as a candidate for substitution if any of the following criteria are met: It meets at least one of the exclusion criteria; It is classified as a respiratory sensitiser; Its toxicological reference values are significantly lower than those of the majority of approved active substances for the same product-type and use; It meets two of the criteria to be considered as PBT; It causes concerns for human or animal health and for the environment even with very restrictive risk management measures; It contains a significant proportion of non-active isomers or impurities.

Secondly, for any biocidal product containing an active substance meeting the substitution criteria, a comparative assessment is performed by the Member State Competent Authorities (MSCAs). According to the applicable guidance this follows a tiered approach where first it should be determined whether at least three chemical alternatives are on the market for a certain use. Only when sufficient chemical alternatives are available on the market to reduce the risk of resistance development and to ensure a sustainable approach, substitution by chemical or non-chemical alternatives will be considered.

Availability of information on alternatives

Facilitating the access to relevant data will support industry to look for alternative active substances as early as possible. ECHA publishes on its dissemination website information on the fulfilment of the substitution criteria of the approved biocidal active substances[18]. Furthermore, a comparison tool for biocidal products allows the identification of authorised products containing active substances meeting the substitution criteria.

The experience shows that the consultations conducted during the approval process for active substances meeting the substitution criteria generates limited relevant information on possible alternatives, which is mainly provided by industry and stakeholders. The collected information is unlikely to affect the outcome of the approval process, in particular due to the fact that during the approval of an active substance only a limited number of representative uses is considered.

The requirement of sufficient chemical alternatives to reduce the risk of resistance development and to ensure a sustainable approach makes the substitution process highly dependent on the availability of authorised biocidal products containing approved active substances.

The current status of the Review Programme where for most of the product types only a limited number of active substances are approved and thus products authorised addressing the different uses hinders significantly the comparative assessment of biocidal products and thus, the substitution in practice.

Authorities' involvement on identification of alternatives

During the authorisation of biocidal products including substances that meet the substitution criteria, MSCAs should perform comparative assessments as part of the authorisation process. This enables the MSCAs to develop knowledge and experience on the search of suitable alternatives and supports their role as key actors during the substitution process.

Thanks to their national transitional legislations which can provide information on available alternatives while the Review Programme is not finalised, some MSCAs may contribute proactively to the consultations.

Strategy to enable an effective and sustainable substitution

To enable an effective substitution possible in the future, it is of vital importance that the review programme of active substances in biocidal products progresses to ensure that more active substances are approved and the corresponding products authorised for the different uses. For this reason, actions to support and speed up the Review Programme are the key enablers for substitution under the BPR.

[18] https://echa.europa.eu/information-on-chemicals/biocidal-active-substances

2. Additional activities to promote informed substitution of substances of concern

Building on the implementation of the regulatory instruments that promote substitution, through the implementation of the strategy in 2018-19, ECHA has succeeded in promoting informed substitution by assisting Member States and industry stakeholders through various means, among which:

- holding substance/function specific supply chain workshops,
- creating a dedicated EU-wide network on substitution,
- establishing a web based hub on substitution activities, and
- identifying with the Commission services the ways of boosting research funding possibilities in order to avoid regrettable substitution.

The lessons learnt[19] from the implementation ECHA's substitution strategy in 2018-19 were encouraging and EU's overall policy is pointing towards a zero-pollution environment and a circular economy. Therefore, ECHA intends to continue to work on promoting informed substitution. ECHA will continue to engage with Member States, the European Commission, industry, NGOs and other stakeholders to ensure a successful implementation.

In 2020-21 ECHA will focus its additional activities in the following areas:

- Capacity building on analysis of alternatives and informed substitution
- Development of networks related to informed substitution of chemicals of concern
- Acceleration of the Review Programme of active substances in biocidal products[20]

In the longer term, it will continue also working on:

- Facilitation of access to research funding and technical support
- Facilitation of the comparative assessment for the biocidal products

2.1 Capacity building on analysis of alternatives and informed substitution

Substitution supply chain workshops

ECHA has gained important experience in the organisation of supply chain workshops to improve intra-sectoral communication and collaboration with the objective of finding substitutes to harmful chemicals. Several Member States indicated to ECHA that they would be interested in organising a supply chain workshop. Furthermore, four Member States have expressed their interest in organising workshops in 2020, namely Austria, Sweden, France and Germany.

ECHA will continue to support Member States and industry stakeholders in organising supply chain workshops, focusing its efforts on events addressing substances on the Candidate or Authorisation Lists, substances proposed for Restriction and on biocidal products containing substances candidate for substitution. Particular attention will be given to convey key

[19] See annex for more details

[20] Even though this activity is in direct relation with the BPR core activities, it is described under this « additional activities » section to highlight the new envisaged actions which should contribute to further support substitution in relation with biocidal substances.

downstream and end-users in these events to maximise the impact of the information sharing and adoption of safer alternatives.

Furthermore, as part of the authorisation process, ECHA will arrange workshops on specific substances of very high concern to learn how they are used, what the substitution possibilities are and how many applications an authorisation requirement would entail. In this way, ECHA continues to promote supply chain communication on the identification of safer alternatives starts early for these substances of very high concern.

ECHA has arranged similar events for selected substances during the preparation of restriction proposals (e.g. lead shots in wetlands and microplastics). These have been helpful ways to identify possible alternatives and thus, ECHA intends to arrange such events on a case by case basis.

Training on analysis of alternatives and substitution

In January 2020, ECHA started providing a free-of-charge online, web-based training on analysis of alternatives and substitution and will promote it to stakeholders (companies, consultants, authorities, etc.) in 2020-21. Depending on stakeholders' feedback and ECHA's resources, it might organise a follow-up training session to apply the theoretical concepts to cases studies. Additionally, ECHA will liaise with other organisations (e.g. Swedish substitution centre, BAuA-SUBSPORTplus) to assess the possibility of adapting the training to local needs.

As part of the authorisation activities, ECHA intends to hold periodically "current issues" workshops as part of the NeRSAP[21] meetings with consultants working with possible applicants for authorisation. These workshops are informal ways of learning from one another on how substitution takes place in companies as part of the application process for SVHCs. Learnings of these events will be shared with others, too. The organisation of webinars for practitioners of analysis of alternatives with cases studies and methodological developments are envisaged as well.

Other actions

To help stakeholders in identifying which alternatives are safer, ECHA will pursue its contribution to OECD's work on a guidance on safer alternatives which can further support EU's work on this issue, including on the broader concept of sustainability.

ECHA will continue raising awareness about the existing tools, methods and guidance relevant to analysis of alternatives and substitution through its activities in this field (conferences, workshops, webinars, website, etc.).

In parallel, ECHA will continue emphasising through keynote speeches or other relevant means the importance of viewing substitution, safe-by-design and circular economy in a broader sustainability context, thereby helping instigate mind-set change.

2.2 Development of networks related to informed substitution of chemicals of concern

ECHA will continue its role in organising, participating, maintaining, developing and animating networks in relation with substitution and safe-by-design to enhance knowledge sharing, communication and coordination among stakeholders in the EU on this topic.

Several networks exist with their specificities and additional ones are likely to be created by

[21] Network on 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

stakeholders in 2020-21 in the EU, such as the European counterparts of the Association for the advancement of Alternatives Assessment (A4)[22] and of the Green Chemistry & Commerce Council[23]. These new networks would complement the existing ones in the EU thanks to a greater focus on the methodology and practice of analysis of alternatives and on the industry challenges and projects. Once established, ECHA will collaborate with these new networks and promote engagement of stakeholders.

ECHA has already been actively engaged with providers of alternatives and in external substitution platforms through e.g. supply chain workshops and as a member of ChemSec's Marketplace advisory board and Enterprise Europe Network COSME project steering committee. ECHA intends to keep connections with these stakeholders, continue promoting their activities and help establishing synergies as much as possible according to its resources.

ECHA organised its first substitution network meetings in 2017, a second one in 2019 and intends to continue doing so around every 18 months to ensure information exchange and collaboration with its stakeholders in this field.

2.3 Acceleration of the Review Programme of biocidal active substances

To identify the reasons for the recent slowdown of the Review Programme and determine possible solutions to accelerate it, a workshop was organised by ECHA in February 2019 with the MSCAs, the European Commission and Accredited Stakeholder Organisations. Based on the outcome of the workshop ECHA has developed an action plan that has been agreed by the Member States at the Competent Authority meeting of February 2020 (CA-Feb20-Doc.5.2[24]). ECHA has started implementing the action plan, providing support to the evaluation by the MSCAs and fostering the identification and solving of issues at an early stage, as well as the collaboration between MSCAs. ECHA will also contribute to the capacity building in the Member States by providing various trainings.

2.4 Further perspectives

In a longer term perspective, ECHA will continue its activities on the access to funding and technical support and envisages the possibility to start at a later stage additional activities related to the comparative assessment for biocidal products and the enlargement of the scope of its substitution strategy towards circular economy and specific objectives related to the zero-pollution ambition, the Industrial Strategy and the SME Strategy.

Facilitation of substitution in European research

ECHA will continue its discussions with Directorate-General Research and Innovation and other services in the European Commission on the importance of allocating research funding toward substitution of hazardous chemicals and safe-by-design projects under any of the existing or forthcoming funding framework (e.g. Horizon Europe, LIFE). Companies' substitution efforts and sustainable product design would indeed be facilitated and enhanced if funding was more specifically targeting these issues. Funding for substitution projects has already been available under various EU funding frameworks and schemes (e.g. LIFE, Horizon 2020, etc.) and several of them have been particularly successful, as shown in the case below.

[22] https://www.saferalternatives.org/
[23] https://greenchemistryandcommerce.org/
[24] https://circabc.europa.eu/d/a/workspace/SpacesStore/9b8a5c0c-9d25-4373-b89f-8ddfeeabe2e8/CA-Feb20-Doc.5.2%20-%20Final%20-%20AS%20Action%20Plan.docx

Case - Diamond-Like Carbon to substitute chrome plating in printing

The Green Gravure project aimed to bring to the market the state-of-the-art Roto-Hybrid Process, which combines two novel pre-press gravure printing cylinder process technologies; Hybrid Cylinder technology to enable size variable printing cylinder production and a Diamond-Like Carbon coating process to replace chrome plating and other electrolytic processes like copper or nickel plating. The Roto-Hybrid Process provides a unique solution to help address key challenges facing the global gravure printing industry, enabling faster, more cost effective and environmentally friendly cylinder production and processing to help strengthen the competitiveness and sustainability of Europe's gravure printing industry.[25] The project received over €2 million support under the Horizon 2020 programme.

ECHA does not have the resources to provide direct technical support on substitution to stakeholders but recognises the importance of having such mechanisms in place. ECHA will therefore continue liaising with and promoting the existing networks, initiatives and structures offering technical support such as the Swedish Centre for Chemical Substitution, the Danish Center for Circular Chemistry and funded alternatives testing projects.

Facilitation of the comparative assessment for the biocidal products

To support the Member States with the comparative assessment once sufficient chemical alternatives are approved and the corresponding products authorised, ECHA will develop the necessary IT tools as part of R4BP.

Possible enlargement of the scope towards circular economy and specific objectives related to the zero-pollution ambition, the Industrial Strategy and the SME Strategy

In the longer term, ECHA might also consider incorporating in its substitution strategy specific activities in relation with the EU's broader circular economy and specific objectives of the zero-pollution ambition, the Industrial Strategy and the SME Strategy in a meaningful and practical way.

2.5 Implementation, monitoring and reporting

ECHA intends to implement the substitution strategy through its annual work plan, where the staff and financial resources are allocated. The implementation of the strategy is monitored as part of other ECHA activities and reported under the annual report.

[25] https://cordis.europa.eu/project/id/738010

Annex 1 – Achievements in ECHA's substitution strategy action areas in 2018-19

ECHA's substitution strategy focussed in 2018-19 on (i) capacity building on analysis of alternatives and substitution, (ii) access to funding and technical support, (iii) access to ECHA data and (iv) networking.

ECHA initiated a significant number of actions to promote substitution and supported several other initiatives from stakeholders, covering these four action areas.

ECHA's core regulatory risk management activities (classification, REACH restrictions and authorisations, biocidal substances approvals and products authorisations) are not reported in this document since these are made available in separate annual reports.

1. Capacity building on analysis of alternatives and substitution

ECHA's substitution strategy stresses the importance of enhancing the overall knowledge capacity in companies and authorities concerning analysis of alternatives, innovation and substitution. It incorporated the following two main elements:

- Organising substitution supply chain workshops, usually at the initiative of a Member State. The intention was to identify how to overcome specific substitution challenges, by bringing together companies within a supply chain together with other stakeholders interested in identifying, testing and adopting safer alternatives that could meet a particular function and end-use requirement.

- Providing training for companies and other relevant stakeholders such as Member State competent authorities or consultants to increase their capacity of carrying out analyses of alternatives.

In 2018-19, ECHA implemented the following actions in relation with capacity building:

- Active participation in, contribution to and facilitation of six sector-specific substitution supply chain workshops in relation with chrome plating, flame retardants and water & oil repellents in textiles, bisphenol A in thermal paper and antifouling paints. These workshops were organised by Member States authorities or other stakeholders to contribute to ECHA's substitution strategy or as part of EU-funded projects, and helped actors from supply chains to exchange on possible safer alternatives.

- With the help of a contractor ECHA developed an online introductory course on analysis of alternatives and substitution. This consist of five modules and has been made available in January 2020[26].

- Redesign of ECHA's substitution web site[27] with improved description of the broader context of substitution, putting together new tools, resources and materials. This site can, among other things, serve as a basis for informed substitution and help in carrying out analysis of alternatives.

- Organisation of four webinars:

[26] https://echa.europa.eu/online-training-on-analysis-of-alternatives
[27] https://echa.europa.eu/substitution-to-safer-chemicals

- Why opt for substitution
- Replacing harmful chemicals in the textiles sector
- Tools supporting substitution
- GreenScreen® tool and methodology for comparing chemical hazard and identifying safer alternatives

These webinars attracted several hundreds of participants and aimed at raising awareness on available tools to support substitution, with examples.

- Publication of four newsletter articles:
  - Promoting substitution to safer chemicals through innovation
  - From substitution to safe design
  - Overcoming a substitution challenge: antifouling
  - Moving away from BPA in thermal paper

2. Facilitation of access to research funding and technical support

Having recognised the need for companies, particularly SMEs, to have access to external funding and technical support, ECHA proposed in the strategy:

- To map and disseminate on ECHA's website the financial and technical support institutions and programmes available throughout the EU which can be relevant for supporting substitution-related projects, and

- To seek ways to have substitution financed through existing funding opportunities or programmes in the EU (e.g. Horizon Europe) or to promote the creation of new funding mechanisms dedicated to substitution.

In 2018-19 ECHA implemented the following actions in relation with financial and technical support:

- ECHA has discussed with the European Commission services, in particular with the Directorate General Research and Innovation, on how to enhance support for research activities that aim at directly or indirectly to substitute away of harmful chemicals. These discussions are held in the context of the forthcoming Horizon Europe, which is an ambitious €100 billion research and innovation programme that will succeed Horizon 2020.

- ECHA has worked with EASME on the promotion of the LIFE funding instrument for substitution-related projects.

- ECHA has supported the work of the Dutch authorities on safe-by-design of materials and chemicals - towards an innovation programme in Horizon Europe.

- ECHA has developed new substitution webpages, which include now a list of funding and technical support organisations and programmes available at EU and national level[28].

[28] https://echa.europa.eu/funding-and-technical-support

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

The strategy intended to make better use of REACH, CLP and BPR data to avoid regrettable substitution.

In 2018-19 ECHA focused its work on the following issues:

- Releasing a simplified QSAR toolbox and considering additional ways of facilitating the access to data relevant for substitution.
- Implementing the grouping approach based on structural similarity to avoid regrettable substitution (work ongoing).
- Compilation of all the alternatives shortlisted by the applicants for authorisation (currently available in Excel format), which could be published in a searchable database.

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

The strategy aimed at setting up collaborative networks for innovation and substitution which can play an important role in coordinating and advancing the practice of informed substitution.

ECHA's main networking activities to promote substitution in 2018-19 have been:

- LinkedIn group Substitution to Safer Chemicals - European Information Sharing Network[29] has been launched. It currently has over 400 members from various horizons and more than 60 posts informing about substitution-related news.
- ECHA has set up a "substitution contact list" which consists of over 160 stakeholders interested in substitution-related events and news.
- ECHA hosted two meetings of the substitution and innovation network in Helsinki on 9-10 October 2018 and on 29 May 2019.
- ECHA co-organised the Network on Socio-economic Analysis and Analysis of Alternatives Practitioners (NeRSAP) meetings in February 2018 with OSHA (Bilbao), November 2018 Eurometaux (Antwerp) and September 2019 KeMI (Gothenburg).

[29] https://www.linkedin.com/groups/13554908

Annex 2 - Lessons learnt and impact of the strategy implementation

Having actively participated in and contributed to organisation of many events and other initiatives centred on substitution of chemicals of concern, ECHA has identified learnings that are summarised below.

1. Capacity building on analysis of alternatives and substitution

Supply chain workshops

- Participants perceived substitution supply chain workshops as a powerful tool for substitution to exchange information, discuss the challenges to adopt the alternatives and eventually initiate activities to overcome them. In this sense, stakeholders are strongly encouraged to organise more supply-chain workshops for an increase impact.

- Such workshops raise awareness about the regulatory status of chemicals of concern as well as the availability of chemical or technological alternatives, and can give an incentive for further activities to promote substitution (research projects, joint testing of the alternatives, development/improvement of information tools, information campaigns, etc.). The workshops can be particularly effective when concrete follow-up actions are undertaken[30].

- Convening a supply chain workshop where all key stakeholders, particularly downstream and end-users, are well represented can be challenging. Given that the push toward substitution is often triggered by actors at the end of the supply chain, it is important that more of them are attracted to such events.
- Some companies substitute harmful chemicals early but most start to engage in substitution activities only when regulation has taken place or is expected to happen. It would therefore be important to convene supply chain workshops at an earlier stage of the regulatory process.
- Member State-level substitution workshops gathering companies of different parts of the supply chain have been concrete and beneficial ways of promoting informed substitution and for learning what challenges companies face when trying to find substitutes.

Training on analysis of alternatives and substitution

- There is a clear shortage of knowledge among many companies and Member States on how to conduct an analysis of alternatives.

- Companies often encounter technical difficulties to test the performance of the identified alternatives, e.g. due to a lack of pilot testing capability.

- It is often complex to include life-cycle considerations in analysis of alternatives. However, many entities increasingly recognise their importance for having a more complete picture of the impacts of the alternatives.

- Companies are relatively uninformed about available tools, platforms, guidance and resources that may help them in carrying out analysis of alternatives.

[30] For instance, the initiation by the Dutch authorities of a testing programme of alternative antifouling techniques for recreational boats, as a follow-up of the 2018 substitution workshop.

- Training companies, especially SMEs, on how to scope their substitution project and conduct analyses of alternatives would help in guiding their substitution/chemicals management decisions, including the consideration of the safe-by-design approach in their day-to-day operations. Public authorities and agencies would also benefit from training on analysis of alternatives for their regulatory activities and support to companies.

- Training on assessment of alternatives and substitution would improve the quality and consistency of these assessment to support a transition to safer chemicals and technologies.

- Networking and connecting of experts is one way to address capacity needs and share lessons and best practices. There is a strong interest in collaboration across stakeholder groups, this need than be addressed through e.g. substitution supply chain workshops or by networking activities (see the corresponding action areas or this strategy).

- Awareness raising to instigate a mind-set change in people holding higher managerial positions so they incorporate safer and more sustainable chemistries and technologies, including safe-by-design approaches in their broader strategic business practices would be necessary.

2. Facilitation of access to research funding and technical support

ECHA collaborated with Directorate General for Research and Innovation of the European Commission and with EASME to identify ways to promote the access to funding and technical support to substitution-related projects. From these interactions ECHA has had with industry stakeholders, the following learnings can be listed:

- Providing financial incentives can play an important role in stimulating industry (especially SMEs) to switch to more sustainable and safer alternatives.

- It is important to provide technical support to companies (particularly SMEs) in testing the identified potential alternatives before these can be introduced and adopted by the market.

- Whereas funding for sustainable chemistry projects is available at both MS and EU level - often under more generic innovation headings - companies' substitution efforts would be facilitated and enhanced if funding was more specifically targeted toward the substitution of hazardous chemicals or safe-by-design projects under any of the existing or forthcoming funding framework (e.g. Horizon Europe, LIFE).

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

Informed substitution cannot be achieved without good quality information on the possible alternatives. Having access to such information can be challenging, especially for alternatives for which the dataset is poorer. When it comes to chemical substitution (substitution to other substances), the following learnings have been drawn from ECHA's discussions with stakeholders:

- Stakeholders call for an easier access to good quality information on the volumes, hazard, exposure, risk, technical function and use of substances from REACH, CLP and BPR data (including for low tonnage ban substances with less complete data sets) to support informed substitution and safe-by-design. ECHA has initiated work on these issues and will continue doing so.

- The grouping approach would be of great help to companies in identifying alternative substances likely to have a similar hazard profile as the substance of concern, or, in contrast, groups of substances with more favourable hazard profiles.

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

The networking activities helped stakeholders in viewing substitution in a broader innovation and sustainability context, thereby helping instigate a mind-set change, moving away from seeing only substitution as a necessary action following a regulatory measure. The main learnings from the substitution networking activities are the following:

- There is an increased interest for sharing information across stakeholders from different Member States about ongoing substitution activities to avoid duplications and to find possible synergies and initiate collaborations.

- The development and maintenance of multi-stakeholders and other networks plays an important role in exchanging information, coordinating and advancing activities in relation with informed substitution. The networks can be particularly useful for sharing information on safer alternatives, methods for evaluating these alternatives, challenges during the evaluation and adoption process, potential trade-offs, etc.

- Networking is necessary to build a community of practitioners who can improve the practice of analysis of alternatives and informed substitution

- ECHA's role in developing and maintaining such networks is seen as helpful by the industry as well as other stakeholders.

5. Impact of ECHA's supporting activities on substitution

Although it is hard to quantify or accurately measure the impact of ECHA's substitution strategy on the extent of substitution activities taking place in the EU, it can be argued that ECHA's involvement in, coordination of, and contribution to various activities under each of the four actions areas has provided an array of benefits listed below. It should be stressed that these impacts are not the result of ECHA's activities alone but also the outcome of the actions performed by several stakeholders.

Impact of ECHA's substitution activities in 2018-19
• Further highlighted the importance of including substitution thinking into innovation and chemicals management practices.
• Stressed the importance of connecting substitution to the EU objectives for a circular economy.
• Helped identify and at least partly meet the capacity and knowledge/information needs for companies to substitute away from chemicals of concern.
• Contributed to sectoral and supply chain collaborations in the EU with the intent of advancing knowledge sharing, research, evaluation and adoption of safer alternatives.
• Developed and animated networks with the intent of sharing knowledge, best practices and know-how among Member States, and collaborating on substitution challenges and opportunities within supply chain.
• Helped elevate substitution thinking to a higher EU-wide level and contributed to the increased awareness of the importance of substitution in terms of meeting REACH objectives, as well as the importance of viewing substitution, sustainable chemistry and safe-by-design as building blocks for reaching the UN 2020 and 2030 Sustainable Development Goals.
• Enhanced ECHA's role as a reference point for promoting substitution in the EU.
• Contributed to the paradigm shift from viewing substitution as regulatory burden toward that of business opportunity.
• Contributed to restrictions in the renewal of authorisations of biocidal products used as rodenticides and wood preservatives.
• Contributed to companies not applying for renewal of biocidal active substances of which the products were targeted by comparative assessment.

ECHA's active involvement into and spearheading of some substitution-centred events has garnered serious interest and appreciation both on behalf of the industry as well as the national authorities. The results of a survey of members of ECHA's substitution networks on the importance of the Agency substitution activities reveal that 79% (19 out of 24) of the respondents view ECHA's role as very important, 13% (3 out of 24) as important and 8% (2 out of 24) as moderately important (Figure 1).

Furthermore, ECHA's substitution web pages receive over thousand visits per month as measured by Google Analytics[31]. The good level of participation and feedback from attendees to substitution events, webinars and the number of readers of ECHA's substitution newsletter articles demonstrate also the stakeholders' interest on substitution issues.

[31] See Annex 2

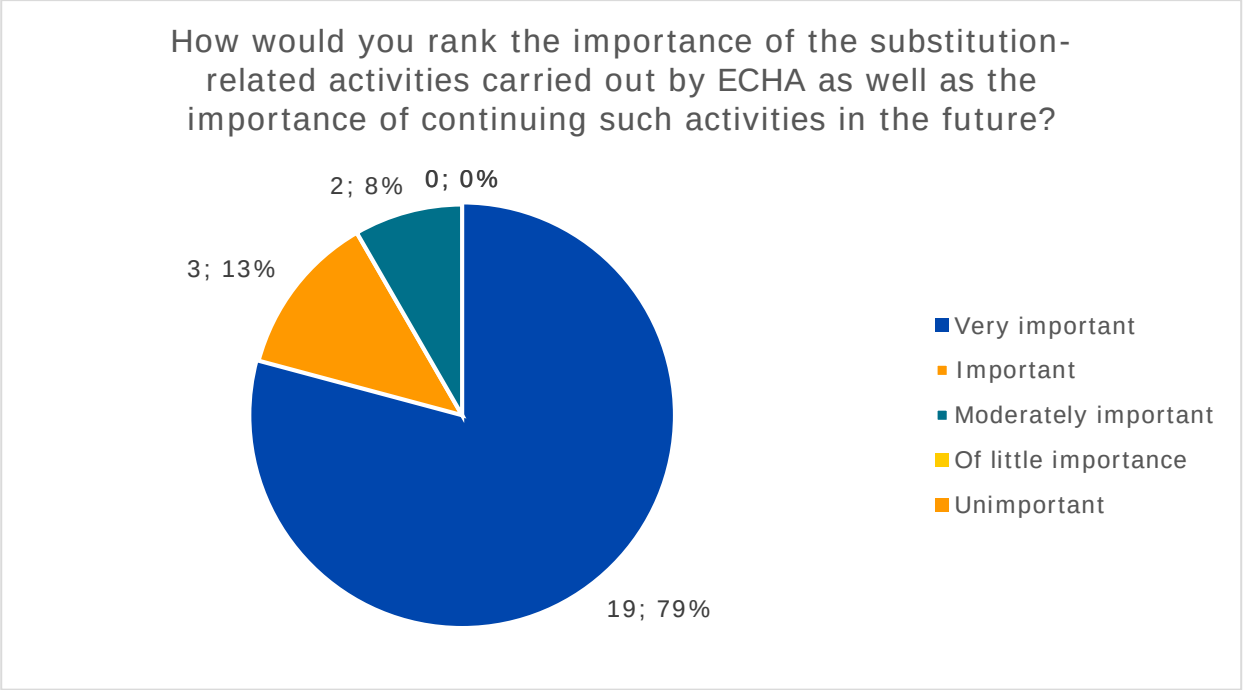

Figure 1 – Importance of the substitution-related activities carried out by ECHA as well as the importance of continuing such activities in the future.

In spite of the fact that it is difficult to provide evidence that ECHA's substitution-supporting activities have directly led to instances of substitution of chemicals of concern, there have been some indications that they have had both direct and indirect impact on encouraging substitution in the EU. One example of direct impact is provided below with Coop's case.

Case – Substituting Bisphenol A in thermal paper in Coop

Coop Danmark A/S - the largest retailer of consumer goods in Denmark – participated in the *supply chain substitution workshop on alternatives to bisphenol A in thermal paper*, co-organised by the Belgian REACH competent authority and ECHA on 26 March 2019 in Brussels. Having become aware of health risks for consumers or workers related to handling of cash register receipts containing Bisphenol A (BPA), Coop Danmark A/S decided to start switching to a non-phenolic alternative in 2015. Having participated in the supply chain workshop, the Quality Manager at Coop Danmark A/S became aware of regulatory developments concerning alternatives to BPA in thermal paper and found out about the availability of non-chemical alternatives to colour developers in thermal paper. As a result, Coop Danmark A/S will now strive to completely phase out the use of chemical solutions in thermal paper.[32]

[32] https://newsletter.echa.europa.eu/home/-/newsletter/entry/moving-away-from-bpa-in-thermal-paper

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