ECHA
EUROPEAN CHEMICALS AGENCY

ECHA Strategic Plan 2019-2023

Draft, March 2018

DISCLAIMER

The following represents the draft of ECHA's strategic plan for 2019-2023 that is subject to further discussion and input. It represents work in progress and will be subject to changes. ECHA's Management Board will be invited to endorse the strategy in December 2018.

The views or positions expressed in this strategic plan do not necessarily represent in legal terms the official position of the European Chemicals Agency. The European Chemicals Agency assumes no responsibility or liability for any errors or inaccuracies that may appear.

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I. Mission Statement

ECHA's legal mandate

The European Chemicals Agency (ECHA) is a European Union (EU) body established on 1 June 2007 by Regulation (EC) No 1907/2006 of the European Parliament and the Council concerning the "Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)".

ECHA was established for the purposes of managing and, in some cases, carrying out the technical, scientific and administrative aspects of the REACH Regulation and to ensure consistency of implementation of the Regulation at EU level. It was also established to manage tasks related to the classification and labelling of chemical substances, which, since 2009, have been governed by the Regulation on "Classification, Labelling and Packaging of substances and mixtures" (CLP Regulation (EC) No 1272/2008 of the European Parliament and the Council).

In 2012, ECHA's mandate was expanded by Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products – the "Biocidal Products Regulation".

The recast Prior Informed Consent (PIC) Regulation (Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals) also entered into force in 2012. Certain tasks related to PIC were transferred from the Joint Research Centre of the European Commission to ECHA in 2014.

These legislative acts are applicable in all EU Member States (MSs) without the need for transposition into national law.

ECHA's Mission[1]

ECHA is the driving force among regulatory authorities in implementing the EU's ground-breaking chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness.

ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern.

ECHA's Vision

ECHA aspires to become the world's leading regulatory authority on the safety of chemicals.

ECHA's Values

Transparent

We actively involve our regulatory partners and stakeholders in our activities and are transparent in our decision-making. We are easy to understand and to approach.

Independent

We are independent from all external interests and impartial in our decision-making. We consult members of the public openly before taking many of our decisions.

Trustworthy

Our decisions are science based and consistent. Accountability and the security of confidential information are cornerstones of all our actions.

Efficient

We are goal-oriented, committed and we always seek to use resources wisely. We apply high quality standards and respect deadlines.

Committed to well-being

We stimulate the safe and sustainable use of chemicals to improve the quality of human life in Europe and to protect and improve the quality of the environment.

[1] ECHA's mission, vision, and values will be reviewed during 2018.

II. The EU regulatory system for chemical safety

ECHA shares the responsibility with many partners to implement the REACH, CLP, BPR and PIC Regulations. In conjunction with other pieces of legislation with effects on businesses in the EU, the range of companies impacted directly or indirectly by the four regulations managed by ECHA is vast and includes a high number of SMEs, which necessitates specific actions and focus by ECHA.

REACH and CLP

The purpose of the REACH and CLP Regulations is to ensure a high level of protection of human health and the environment as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. REACH is also designed to promote the development of alternative methods for assessing the hazards of substances. REACH makes industry responsible for assessing and managing the risks posed by chemicals and providing appropriate safety information to their users. At the same time, where needed, the European Union can take additional regulatory risk management measures on the most hazardous substances.

The core processes that ECHA was set up to manage are the following:

1. Registration

Companies are required to ensure that substances are used safely. All the information necessary to ensure the safe use of the substances they manufacture or import needs to be documented in a registration dossier and submitted to ECHA. This information is also the basis for communicating safe use up and down the supply chain. In order to promote the harmonised interpretations of data, and to reduce registration costs and testing on animals, registrants of the same substance have to share their data and submit their registration jointly. Prior to registration, ECHA clarifies companies' duties, facilitates data-sharing and arbitrates data-sharing disputes. After registration, ECHA verifies the completeness of registration information before assigning a registration number and thereby granting access to the market. The aim is to ensure that each registration dossier contains all the required data elements. The information verified at the completeness check stage provides the basis for the subsequent regulatory processes under REACH, such as dissemination, evaluation and risk management.

2. Evaluation

Evaluation under REACH focuses on three different areas:

- Examination of testing proposals submitted by registrants – ECHA and Member States examine the testing proposals made by registrants and decide whether the tests are necessary.
- Compliance check of the dossiers submitted by registrants – ECHA and Member States verify whether information requirements under the REACH Regulation are met.
- Substance evaluation - ECHA and Member States verify whether further information is needed to clarify if a use poses a risk to human health or the environment.

As a result of the evaluation, registrants may be required to submit further information on the substance. This is done in a form of an ECHA decision, adoption of which always involves Member States. If Member States propose amendments to the draft decision, the case is referred to the Member State Committee to seek unanimous agreement and failing this the European Commission, together with the Member States, takes the final decision.

3. Classification and Labelling

The CLP Regulation aims to provide basic safety information to workers and consumers which helps them to manage risks when using the substances. It sets the rules on determining when a substance or mixture is hazardous and if so how the substance or mixture should be packaged and labelled. The information on properties of substances that is part of the registration dossiers allows to check whether the criteria for classification under the CLP Regulation are met. All operators on the EU market need to assess their substances in this regard and submit the result to ECHA's publicly available Classification and Labelling Inventory. A Member State can propose to harmonise the classification and labelling where this is needed, not only for industrial chemicals, but also for

pesticides[2] and biocides. After receiving the opinion of ECHA's Committee for Risk Assessment, the European Commission, together with the Member States, takes the final decision. Furthermore, ECHA decides on alternative name requests where a company wishes to keep the precise name of a substance used in a mixture confidential.

4. Authorisation

Authorisation aims to assure that the risks from substances of very high concern (SVHCs) are properly controlled and that these substances are progressively replaced by suitable alternatives while ensuring the functioning of the EU's internal market. After a two-step regulatory process managed by ECHA, SVHCs may be included in the Authorisation List by the European Commission, together with the Member States, and thereby become subject to authorisation. These substances cannot be placed on the market for a use after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation. Authorisation applications are submitted to ECHA. After the Committees for Socio-economic Analysis and Risk Assessment have issued their opinion, taking due account of the information provided during a public consultation, the European Commission together with the Member States, takes the decision to grant or refuse authorisation.

5. Restrictions

Restrictions are designed to manage unacceptable risks to humans or the environment in the EU. They limit or ban the manufacture, placing on the market or use of certain substances within the EU. A Member State, ECHA on request of the European Commission, or ECHA on its own initiative, can propose restrictions if they find that there are risks that need to be addressed on a Union-wide basis. After receiving the opinions of ECHA's Committees for Socio-economic Analysis and Risk Assessment, the European Commission, together with the Member States, takes the final decision.

In addition to the above core processes of REACH and CLP, ECHA is required to provide free and easy access to data on substances collected, including information on their properties (hazards), classification and labelling, authorised uses and risk management measures. The dissemination of information to the general public is balanced against the right of companies to protect their confidential business information.

BPR

The Biocidal Products Regulation (BPR) establishes an authorisation system for the placing on the market and use of biocidal products. Biocides are typically used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, through the action of the active substances contained in the biocidal product[3]. ECHA coordinates the evaluation of active substances and the Union wide authorisation of biocidal products and issues opinions, which the European Commission, together with the Member States, uses to take the decision to grant or refuse the active substance or the EU authorisation. ECHA is also the central hub for all national authorisation applications, establishment of technical equivalence, assessment of applications for alternative suppliers, resolution of data sharing disputes, dissemination, preparation of guidance, and communication.

PIC

The Prior Informed Consent (PIC) Regulation implements the international Rotterdam Convention in the EU. It applies to banned or severely restricted chemicals within the EU and provides for information exchange mechanisms regarding the export outside and import inside the EU of those chemicals. ECHA manages the practical functioning of the PIC mechanisms and provides the European Commission, upon request, with technical and scientific input and assistance.

[2] The EU regulatory term is Plant Protection Products.
[3] By contrast, Plant Protection Products are used to protect crops and food against harmful organisms. The European Food Safety Authority plays a similar role for them as ECHA does for biocides.

III. General Context

ECHA's ambition

ECHA aims to become, by 2023, the main source of scientific knowledge and technical know-how on chemicals hereby serving a wide range of EU policies and stakeholders.

Enabling the ambition is ECHA's scientific and technical competence in data management and dissemination, hazard and risk assessment, risk management and the assessment of socio-economic consequences of risk management decisions, built up through implementing the legislative tasks entrusted to it. This places ECHA at the centre of capacity building and support to decision making concerning chemicals management.

ECHA adds value by improving synergies, consistency and efficiencies in implementing EU chemicals legislation, reducing costs and bringing more transparency and predictability to all parties involved. This supports a more effective internal market for chemicals and contributes to the strategic priorities of the European Union. Ultimately, EU citizens, workers, and the environment will benefit from the improved safety of chemicals.

ECHA aims to:

1. Support industry in assuming its regulatory responsibilities for the safe use of its substances within the supply chain, improving product quality and creating business strategies that are aligned with the Sustainable Development Goals;
2. Enable European regulatory authorities to be in a better position to focus their regulatory interventions on those chemicals which matter most to protect human health and the environment;
3. Make it possible for interested parties to have confidence that the substances used in their everyday lives are becoming safer.

ECHA's strategic outlook

Anticipating challenging times ahead

During the time period 2019 – 2023, the EU will take significant decisions and agree on its future political direction. In 2018 the Commission will finalise a series of activities assessing the functioning of the current chemicals policies against the political needs, in particular:

- An in-depth evaluation of REACH under the Better Regulation Programme[4];
- A fitness check under the Better Regulation Programme of all chemicals legislation, including Biocides and CLP[5];
- An assessment of the interface between chemicals, product and waste legislation under the Circular Economy Action Plan[6];
- A report taking stock of the outcome of these three activities[7];
- The development of a non-toxic environment strategy[8].

Furthermore, the UK will leave the EU in 2019, with no clarity currently on the future EU UK relations.

ECHA will inevitably face challenges and uncertainties resulting from these ongoing developments. In particular the discussion on the overall direction of the EU will have an impact on ECHA as will the specificities resulting from the UK withdrawal from the EU, both in terms of the implementation of any possible transitional agreement as well as the possible future trade deal between the Union and the UK. For ECHA the uncertainties will become directly tangible through the Union-wide

[4] http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_env_005_reach_refit_en.pdf.
[5] http://ec.europa.eu/environment/chemicals/better_regulation/pdf/roadmap_chemicals_fc.pdf.
[6] http://ec.europa.eu/smart-regulation/roadmaps/docs/plan_2016_116_cpw_en.pdf.
[7] [Reference to be added at a later stage].
[8] See the 7th Environmental Action Programme (EAP) at http://ec.europa.eu/environment/action-programme/.

discussions on the new Multi-annual Financial Framework (MFF), which will run from 2021 onwards. Looking at ECHA's activities, the year 2019 marks the end of the phase-in period for REACH registration. All substances above 1 tonne already on the market before the REACH era started are now phased-in to one uniform system and all new substances entering the EU market must be registered. REACH and CLP remain the main instruments to ensure safety of chemicals on the EU market. With the ever increasing number of substances regulated in the EU, also PIC will continue being relevant. It ensures that Europe's trading partners know the reasons why the EU has restricted chemicals which they want to import.

In the biocides field the 2019-2023 time period marks the final years leading to the 2024 deadline for the finalisation of the review programme for active substances. All biocides on the market will then be subject to one uniform EU system. ECHA plays a crucial role in supporting the Member States to accomplish this milestone in biocides legislation.

ECHA's current and future role

ECHA's current central role in driving the implementation of the four key regulations – REACH, CLP, BPR and PIC – continues to be the backbone of its future activities. Since its founding in 2007, ECHA undertakes the technical, scientific and administrative tasks of these chemicals regulations ultimately enabling the European Commission and Member State authorities to deliver on chemicals management, as well as in aiding industry to comply with their obligations. In implementing all these Regulations ECHA will commit to further strengthen its approach to transparency.

REACH & CLP

The European Commission's REACH Refit Evaluation[9] concludes that REACH is effective, but not yet efficient and that the implementation of REACH is lagging behind the original expectations in meeting its political objectives. Indeed, there are gaps and severe shortcomings in data provided by industry through REACH registration dossiers, especially with regards to long-term effects of their substances on human health and the environment and in relation to the uses and exposure. Also industries knowledge on substances in articles needs to improve, not only to meet REACH obligations, but also to face the challenges coming from the EU's objectives on Circular Economy[10].

The REACH review also identifies opportunities for improvement and simplification, in particular in relation to extended Safety Data Sheets, evaluation, authorisation and restrictions. The issues requiring most urgent action are: non-compliance of registration dossiers, simplification of the authorisation process, ensuring a level playing field with non-EU companies through effective restrictions and enforcement, clarifying the interface of REACH and other EU legislation, in particular that on Occupational Safety and Health (OSH) and on waste. ECHA is preparing to address these recommendations and is ready to propose adequate initiatives to tackle the outstanding issues.

This means that, on the one hand, ECHA's, Member States' and European Commission's activities implementing REACH and CLP will need, on all fronts, to be intensified in order to meet the political objectives set in the legislation and, on the other hand, that the evaluation activity (including examination of testing proposals and compliance checks) will need to continue at high intensity longer than originally planned. Hence, rather than decreasing during the next Multi-annual Financial Framework, it will need to continue at the current intensity. In addition new ways of accelerating data generation and increasing compliance may need to be explored. Where the available data is sufficient to take action, the efficiency of the regulatory risk management machinery needs to be further improved.

Other REACH core processes will also continue after the 2018 registration deadline under these challenging circumstances. In fact, REACH is first then fully up and running. ECHA will no longer face the peaks of phase-in registration, but with all substances registered, there will be a continuous activity to handle registrations coming in for new substances, substances exiting or re-entering the market and updates of existing registrations. ECHA is going to maintain most tasks that are crucial in the implementation of the legislation: the manual verification of the completeness check,

[9] https://ec.europa.eu/growth/sectors/chemicals/reach/review_en.

[10] Commission Roadmap for the Fitness check on the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries and the Commission Communication on the implementation of the circular economy package: options to address the interface between chemical, product and waste legislation COM(2018) 32 final.

handling of confidentiality requests and data sharing tasks. This demonstrates the continuous necessity to focus on core REACH work.

The REACH processes of registration, evaluation, restriction and authorisation of chemicals allow authorities to focus their work on the substances that are of concern, and to provide a sound scientific and technical basis for regulatory action that may be needed. Where substances have hazardous properties and the known uses show that there is a concern for human health or the environment, this information becomes a starting point for authorities to consider the need for additional risk management and possible substitution by safer alternatives. ECHA will continuously improve the interplay between all REACH processes, so that more relevant outcomes can be generated as a joint effort of all involved authorities.

In addition, ECHA works with the Members States to make sure that REACH is enforced consistently throughout the EU. Cooperation with topically linked other EU Agencies brings synergies and enhanced knowledge sharing in regulatory risk assessment and management.

All users – industrial workers, professionals and consumers – may see immediately whether they need specific attention and safety measures when handling substances thanks to the labelling of packages in a globally standardised way, to which ECHA contributes under CLP.

BPR & PIC

In line with sustained efforts needed for the REACH processes, and to meet the political objectives of BPR, ECHA will need to increase also efficiencies. In the area of Biocides. Biocides activities must be intensified based on continued accumulation of experience and competences to ensure that by 2024 only fit-for-purpose biocidal active substances remain on the EU market. ECHA's continued work to improve the safety and functioning of the biocidal products market in the EU under BPR is needed to achieve this. It is possible by providing the necessary tools and coordinating the processes for approving active substances, authorising at Union level the products that help to control harmful organisms and the execution of the Review Programme.

For PIC, a high level of efficiency has been achieved already. The expected continued increase in number of PIC notifications will test this capacity to handle PIC processes even more efficiently. Given the global perspective of PIC, its implementation by the Agency makes international trade in hazardous chemicals more transparent allowing third countries to control the import of unwanted chemicals or by giving access to safety information if the import is accepted.

IV. Multi-annual Programming 2019 – 2023

With the aim to keep serving the Union in an adequate and efficient manner, the Agency needs to set out new strategic priorities. These will be revisited in light of the outcome of the Commission's work on chemicals[11]. The following section includes s a detailed description of the scope, purpose and measures of success for ECHA's new strategic priorities.

Main Focus on Identification and Risk Management of Substances of Concern

First and foremost, ECHA will focus at its Strategic Priority number 1 on its core processes, as described above: more explicitly, by intensifying the identification and risk management of substances of concern, it will continue at high intensity and with maximum impact the REACH, CLP, BPR processes. These core processes will absorb the majority of ECHA's resources and attention. With this approach ECHA strives to ensure that it can, in any case, deliver on strategic priority 1, as this is the foundation.

Complementary Work on Safe and Sustainable Substances & Data Utilisation

Forward looking and making a difference in the safe and sustainable use of chemicals by industry (strategic priority 2), ECHA will invest more than until now on functioning supply chains and circular economy themes, complementing the core regulatory tasks. Finally, maximising the use of data and competences for the sustainable management of chemicals through the implementation of EU legislation (strategic priority 3) takes account of the knowhow and knowledge ECHA has obtained

[11] Ibid. available at http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_env_005_reach_refit_en.pdf.

– this asset has the potential to grow and play an increasingly important role in the assessment and management of substances.

On priorities 2 and 3, while ECHA is committed to analysing how it can advance them, the actual ambition level on their implementation is more directly dependent on the availability of additional resources. Hence, while Strategic Priorities 2 and 3 will start with limited resources, they remain vital components to maximise the effectiveness of diverse chemical safety regulations across various sectors within the internal market. Indeed, mastering the challenges described above and living up to its future role will reinforce ECHA's mission as the EU implementing agency for chemicals legislation. ECHA will be ready to continue its 10 year track record on delivering on its core tasks while, should the EU decide to do so, taking on additional implementing tasks from more legislation[12], thus establishing synergies and consistency between various pieces of legislation.

ECHA's competence basis

ECHA can build on its competences, knowledge, and experience, and optimise its collaboration with the Member States' competent authorities and other EU Agencies, remaining focused on delivering sound science-based opinions, decisions and advice.

ECHA keeps on adapting its processes, methodologies, tools, as well as its staff competences to reflect the advancing science, technology and changes in the regulatory environment. ECHA will actively explore the potential of IT-based approaches, using opportunities offered by new developments in search and computing algorithms. It is expected that the international dimension of ECHA's work as a cross-cutting element will further increase.

[12] Starting with REACH in 2006, CLP in 2008, Biocides in 2012, PIC in 2012 and possibly POPs and certain tasks regarding the Waste Framework Directive in 2018.

ECHA will pursue the strategic priorities as described below. Progress in achieving each of these priorities is monitored via objectives and their measure of success.

Strategic priority	Objective	Measure of success[13]
1. Identification and risk management of substances of concern	[1] Accelerate data generation and intensify identification of substances of concern	By 2025, conclusions are available on whether registered substances i. Are of concern; ii. Are currently not of concern; or iii. Need more data for a judgement to be made and the data that is missing has been defined.
	[2] Accelerate regulatory action on substances of concern	By 2025, all substances of concern are identified and regulatory action initiated
2. Safe and sustainable use of chemicals by industry	[3] Effective communication up and down the supply chain becomes mainstream	Increased uptake of and use of recognised tools and formats for supply chain communication
3. Sustainable management of chemicals through the implementation of EU legislation	[4] ECHA's information, knowledge and competences on safe use of chemicals support the implementation of EU legislation.	ECHA demonstrates synergies and consistencies created by the further interaction and integration of EU legislation. ECHA acts as provider and facilitator for new data and data analytics. This improves the safe use of chemicals and to lead to evidence-based regulatory changes.

V. Strategic priorities

1. Identification and risk management of substances of concern

The REACH and CLP regulations make industry responsible to ensure the safety of chemicals they manufacture, import and use. ECHA's role in evaluating testing proposals and checking compliance is fundamental in ensuring the right data is generated and industry takes its responsibility. Authorities may complement the industry role, identify the need to generate further information to clarify the potential concerns and initiate regulatory intervention. Once all substances on the EU market above 1 tonne are registered, there is a unique opportunity to address all substances of potential concern. The integrated implementation of REACH and CLP aims at bringing the above processes together in consistent and efficient way.

The ambition to prioritise and address all higher tonnage substances (above 100 tonnes) by 2020 continues to be the driving factor for our work as part of meeting the WSSD 2020 goals established in 2002 (see text box below). However, in light of ECHA's experience in facing deficiencies in the quality and compliance of the current REACH registration dossiers, continued efforts are needed beyond this date to generate the requisite information, in particular on their long-term hazards, uses and presence in articles. ECHA is aware that this will still take a longer period of time than

[13] Targets and indicators to be developed.

originally planned, whereby it is of paramount importance to fill the existing data gaps, which do not allow all chemicals of concern to be assessed.

ECHA and the Member States will strive to further integrate and optimise their actions, including those related to enforcement. Where necessary the Commission may decide to initiate infringement procedures. The time between identifying and characterising a problem and implementing appropriate risk management measures needs to be significantly reduced. Substances will be regularly addressed in groups instead of one-by-one, in close cooperation with the Member States and involving relevant industry sectors to ensure a higher throughput.

The identity of all chemicals on the EU market above 1 tonne, will be known after the 2018 REACH registration deadline. The high number of substances expected to be registered means that new ways of identifying those which need closer scrutiny will have to be found: effective prioritisation is based on full use of internal and external data sources, the deployment of qualitative and quantitative estimation methods and, where available, new approach methodologies.

Biocides have the intention of exerting a controlling effect on harmful organisms. This implies that biocides have in many cases a mode of action that would lead to a categorisation as a substance of concern in the context of other legislation – this is why they undergo an authorisation system. The Biocidal Products Regulation aims at ensuring that all active substances and products on the market do not have a negative impact on humans or the environment. However, in light of the slower than originally planned assessment by Member States of active ingredients and the thereby slowing down of the product authorisations, efforts are needed to accelerate.

For REACH, CLP and Biocides there will be a need to evolve the risk assessment and management approaches and research over time and to accommodate emerging priorities, such as managing substances with endocrine-disrupting properties.

The WSSD success factors 2020

ECHA will continue to contribute to the "World Summit of Sustainable Development (WSSD) 2020 goals" in order to honour the commitment of the EU and Member States in achieving a "toxic-free" environment. REACH and CLP Regulations are the main tools in the EU for implementing the goal of sound management of chemicals throughout their lifecycle so that, by 2020, chemicals are used and produced in ways that lead to the minimisation of significant adverse effects on human health and the environment.

The full achievement of the WSSD 2020 goal will take considerably longer than originally estimated, as takes the fulfilment of all REACH and CLP objectives. In the context of ECHA's strategy for the next years, and to make as much progress as possible, ECHA considers that the WSSD 2020 goal means that:

1. Robust data is available on all chemicals in Europe
    a) Registration dossiers are up to date and contain appropriate and complete data covering the hazards and uses of substances. This allows them to be adequately classified, labelled and used safely. Companies can use the information for substituting hazardous substances, and by that spur innovation.
    b) Hazard data is generated using non-animal testing methods and new approaches wherever possible.
    c) ECHA has concluded, preferably in co-operation with the relevant stakeholders, which high-volume substances (above 100 tonnes per year):
        i. Are of concern;
        ii. Are currently not of concern; or
        iii. Need more data for a judgement to be made.
    d) All chemicals critical for the supply chain in Europe are registered without unnecessary market disruption.
    e) A plan describes how ECHA will identify candidates for further evaluation and/or risk reduction amongst the lower volume substances (1-100 tonnes per year).
    f) Divergence in industry self-classification has decreased significantly.

2. Effective regulatory risk management of the most hazardous chemicals takes place

   a) Substances of concern are identified, either individually or in groups. The most appropriate regulatory risk management measure to protect health or the environment, either under REACH and CLP or other legislation has been initiated.

   b) The processes for authorisation, restrictions, and harmonised classification and labelling are fully optimised and operate based on fit-for-purpose dossiers. They allow efficient opinion-forming in the committees and swift decision-making by the Commission.

3. Effective communication takes place about the safe use of chemicals up and down the supply chain

   a) Information about substances flows effectively up and down the supply chain. Companies that use chemicals inform their suppliers about what they do with them, and in return, manufacturers and importers provide information on how to use them safely.

   b) Importers and EU producers of articles have improved their knowledge on the substances present in their articles to provide adequate safe use advice to their customers and promote substitution.

4. A step-change for citizens, businesses and the regulators takes place

   a) Information on chemicals is reliable, understandable, freely available, and easy to use. This allows citizens, stakeholders, businesses and regulators to make informed choices on using and substituting hazardous substances, and to increase their confidence in the safety of chemicals – not just in Europe, but around the world.

   b) The experience of REACH and CLP, the information, methods and tools developed are increasingly recognised and used worldwide.

Companies experience firm, and fair enforcement, focusing on ensuring the safe use of hazardous chemicals and fostering a level playing field.

Areas of Operation for Strategic Priority 1

REACH requires ECHA to manage the registration process of substances, to perform evaluations, run the opinion forming process for restriction proposals as well as for applications for authorisations, and to establish and maintain databases with (disseminated) information on all registered substances. The latter includes also the classification and labelling inventory. These core processes under REACH may not generate the desired impact if executed in isolation and without use of external information. ECHA therefore prioritises and screens substances, using also information external to the registration dossiers, with a view to map whether they are of possible concern. In fact, REACH stipulates that prioritisation is needed explicitly for compliance checks, substance evaluation and the identification of substances for possible inclusion into Annex XIV of REACH. Due to the fact that there is not sufficient data available for many substances, the evaluation activity is and will be needed for obtaining the necessary information and achieve a high level of compliance with information requirements.

In relation to registrants and stakeholders, ECHA has to provide guidance, advice and assistance with special attention to the needs of SMEs. This comprises to promote best proactive behaviour in identifying and managing substances of possible concern and ensuring safe use.

With PIC and Biocides ECHA has the legislative basis to perform regulatory tasks in managing the notification of exports of hazardous substances and the opinion forming processes for active substances and Union authorisation under BPR and related processes that involve gathering and managing of information.

The activities mentioned below are designed both to improve the execution of the core regulatory tasks and to complement them, thus materialising in a more efficient and impactful execution of ECHA's core regulatory tasks.

1. Concerted regulatory action

- Use completeness check, dossier and substance evaluation and regulatory risk management processes to address the potential/identified concerns in as short a time as possible.

- Continue increasing the efficiency of the formal processes, including the evaluation decision making, covering both the role of the ECHA Secretariat, the MSCAs and that of the Committees.
- Enhance shared understanding and agreement on priorities and the best use of different regulatory instruments across ECHA, the Commission and national authorities, including enforcement.
- Continue working with MSCAs and the European Commission to find ways of expediting the biocides review programme
- Perform CLP, BPR and PIC processes in an efficient and impactful way. Increase the overall regulatory efficiency and support alignment of implementation practices by reducing duplication of efforts.
- Increasing the usefulness of ECHAs work for the Committees and exploring new ways of sharing the work and knowledge between ECHA, the Member States and the Commission.

2. Enhanced mapping and prioritisation of substances

- Use all data sources and also novel methods for mapping and prioritising substances based on hazard and use/exposure data.
- Results of the mapping, both in terms of conclusions that can be drawn and identified data gaps, are recorded and communicated in an explicit and transparent manner.
- Increase data availability for prioritising data poor substances with an aligned strategy for further generation and use of data from new approach methodologies (NAMs).
- Anticipate and address emerging substances, hazards and issues by sharing knowledge with the scientific community and other regulatory and policy fields.
- Develop regulatory strategies and assessment methods for specific (groups of) chemicals or effects, such as nanomaterials and endocrine disruptors, support development of alternative methods to animal testing and explore how these can be used in risk assessment.

3. Induce faster action by industry

- Promote proactive behaviour and continued investment by industry to comply with information needs and their responsibility in updating and improving the information on their substances in their registration dossiers as well as in identifying and managing substances of concern.
- Work in collaboration with industry actors, including those in specific sectors, and Member States on prioritised groups of substances to create a comprehensive and shared overview on the data and areas where additional effort by industry and regulatory attention is needed.
- Explore how ECHA could, without assuming the burden of proof or compromising its regulatory authority role, give direct substance/case-specific advice to registrants on dossier compliance including for specific groups of substances.

2. Safe and sustainable use of chemicals by industry

Companies are responsible for safely manufacturing and using chemicals on their own, in mixtures and in articles. They achieve this by characterising the risks, communicating up and down the supply chain how to handle harmful chemicals safely, by implementing appropriate risk management measures and substituting from harmful to safer chemicals. This communication needs to be established between the manufacturers, formulators, users, retailers and even consumers of chemicals. REACH codifies the responsibilities and mechanisms under which operators should work and communicate.

The service–life of articles and waste stages, which are currently often neglected, are an important part of safe use of substances. By investing comprehensively in this, industry can make a significant contribution to reaching a non-toxic environment and making the EU's economy circular. A significant improvement in compliance with legal obligations is achieved if more companies assume their responsibility and make full use of the tools, templates and guidance that ECHA has developed

and provided in collaboration with industry associations. ECHA will intensify its support and information activities, thus helping companies to improve their safety advice and fulfil their obligations related to communication in the supply chain, as well as with requirements of related legislation.

Whereas sustainability has become an important element of corporate agendas and is increasingly seen as a driver for innovation and continued growth, chemicals management is generally seen to be connected more to regulatory compliance. Many companies do though recognise that knowing the properties and uses of their substances helps them establish safer production processes and substitute substances as part of their business models. By staying at the forefront, they safeguard their competitiveness in an ever-changing domestic and international socio-economic environment. Some investors also include sustainability, green chemistry and chemical safety into their risk assessments – compliance becomes a business and market asset for companies.

Further demand is already coming from retailers and consumers wanting safe(r) products that, for instance, do not contain substances of high concern. Using multiple media channels, ECHA will put exemplary behaviour into the spotlight and highlight the business potential of forward-looking policies, such as the non-toxic environment and circular economy, for which substance knowledge is key.

The data that ECHA generates and provides publicly and free of charge, as well as the analyses and tools that the Agency develops, benefit companies, academia, industry, and consumer organisations. It can also help to avoid "regrettable substitution". ECHA will cooperate with relevant stakeholders to increase the skill base of companies in sustainable portfolio management.

ECHA will collaborate with intermediaries and multipliers that communicate risk-related information to the public, allowing citizens to better value chemical safety in their lives.

Areas of Operation for Strategic Priority 2

REACH provides a legal mandate for ECHA to provide scientific and technical guidance and tools, in particular to assist the development of chemical safety reports and safety data sheets. The Regulation asks ECHA also to facilitate the communication on the safe use of substances on their own, in mixtures or in articles, and requires ECHA to operate certain processes to gather and assess information about substances in articles. These activities support a sustainable and well-functioning information flow in supply chains through extended safety data sheets. A better information flow improves the registration dossiers, enabling better priority setting, and improves authorisation applications, enabling better opinion forming by ECHA's committees. As chemicals legislation places many duties on companies, ECHA's support to industry aims to ensure that the companies understand how to comply with the legislation. Eventually, end-users will also be supported to ensure that the information received through the SDSs will also help them with their obligations under environmental, product and in particular worker protection legislation.

The guiding principle of REACH to substitute harmful substances by safer, less harmful alternatives mandates ECHA to support this aim and to work on the more sustainable use of chemicals in line with the WSSD 2020 goals. Such activities ultimately improve the functioning of the REACH authorisation system and industry responsibility for safe use.

The activities mentioned below are designed both to improve the execution of the core regulatory tasks and to complement them, thus materialising in a more efficient execution of ECHA's work.

1. Strengthen the knowledge base on substances in articles

- Support registrants to develop better article service life, waste stage and recycling descriptions and associated exposure assessments in their registration dossiers.
- Enhance the EU supply-chain communication on substances in articles from downstream users to retailers and to waste managers and recyclers by developing suitable tools and communication practices including access to relevant information on chemicals to the latter user group.
- Support the availability of relevant information on the presence of substances in articles to importers of non-EU articles. This will allow ECHA to design concrete actions by taking an active role in the development of (or adaptation of existing) IT tools.
- Develop and implement approaches to identify priority articles that would require further

regulatory actions and define the most appropriate EU legislative frameworks.

- Continue communication and networking activities to raise the awareness of all actors involved – i.e. EU companies, EU consumers and non-EU actors – on substances in articles.

2. Support to substitution and sustainable use of chemicals

- Facilitate the use of registration, classification and risk management data for sustainable substitution. Support to maintaining and developing associated tools (e.g. QSAR Toolbox) will help in the screening of the data
- Support the capacity building in companies and Member States on substitution. This may also include improving the public consultation of active substances regarded as potential candidates for substitution under the BPR. Improving awareness by mapping the available funding and technical support relevant for substitution-related projects and making the information more accessible to companies.
- Develop networks that can coordinate and help advancing the practice of substitution.
- Explore ways in which companies can better link good chemicals management (including good registration dossier quality) to their integrated corporate sustainability strategies and goals.

3. Improved safety data sheets

- Facilitate that downstream users receive more consistent and useful safety advice from their suppliers for their own uses and for all the uses further down the supply chain, including the article service. Support in particular end-users in making the connection to their risk assessments under occupational safety and health legislation, and the control of environmental emission and product safety (for consumer mixtures and articles).
- Identify the barriers to the more comprehensive uptake of supply chain communication related tools and methodologies. This will include communication and marketing of the existing tools, and where needed further development.
- Collaborate with national enforcement authorities and national helpdesks to promote the use of supply chain communication tools.
- Support the further development of the related exposure tools and broaden the scope of the chemicals safety assessment (CSA) methodologies thereby improving supply chain communication.

3. Sustainable management of chemicals through the implementation of EU legislation

Further synergies between the regulations (REACH, CLP, PIC and the BPR) currently assigning tasks to ECHA and Member State authorities are actively sought to release the full potential of integrated implementation and enforcement of the laws. It is obvious that REACH serves many more needs than only for itself. In fact, it feeds into all chemicals legislation of the EU on the one hand and documents the results of all chemicals legislation on the other hand – the functioning of REACH is the key indicator of how well chemicals management works overall. By the same token, CLP reaches with its classification and labelling provisions into many pieces of chemicals legislation and PIC provides for a safety net across regulations for the most hazardous substances.

A holistic view on all chemicals legislation is for the benefit of human health and the environment and also improves efficiency and effectiveness, as well as helping industry to comply with their obligations. Besides optimising its current synergies, the aim is that ECHA's information, knowledge and competences are increasingly used to support the implementation of other pieces of legislation and policy areas related to the safe use of chemicals. This may comprise interaction, meaning for example that ECHA has an advisory or support role and helps authorities responsible for other legislation in identifying and managing the risks of chemicals by providing a sound scientific basis. Subject to potential extension of ECHA's legal mandate, it may also take the form of integration, where ECHA is formally given a role in the implementation of other legislation such as for waste legislation activities. This will depend on the availability of resources overall for this activity and in particular for new future tasks and the resource needs for the other strategic priorities.

The focus of ECHA so far has been on its regulatory role in support of REACH, CLP, PIC and the BPR. The investments made and competences gained to implement these four regulations can benefit other pieces of legislation or policies related to chemicals' safety, ECHA will reinforce the competences on the interfaces to improve efficiencies in the current implementation of the four legal instruments – this can show where the competence is as well suitable for possible new tasks. Ongoing developments in this regard include, for example, the use of REACH and CLP data to support the occupational safety and environmental legislation. As such, this is not something new; due to opportunities for synergies and efficiencies ECHA's original mandate has already been expanded (by BPR and PIC), and is being expanded (waste legislation, and POPs soon expected) with additional regulatory tasks.

In general, the Agency will continually expand its data and knowledge-base, aiming to provide user-friendly data access. ECHA will also continue to enable safety information and data to be provided in a manner that allows companies to use it to fulfil multiple regulatory needs beyond chemical safety legislation, such as under workplace, products or other pieces of legislation. This will help to reduce the cumulative compliance costs for companies and can thereby contribute to better regulation. More generally, ECHA will also follow developments within the digital single market strategy, and look for opportunities for new activities and services based on the data and competences it holds.

Creating synergies and efficiencies will help also public authorities at national and EU level as resources are scarce.

A stepwise approach is needed to show the benefits of this ambition and to ensure a controlled approach to the possible extension of ECHA's role and remit. ECHA also needs a framework to determine the relevance and feasibility of the potential areas of work, including assessing and ensuring resources. This work is done in close collaboration with the Commission, who has the right of initiative to propose new legislation or amend the existing ones.

This priority is linked to ECHA's integrated regulatory strategy, as it is meant to integrate the data generation with the use of the data to enhance risk management. It should be noted that the benefits and synergies are expected to be two way, i.e. to enable other pieces of legislation to perform better in terms of addressing chemicals safety, but also e.g. to support the implementation of REACH by getting improved information on use of and exposure to chemicals through other pieces of legislation.

Areas of Operation for Strategic Priority 3

ECHA has the mandate under REACH to define formats and software for the submission of information to the Agency and to establish and maintain databases based on information it receives from companies. Moreover, REACH foresees cooperation between the Agency and Member States, EU institutions and third countries, including the sharing of information obtained by the processes run under REACH, CLP, BPR and PIC. This also comprises, at the Commission's request, participation in technical assistance and capacity building activities on sound management of chemicals in developing countries.

The gathering of information should not be a reason in itself but rather provide for the basis to perform Biocides, REACH and CLP processes, allow to development of alternative methods to testing and is needed for the provision of guidance documents that allow industry to meet their obligations. The more efficiently ECHA obtains information and manages its processes, the more flexibility it can achieve for deepening collaboration, seeking synergies and sharing knowledge.

The activities mentioned below are designed both to improve the execution of the core regulatory tasks and to complement them, thus materialising a more efficient execution of ECHA's core regulatory task.

1. Synergies across new and existing legislative tasks and policies

- Working with the Commission and Member States, identify legislation and policy areas to which the Agency can contribute. Priority is given to areas that can contribute significantly to an improved level of protection and where synergies exist regarding ECHA's current knowledge and competences.
- In each priority area, prepare a strategic plan with the relevant partners and stakeholders

on what support ECHA can provide, what the additional resource needs are and what role it can play in realising the synergies and increased consistency.

- Where new responsibilities or tasks are assigned to ECHA and resources are made available, prepare an implementation plan to ensure successful execution, integration of the tasks into ECHA's planning cycle, and to monitor and report on its implementation, including how the benefits and synergies are realised.

2. Use of data, information and knowledge on safe use of chemicals

- Further develop the capabilities and tools to manage qualified knowledge on chemicals based on submitted data, interpretation of data achieved by applying IT-based approaches.
- Increase ECHA's activity at EU and international level to create synergies with data sources from international programmes and third countries.
- Analyse what strategic opportunities the implementation of the EU digital agenda can provide, and how ECHA can contribute to it.

3. Foster synergies at international level

- Continue to contribute actively to the OECD chemicals programme, and increase its activities in other international fora (e.g. SAICM), if requested by the European Commission.
- Prepare and implement an action plan for providing capacity building support for countries that are developing their chemicals management schemes, if requested by the European Commission.

4. Actions to invest in enabling components

Successfully executing these three strategic priorities requires sufficient resources, infrastructure, knowledge and competences to be available, while maintaining a high level of efficiency, motivation and staff wellbeing. New regulatory tasks should be combined with adequate additional resources when redeployment of available resources is not possible.

ECHA will analyse possibilities to benefit from alternative funding sources in line with discussions at institutional level about the funding structures of EU agencies. To be able to manage the changes in its legal mandate and policy objectives, ECHA will further invest in proactively building the necessary staff competences and in having flexibility in reallocating resources. In 2018, ECHA will prepare a new multiannual human resources strategy, in light of the identified strategic priorities of the Agency, encompassing the period 2019-2023. Furthermore, ECHA depends on the active contribution and fulfilment of the respective duties of other authorities, industry and stakeholders in implementing this strategy.

<u>Enabling areas of operation</u>

1. Maintain and build identified staff competence for current and future tasks

- Ensure that staff maintain up to date knowledge in scientific, technical and technological advancements, trends and challenges.
- Adapt ECHA's communications to a fast changing environment.
- Develop and strengthen sufficient competence for current responsibilities and future needs by ensuring robust processes for people and resource management.
- Foster a culture of flexibility and adaptability that supports agile internal deployment and mobility and a dynamic organisational structure. This can be achieved by providing support for new ways of working that facilitate flexibility, mobility and collaboration among all the actors (internal or external to ECHA) involved in ECHA's work processes.

2. Continuously investment in IT to deliver ECHA's mandate and improve efficiency

- Further develop ECHA's IT architecture of tools and cloud services to support the strategic priorities in the areas of operations and the overall efficiency of the Agency.
- Optimise the cost of operating IT on well-established IT services while simultaneously and, efficiently implement new IT services and new delivery models to address new needs and opportunities.

3. Sustainable and flexible finance and governance structures

- Explore, with the European Commission, options for a new financing model for ECHA, including revisiting the possibility of an overall EU subsidy and/or a reserve to smoothen the annual income variations.
- Examine, with the European Commission, the best way to ensure sustainable income for ECHA in a context of reduced own fee income.
- Explore further options to increase the transparency in decision making.