

# ECHA Strategic Plan 2019 – 2023

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#### ECHA Strategic Plan 2019-2023

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## **Mission Statement**

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## 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 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

ECHA's mandate is to manage and carry out technical, scientific and administrative aspects of REACH. ECHA was also established to manage tasks related to the classification and labelling of chemical substances, which, since 2009, have been governed by Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (CLP).

Since 2012, ECHA's mandate covers Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR).

The recast Prior Informed Consent (PIC) Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals transferred certain tasks from the European Commission to ECHA in 2014.

In 2018, ECHA was allocated a specific task concerning substances in articles under Directive (EU) 2018/851 on Waste.

The four regulations are directly applicable in all EU Member States without the need for transposition into national law. The directive is transposed into national legislation, which is the applicable law in the respective EU Member State.

## **ECHA's Mission**

We, together with our partners, work for the safe use of chemicals.

## **ECHA's Vision**

To be the centre of knowledge on the sustainable management of chemicals, serving a wide range of EU policies and global initiatives, for the benefit of citizens and the environment.

## ECHA's Values<sup>1</sup>

## 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.

<sup>&</sup>lt;sup>1</sup> ECHA's values will be reviewed during 2019.

## **I GENERAL CONTEXT**

## **ECHA's role**

ECHA is an EU decentralised agency, set up to contribute to the implementation of the common chemicals policy. As a European Agency, ECHA is a distinct EU body with its own legal personality. ECHA is a public body, serving the EU citizens, works transparently, and is independent of any specific or policy interests, of national interests and of the EU institutions. ECHA provides opinions to the European Commission on the scientific and technical aspects of hazard assessment, risk assessment, risk management and the societal and economic consequences of risk management decisions. The European Commission, together with the Member States, takes decisions based on ECHA's opinions. ECHA also takes decisions granting rights to or imposing duties on specific economic operators.

For all its work ECHA consults and coordinates with the European Commission and the Member State authorities. ECHA relies on the technical, scientific and administrative specialist expertise from the Member State authorities and pools their knowledge through its committees to develop opinions and agree on decisions. The staff of ECHA provides the secretariat for this close collaboration, drafts dossiers and decisions for the committees' opinion or agreement and in certain cases drafts decisions without needing to involve the committees. Overall, ECHA supports the cooperation between on the one hand the EU and national governments and on the other hand between the EU and international organisations concerning chemicals policy. ECHA also provides advice and support for companies in fulfilling their duties under the legislation.

ECHA manages and in some cases carries out the technical, scientific and administrative aspects of REACH, CLP, BPR, PIC and a specific task under the Waste Framework Directive (WFD) to ensure consistency at EU level in relation to these regulations and directive. Box 1 describes the tasks carried out by ECHA.

Much of ECHA's international work focuses on developing standards internationally and implementing them in the EU. There is therefore no single section on the international work of the Agency in this Programming Document. Instead both the EU and international work is covered together by topic.

## The EU regulatory system for chemical safety

The EU has an extensive system of legislation controlling chemicals. REACH, CLP, BPR, PIC and the specific task under the WFD form an integral part of this system.

Excluding pharmaceuticals and veterinary products, the system starts with the basic regulation REACH on industrial chemicals, the Regulation on plant protection products and BPR on biocides. They lay out the marketing and use conditions for these three types of chemicals. The regulations have similar approaches: before a chemical is allowed on the market or to be used, information on its hazards and uses must be generated. Authorities assess the information before granting market access (or not). This assessment is in-depth within an authorisation system for plant protection products, biocides and certain industrial chemicals and a screening level for all other industrial chemicals. The three regulations have clear interfaces: all active plant protection and biocidal ingredients are automatically registered under REACH.

Reaching across these three basic regulations, the CLP Regulation (classification and labelling of chemicals), which implements the UN globally harmonised system into EU law, sets harmonised rules on how to classify, package and label the industrial chemicals, plant protection products and biocides. The application of the CLP rules forms an integral part of the authorities' decision for market access for all three types of chemicals. Furthermore, product specific regulations, covering for example, cosmetics, toys, food contact materials, detergents and electronic equipment, form a second layer of legislation setting particular conditions for chemicals in those products. Finally, there are regulations and directives involving chemicals, for example concerning the import and export of certain hazardous chemicals (PIC), chemical accidents, water, workers, ecolabelling, fertilisers, industrial emissions, or waste, adding conditions on the manufacture, marketing and use of chemicals.

The second and third layer of EU legislation do not require the generation of hazard information. They generally rely on REACH for the hazard information, always rely on CLP to determine hazards and often rely on REACH for risk management. REACH therefore interfaces with most of the EU's chemicals legislation, whereas most chemicals legislation depends on the CLP classification.

## The objectives of the legislation

The main aim of the four regulations and the directive<sup>2</sup> is to ensure a high level of protection of human health and the environment, as well as the smooth functioning of the EU internal market.

There are numerous factors determining the competitiveness and innovation of the EU industry. One contributing factor is the chemicals legislation. REACH and WFD aim explicitly to enhance competitiveness. They establish a harmonised standard which ensures a high level of protection for all products on the EU market. Through harmonised legal requirements they also internalise the cost of meeting the norm thus eliminating the competitive advantage arising from undercutting the standard. The BPR, although not as an explicit aim, contributes similarly to competitiveness. CLP contributes by establishing transparency between substances and mixtures regarding their hazards. On innovation, REACH and BPR establish legal obligations and incentives as to which substances need to be substituted. This gives the needed long term legal certainty and clear direction for increased investment in innovation.

REACH and BPR are underpinned by the precautionary principle. The precautionary principle can be invoked by the European Commission, together with the Member States, when taking risk management decisions based on ECHA's opinions.

Finally, REACH establishes the objective of promoting alternatives to testing of vertebrate animals, which is relevant in the generation of hazard information and sharing of available information amongst operators – applied as well under BPR and CLP. ECHA therefore contributes to the development of alternative methods, and requires testing using vertebrate animals to ensure a high level of protection of human health or the environment, where the same information cannot be achieved through the use of alternative methods.

## ECHA's strategic outlook - Anticipating challenging times ahead

During the time period 2019 – 2023, the EU will take significant decisions and agree on key aspects of its overall future political direction. To determine the political direction of the EU's chemicals policies, the Commission finalised a series of activities assessing these policies against the political needs, in particular:

- An in-depth evaluation of REACH under the Better Regulation Programme<sup>3</sup>;
- A fitness check under the Better Regulation Programme of all chemicals legislation, including Biocides and CLP<sup>4</sup>;
- An assessment of the interface between chemicals, product and waste legislation under the Circular Economy Action Plan<sup>5</sup>;
- The development of a non-toxic environment strategy<sup>6</sup>.

In line with the conclusions of the evaluation of REACH, ECHA expects the political discussion and the results of the other assessments to conclude that the overall EU regulatory system for chemical safety must increase efficiencies in the current work, increase integration and improve consistency of the EU regulatory system and improve transparency. The Agency supports this view, shares the findings of the evaluation and consequently sees the need to focus on compliance of dossiers with direct effect on ECHA's priority areas of work in the years to come (See Box 2).

Furthermore, the UK will leave the EU in 2019 [with no clarity currently on the future relations between the EU and the UK or on any possible transitional agreement].

<sup>&</sup>lt;sup>2</sup> REACH, CLP, BPR, PIC Regulation and Waste Framework Directive.

<sup>&</sup>lt;sup>3</sup> <u>http://ec.europa.eu/smart-regulation/roadmaps/docs/2017 env 005 reach refit en.pdf</u>.

<sup>&</sup>lt;sup>4</sup> <u>http://ec.europa.eu/environment/chemicals/better\_regulation/pdf/roadmap\_chemicals\_fc.pdf</u>.

<sup>&</sup>lt;sup>5</sup> <u>http://ec.europa.eu/smart-regulation/roadmaps/docs/plan\_2016\_116\_cpw\_en.pdf</u>.

<sup>&</sup>lt;sup>6</sup> See the 7<sup>th</sup> Environmental Action Programme (EAP) at <u>http://ec.europa.eu/environment/action-programme/</u>.

Parallel to these political processes ECHA has to find a sustainable balance between its regulatory role, transparency, stakeholder engagement and its independence. In this area, the public trust in EU institutions and Agencies, and in evidence based decision making is at stake, which creates high demands for ECHA in its communication towards and engagement with the stakeholders and public.

ECHA will need to proactively and regularly adapt to these, and any new, challenges. The Unionwide discussions on the new Multi-annual Financial Framework (MFF), running from 2021 to 2027, will set the human and financial framework for ECHA to implement its current mandate and meet these challenges.

Looking at ECHA's activities, the year 2019 marks a new era in chemicals management after the last REACH registration deadline and the beginning of a uniform EU system for market access for chemicals. 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's competences and impact

Since its establishment in 2007 to implement REACH, ECHA has regularly taken on and integrated new tasks: CLP in 2008, BPR in 2013, PIC in 2014, ad-hoc tasks on persistent organic pollutants (POPs) from 2015 to 2018, ad-hoc tasks for building the EU observatory on nanomaterial from 2016 to 2018, ad-hoc tasks on occupational safety and health (OSH) in 2017 and 2018 and finally a specific task under the WFD in 2018. ECHA has thereby built up competences inter alia on:

- 1. *Information*: Tools for information submission, storage, access and web-publication, operational guidance and helpdesks (REACH, CLP, BPR and PIC) and data processing and analytics tools (REACH, CLP and BPR).
- Assessment: Information generation (REACH and BPR), hazard assessment and hazard identification (REACH, CLP and BPR), identification of safe levels (REACH, BPR and OSH), exposure assessment and risk characterisation (REACH and BPR), efficacy assessment (BPR).
- 3. *Management*: Authority's (REACH, BPR and PIC) or industries (REACH and BPR) assessment of risk leading to the determination of risk management needs, including assessment of alternative substances or technologies.
- 4. *Impacts*: Authority's (REACH and BPR) or industries (REACH) assessment of efficacy and the socio-economic impacts of risk management.
- 5. Administration: Administering an independent EU Agency.
- 6. *Taking on Tasks*: New technical, scientific and administrative tasks using its competences.

ECHA has improved synergies and consistency between the pieces of legislation it implements. There are numerous interfaces and interdependences: REACH, BPR, OSH and POPs use the outcome of CLP; POPs use the outcome of REACH and vice versa; and PIC uses of the outcome of BPR, POPs and REACH. The IT systems and methodologies applied in REACH, CLP and Biocides have also been made more consistent.

In 2018, ECHA obtained for the last REACH registration deadline information for all existing substances brought on the EU market between 1 and 100 tonnes per year. This closes the transitional period since the entry into force of REACH. ECHA now holds the knowledge of all chemicals on the EU market above 1 tonne, including all chemicals newly introduced to the EU market, bringing our knowledge on industrial chemicals close to that on Biocides. This marks an entirely new phase of understanding and ability to react to the challenges of regulating chemicals compared to the past, where only a limited number of substances were well characterised and regulated compared to the many chemicals that were on the market already at that time. However, the experience from the first ten years in operation and ECHA's ongoing regulatory work, confirmed by the Commission evaluation of REACH, shows that the level of compliance with the requirements established by the EU legislator is not at the expected level. Nevertheless, having obtained information on all chemicals in the EU is an asset which provides for a unique opportunity to comprehensively and systematically identify all chemicals needing regulatory action – serving not only REACH, CLP, BPR and PIC, but also all the other legislation linked to chemicals safety.

In the past 10 years, ECHA has been instrumental in implementing REACH, CLP, BPR and PIC. Exemplified by the conclusion of the European Commission's evaluation of REACH, the EU citizen and environment are safer now than 10 years ago. ECHA adds value through improving synergies, consistency and efficiencies in implementing EU chemicals legislation, reduces costs and improves predictability. At the same time, ECHA aims to be transparent, leading to trustworthy scientific decision making. 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 benefit from the improved safety of chemicals. ECHA's impact is enabled by its competences, a strong regulatory framework and a strong cooperation with the European Commission, Member State national authorities and all its stakeholders.

## **ECHA Today**

Today ECHA manages the implementation of the following legislation:

**REACH** requires companies to ensure that substances manufactured or imported above 1 tonne per year are used safely. They must collect or generate specified chemical safety information, use this information to develop and apply safe use instructions and communicate these instructions to users of the substances. Finally, to gain EU market access, they must document this in a registration dossier and submit it to ECHA. In order to promote the harmonised interpretation 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. ECHA, working with the Member State competent authorities, evaluates if the safety information collected by industry is sufficient and, if not, requires additional information.

All companies – manufacturing, importing or using substances, also below 1 tonne – must assess their substances against the **CLP** classification criteria using all available chemical safety information and then package the chemical and label the package accordingly. This obligation ensures that safety information, e.g., 'Causes Serious Eye Irritation', 'Keep out of reach of children', is available to workers and consumers. The company must submit the classification to ECHA's publicly available Classification and Labelling Inventory.

Under **CLP**, a Member State can propose to harmonise the classification and labelling where this is needed, and it is also obligatory for plant protection products and biocides. Similarly under **REACH**, a Member State, ECHA on request of the European Commission, or ECHA on its own initiative, can propose restrictions, i.e. a ban or a restriction of the use of the substance, if they find that there are risks that need to be addressed on a Union-wide basis. ECHA assesses the scientific and technical aspects of the proposal and based on it, the European Commission, together with the Member States, takes the final decision.

**REACH** Authorisation checks that substances of very high concern are used safely and are progressively replaced by suitable alternatives. Substances of very high concern are subject to authorisation when the European Commission and the Member States includes them in the Authorisation List, based on a proposal from ECHA. These substances cannot be placed on the market for a use after a given date, unless an authorisation is granted for the specific use. ECHA assesses the scientific and technical aspects of the authorisation application and based on it, the European Commission, together with the Member States, takes the final decision.

The **BPR** establishes an authorisation system for the placing on the market and use of biocidal products. ECHA coordinates the Member States' evaluation of active substances and the Union wide authorisation of biocidal products, containing approved active substances. ECHA assesses the scientific and technical aspects of active substance approvals and Union authorisation applications and based on this assessment, the European Commission, together with the Member States, approves or refuses the active substance or the EU authorisation. ECHA is also the central hub for all national authorisation applications, establishment of technical equivalence, assessments of applications for alternative suppliers and resolution of data sharing disputes.

**PIC** implements the UN 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.PIC thereby contributes to the global efforts on chemical safety.

Under the **WFD**, ECHA must develop and operate a database, which tracks the presence of substances of very high concern in articles throughout the supply-chain.

**In addition**, for all legislation, ECHA disseminates information, prepares guidance, develops tailored IT systems, and promotes harmonised enforcement actions by Member States.

## **ECHA Tomorrow**

The European Commission's evaluation of **REACH**<sup>7</sup> concluded that REACH is effective, but not efficient and its implementation is lagging behind in meeting its political objectives. Indeed, there are gaps and severe shortcomings in the chemical safety information submitted by industry, especially with regards to long-term effects on human health and the environment and in relation to the uses and exposure. ECHA's assessment of the past and current situation on the level of compliance in registration dossiers with information requirements has been and is in line with the findings of the evaluation by the Commission indicating the absolute need for action. 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. Improvement and simplification are also needed in relation to the extended Safety Data Sheets, evaluation, authorisation and restrictions. The issues requiring most urgent action are: acceleration of evaluation, simplification of the application for authorisation process, ensuring a level playing field with non-EU companies through effective restrictions and enforcement and clarifying the interface of REACH and other EU legislation, in particular that on Occupational Safety and Health (OSH) and on waste.

Consequently ECHA's, the Member States' and the European Commission's activities implementing **REACH** and **CLP** will need, on all fronts, to be accelerated. The evaluation activity must continue at higher intensity longer than planned and harmonised classification and labelling, restrictions and authorisation activities must accelerate. Registration activities will no longer have big peaks, but as of 2018 all substances above 1 tonne are in REACH, so there will be a larger steady stream of updates and new registrations than before 2018. Total resources will therefore need to be maintained, rather than decreased during the next Multi-annual Financial Framework.

In line with sustained efforts needed for the REACH processes, and to meet the political objectives of **BPR**, ECHA will need to work with the Member States to increase efficiencies. Biocides activities must intensify, using the accumulation of experience and competences to ensure that by 2024 only fit-for-purpose biocidal active substances remain on the EU market. This provides the basis for the authorisation of all biocidal products by the Member States and the Commission.

For **PIC**, a high level of efficiency has been achieved already. The expected continued increase in the 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.

<sup>&</sup>lt;sup>7</sup> https://ec.europa.eu/growth/sectors/chemicals/reach/review\_en.

## II MULTI-ANNUAL PROGRAMMING 2019 – 2023

## 1. Multi-annual priorities

With the aim to keep serving the Union in an adequate and efficient manner, ECHA has set out new strategic priorities. They take ECHA's role as their basis, build on ECHA's competences and achieved impact, recognise the central importance of the legislation ECHA implements in the EU regulatory system, and attempt to anticipate the challenges ahead. ECHA expects that through the new strategic priorities it will be able to better contribute in meeting the policy objectives of the legislation and address its remaining challenges, including the outcome of the Commission's REACH Review<sup>8</sup>. The following section includes a detailed description of the scope and purpose of ECHA's new strategic priorities.

First and foremost, ECHA, together with its partners, will use its competences and comprehensive knowledge of chemicals on the EU market to identify groups of substances of concern, decide which regulatory action is needed and take the necessary action under REACH, BPR and CLP, or under other relevant legislation, such as OSH (Strategic Priority 1). Strategic priority 2 takes the knowledge coming from Strategic Priority 1, uses the legislative obligations of industry set out in REACH, CLP, BPR, PIC and WFD and ECHA's mandate therein, and aims to improve the knowledge and capacities in industry to take action before ECHA does. Finally, Strategic Priority 3 takes the knowledge coming from Strategic Priority 1, uses it within ECHA's mandate to improve the knowledge and integration within the EU chemicals regulatory system and towards the international work on chemicals management.

ECHA will thereby be ready to continue its 10 year track record on delivering on its core tasks while, should the EU decide to do so, take on additional implementing tasks from more pieces of legislation<sup>9</sup>, thus establishing synergies and consistency between various pieces of legislation.

In implementing the Strategic Priorities, ECHA will build on its competences, knowledge, and experience, and improve its collaboration with the Member States' competent authorities, other national and EU Agencies and its stakeholders, remaining focused on delivering sound science-based opinions, decisions and advice. ECHA will also keep 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.

## **2. Strategic priorities**

ECHA will pursue the three strategic priorities with their respective objectives. The strategic priorities with their respective objectives come along with performance indicators that will allow to monitor how much progress against the strategic priority will have been made. Furthermore, each strategic priority contains areas of operation that are implemented by specific actions and outputs as stipulated in the annual work programme of the Agency monitored through specific indicators (see section III below).

Strategic priority	Objective	Performance indicator(s)
1. Identification and risk management of substances of concern	[1] Accelerate data generation and intensify identification of substances of concern	1. Screening and pre-check of substances with assignment of the particular substances or group to any of the three priority
	[2] Accelerate regulatory action on substances of concern	groups:

<sup>&</sup>lt;sup>9</sup> 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.

		<ul> <li>High priority for risk management</li> <li>Need for data generation</li> <li>Low priority for regulatory action</li> </ul> Indicators based on measuring progress in the number of the substances in each of the three priority groups. 2. Number of conclusions on the need for information generation for high priority substances. 3. Number of substances for which regulatory risk management has been initiated.
2. Safe and sustainable use of chemicals by industry	[3] Effective communication up and down the supply chain becomes mainstream	Qualitative measurement with use of sub-indicators where possible. This may include improved methodologies for linking submission tools to those for chemical safety, developed standardised tools and formats for the EU supply-chain communication and for Substances in Articles, broadened scope of the CSA methodologies, etc.
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.	Qualitative assessment of the milestones may include areas/legislation where ECHA has initiated contact and achieved a successful interaction/collaboration with the responsible authorities, synergies when implementing new assigned tasks, intensified cooperation with international partners or relevant pieces of new/existing legislation being implemented by the Agency over time, etc.

Progress in achieving each of these priorities is monitored via the performance management system of the Agency. ECHA's aim and commitment towards the priorities are not self-standing but have to be seen in light of the 2030 Agenda for Sustainable Development<sup>10</sup>. Indeed, ECHA's contribution to the 2030 Agenda honours the commitment of the EU and its Member States to reduce the negative impacts of urban activities and of chemicals which are hazardous for human health and the environment, including through the environmentally sound management and safe use of chemicals, the reduction and recycling of waste. It is already clear that the full achievement of this work will take considerable time and effort. The 2030 Agenda for Sustainable Development

<sup>&</sup>lt;sup>10</sup> <u>https://sustainabledevelopment.un.org/post2015/transformingourworld.</u>

functions as the guiding goal for any regulatory work which the Agency and its partners contribute to.

By putting the three strategic priorities into practice by 2023 – the duration of ECHA's Strategic Plan – ECHA intends to demonstrate that progress has been made towards the objectives of the legislation ECHA implements, the objectives of the overall EU regulatory system and the Sustainable Development Goals.

In the context of ECHA's Strategic Plan for the next years, and to make as much progress as possible on it, ECHA considers that putting the 2030 Agenda for Sustainable Development into practice 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 10 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) 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, CLP and BPR 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, CLP and BPR, the information, methods and tools developed are increasingly recognised and used worldwide.
  - c) Companies experience firm, and fair enforcement, focusing on ensuring the safe use of hazardous chemicals and fostering a level playing field.

## **1. Identification and risk management of substances of concern**

ECHA aims to have addressed all REACH substances of concern above 10 tonnes by 2030 and have completed the BPR active substance review programme by 2024 which forms the basis for having all biocidal products on the EU market licensed under BPR by 2030. Addressing determinina whether means the substances are of concern, which further information is needed or which regulatory action is required.

To achieve this aim ECHA, together with the European Commission and the Member State Competent Authorities, will use the knowledge of all REACH substances on the EU market and all BPR substances, identify groups to of substances of concern, identify which regulatory action is needed and subject them to the action. ECHA, the European Commission and the Member States must also improve efficiencies, including those related to enforcement, as requested for REACH and CLP under the European Commission's evaluation of REACH and the slower than expected assessment of active substances. Extra efforts are needed on REACH evaluation and BPR active substance approvals, as



this first step determines how fast regulatory action can be taken.

For REACH, CLP and BPR, 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.

## Areas of Operation for Strategic Priority 1

## **1.** Prioritise groups of substances

- **REACH**, **CLP** and **BPR**: Use all relevant data sources, including new approach methodologies, to group all substances.
- **REACH and CLP:** ECHA, the European Commission and Member State Competent Authorities prioritise groups of substances for concerted regulatory action and identify the required regulatory actions<sup>11</sup>, considering also the need for a level playing field for all parties involved.

## 2. Concerted regulatory action

- **REACH** and **CLP**: Execute the required regulatory actions for prioritised groups of substances using evaluation, harmonised classification and labelling, restrictions and authorisation in an integrated manner.<sup>12</sup>
- **BPR** and **PIC**: Execute the required regulatory actions in an integrated manner.
- **REACH**, **CLP** and **BPR**: ECHA, the European Commission and the Member State Competent Authorities increase efficiency of the regulatory decision-making and increase transparency, by e.g., communicating explicitly on the progress made in taking regulatory action.

<sup>&</sup>lt;sup>11</sup> See Action 13(2) of the REACH Review.

<sup>&</sup>lt;sup>12</sup> See Actions 2, 7, 8, 9, 10, 11 and Action 13(2) of the REACH Review.

## 3. Induce faster action by industry

- **REACH**, **CLP**, **BPR** and **PIC**: Provide guidance, advice and assistance, with special attention to the needs of SMEs, including promoting best proactive behaviour.
- **REACH** and **CLP**: Identify and apply measures such as legal obligations, incentives or targeted enforcement for continued updating of data by industry for improving the information on their substances and the way they document and communicate the chemical safety.
- **REACH** and **CLP**: Explore how ECHA could, prior to concerted regulatory action and without deviating from its role, give advice to registrants for specific groups of substances.

## 2. Safe and sustainable use of chemicals by industry

ECHA is required by REACH and BPR, and now also by its new tasks under the WFD, to work on substances in articles. It must make available its information on chemicals of concern used for and present in articles and in particular assess this knowledge to prioritise its actions. Through investing on better knowledge on the presence and fate of substances in the service–life of articles, including those imported into the EU, and waste stages, ECHA can make a significant contribution to moving towards non-toxic material cycles and making the EU economy more circular.

Companies comply with their responsibility for the safe manufacturing and use of chemicals on their own, in mixtures and in articles by characterising the risks, communicating up and down the supply chain on how to handle harmful chemicals safely, by implementing appropriate risk management measures and substituting from harmful to safer chemicals.

A significant improvement in compliance is achieved if more companies make full use of the tools, templates and guidance that ECHA has developed in collaboration with industry associations. ECHA will intensify its support and information activities, thus helping companies to improve their safety advice, which will also help them with their obligations under environmental, product and in particular worker protection legislation.

Whereas sustainability has become an important element of corporate agendas, chemicals management is generally seen to be connected more to regulatory compliance. Nevertheless, many companies focus on establishing safer production processes and substituting substances of concern as part of their business models, responding also to an increasing demand from retailers and consumers. ECHA will cooperate with interested stakeholders to increase the skill base of companies in substitution towards safer substances and sustainable portfolio management.

The guiding principle of REACH and BPR to substitute harmful substances 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.

## Areas of Operation for Strategic Priority 2

## 1. Strengthen the knowledge base on substances in articles

- REACH: Support industry in generating chemicals safety assessments and associated exposure assessments that adequately cover the full article service life, waste and recycling stages.
- **REACH and WFD:** Develop standardised tools and formats to track substances of concern throughout the supply-chain. Provide access to relevant information to waste operators and consumers.
- **REACH:** Improve the availability of relevant information on the presence of substances entering the EU, in particular through engaging in collaborations with pro-active private and public initiatives aimed at avoiding substances of concern in imported goods.
- **REACH:** Develop and implement approaches to identify priority materials that would require further regulatory actions and define the most appropriate EU regulatory risk management measure.

## 2. Support to substitution and sustainable use of chemicals

- **REACH:** Make available data from registration, classification and risk management to support sustainable substitution. Support associated tools (e.g. QSAR Toolbox).<sup>13</sup>
- REACH, BPR: Support capacity building in companies and Member States, in particular through the development of networks that can coordinate and help advancing the practice of substitution. Promote carrying out analyses of alternatives to substances of concern – through showing concrete examples, as appropriate.<sup>14</sup>
- **REACH:** Explore ways in which companies can better link good chemicals management (including compliant registration dossiers) to their integrated corporate sustainability strategies and goals.

## 3. Improve supply chain communication

- REACH: Facilitate that downstream users receive more consistent and useful safety advice from their suppliers through the (extended) safety data sheets, covering the full article service-life and waste stages. Create synergies by connecting this advice to industry's obligations under occupational safety and health legislation, the control of environmental emissions and product safety legislation.<sup>15</sup>
- **REACH:** Identify the barriers to the more comprehensive uptake by industry of supply chain communication related tools and methodologies and initiate further actions to overcome these.
- **REACH:** Support the further development of the exposure assessment 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**

ECHA aims to improve the consistency and integration of the EU regulatory system on chemicals safety. The two-way interfaces and interdependencies of REACH, CLP and BPR with other pieces of legislation on chemicals safety have been explained previously (see p. 4). ECHA also aims to improve consistency and integration between the legislation ECHA implements and the implementation of the international agenda on chemicals management.

ECHA must therefore coordinate and aim to converge in the implementation of ECHA's legislation with the implementation of other legislation and the international agenda, in cooperation with other EU agencies, national authorities, and international partners.

Over the last 10 years ECHA's information, knowledge and competences have been increasingly used to support the implementation of other pieces of legislation and policy areas related to the safe use of chemicals. As this improves consistency between the legislation ECHA implements and creates synergies and cost savings, this is continuing with the European Commission proposing ECHA to take on implementation tasks on POPs. ECHA therefore expects this to continue with other new responsibilities in the years to come. This will require a request from the Commission to carry out certain tasks or the extension of ECHA's legal mandate, accompanied by the necessary resources.

Creating synergies, consistency and efficiencies will help public authorities at national and EU level as resources are scarce. But it will also help industry and the citizen. For example enabling safety information and data to be provided in a manner that allows companies to use it to fulfil multiple regulatory needs beyond that implemented by ECHA reduces costs, increases predictability and efficiency.

<sup>&</sup>lt;sup>13</sup> See Action 5 of the REACH Review.

<sup>&</sup>lt;sup>14</sup> This links to Action 11 of the REACH Review. (using Art 69(2) early) – Analyses of alternatives is one of the key issues in this.

 $<sup>^{\</sup>rm 15}$  See Action 3(2) of the REACH Review.

Similar gains exist at the international level. By influencing and aligning with international work consistency and synergies increase. In addition, ECHA will participate in technical assistance and capacity building activities on sound management of chemicals in developing countries.

## Areas of Operation for Strategic Priority 3

- 1. Consistency and integration of the EU regulatory system for chemicals safety
  - **REACH**, **CLP**, **BPR**, **PIC** and **WFD**: Co-ordinate and aim to converge the implementation of the ECHA legislation with other legislation to achieve consistency and synergies. This includes co-ordination with EU Agencies implementing other, related legislation relevant within the EU regulatory system for chemicals safety.
  - Where new tasks are assigned to ECHA and resources are made available, ensure successful integration of the tasks, monitor and report on the implementation, including how the benefits and synergies are realised.

## 2. Foster synergies at international level

- **REACH**, **CLP**, **BPR**, **PIC** and **WFD**: Contribute to the OECD chemicals programme and to main international instruments (SAICM<sup>16</sup> and the global chemical conventions) with the objective of developing OECD standards and tools that can be directly used in the EU and exchanging implementation experiences.
- **REACH**, **CLP**, **BPR**, **PIC** and **WFD**: Intensify cooperation with international partners, sharing EU implementation experiences, learn from other international chemicals management programmes and provide capacity building support for countries that are developing their chemicals management schemes.

## 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 Strategic Plan.

## Enabling areas of operation

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

- Develop and strengthen sufficient scientific, technical and administrative competence for current responsibilities and future needs by ensuring robust processes for people and resource management.
- Adapt ECHA's communications to a fast changing environment.
- Foster a culture of flexibility and adaptability that supports agile internal deployment and mobility within a dynamic collaborative organisational structure.

<sup>&</sup>lt;sup>16</sup> Strategic Approach to International Chemicals Management.

## **2. Continuous investment in IT and data to deliver ECHA's mandate and improve efficiency**

- Further develop ECHA's IT architecture of tools and cloud services to support the implementation of the strategic priorities 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.
- Enable regulatory assessors and decision makers to use ECHAs data, promote its use to third parties via an easy-to-use access to the underlying information, and via development of data analytics and intelligence.
- Analyse what strategic opportunities the implementation of the EU digital agenda can provide, and how ECHA can contribute to it.

## 3. Sustainable and flexible finance and governance structures

• Examine, with the European Commission, options and the best way to ensure sustainable income for ECHA in a context of reduced own fee income and to smoothen the annual income variations.