

Annual Report 2019 - Executive summary



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This is an extract of ECHA's Annual Report 2019.

This document covers the Foreword and the Executive summary of the report.

The complete report is available in English at:

echa.europa.eu/about-us/the-way-we-work/plans-and-reports

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Foreword

ECHA commenced the implementation of its five-year Strategic Plan in 2019 with a focus on its core regulatory processes, maximising its impact and laying the groundwork for its long-term future.

To support this, we restructured the Agency at the beginning of the year bringing together and aligning staff competencies and operational tasks to capitalise on efficiency gains and make our work more impactful. As a result, the Agency is operating with increased levels of cooperation and staff engagement resulting in real and substantial progress in the work we do with our partners to ensure chemicals are used safely.

The more than 300 full compliance checks carried out last year exemplifies the efficiencies we have gained by prioritising and simplifying decision making. This is an area that we will continue to prioritise in the coming years: checking the extent to which registrants submit data that meets the information requirements is necessary to conclude whether substances are safe or of concern for human health or the environment and to initiate risk management measures where needed.

This work follows up on the second REACH Review by the European Commission, and together, we have set up an ambitious Joint Evaluation Action Plan. The plan foresees that, by 2027, the Agency will have screened all registrations between 1 and 100 tonnes submitted by the final registration deadline, and that the compliance of all substances where data gaps prevent us from concluding on possible concerns will have been checked.

For substances of very high concern, the authorisation process is an important and impactful tool for managing risks. In 2019, we received guidance on the authorisation process from the General Court and followed up on feedback from our stakeholders and the European Parliament. The Management Board played an active role in supporting and implementing a range of improvement actions. As a result, there are now revised formats on how ECHA's committees should present their opinions, with the aim of making them more concise and consistent.

For biocides, we developed an action plan to proactively re-accelerate the Review Programme. The plan proposes to prioritise substances, provide support to Member States, and streamline assessments and peer reviews.

ECHA also made significant progress in taking on new tasks: developing a database for substances of very high concern in articles, getting ready to launch an online service that gives companies an overview of EU legislation relevant to their substances (EUCLEF), and preparing to assess substances that come into contact with drinking water.



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Bjorn HANSEN
Executive Director



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For ECHA to deliver on its growing legal mandate and its vision there is a need to identify and assess upfront what resource requirements are needed to ensure that the Agency has the means to perform all new tasks.

Sharon McGUINNESS

Chair of the Management Board

The seamless integration of these new legislative mandates and tasks into the Agency's growing portfolio is encouraging and shows that ECHA is delivering on its 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.

However, for ECHA to deliver on its growing legal mandate and its vision there is a need to identify and assess upfront what resource requirements are needed to ensure that the Agency has the means to perform all new tasks.

In the mid-term, the next Multi-Annual Financial Framework of the EU and the remaining uncertainty about the financial implications of the UK's withdrawal need our attention.

With our new organisation and committed staff, we believe we are prepared for the coming years. The political agenda of the EU, more explicitly the Commission's Green Deal and upcoming Chemicals Strategy are areas that ECHA can and will contribute and add value to – based on what we have achieved not just in 2019 but over the past 12 years.

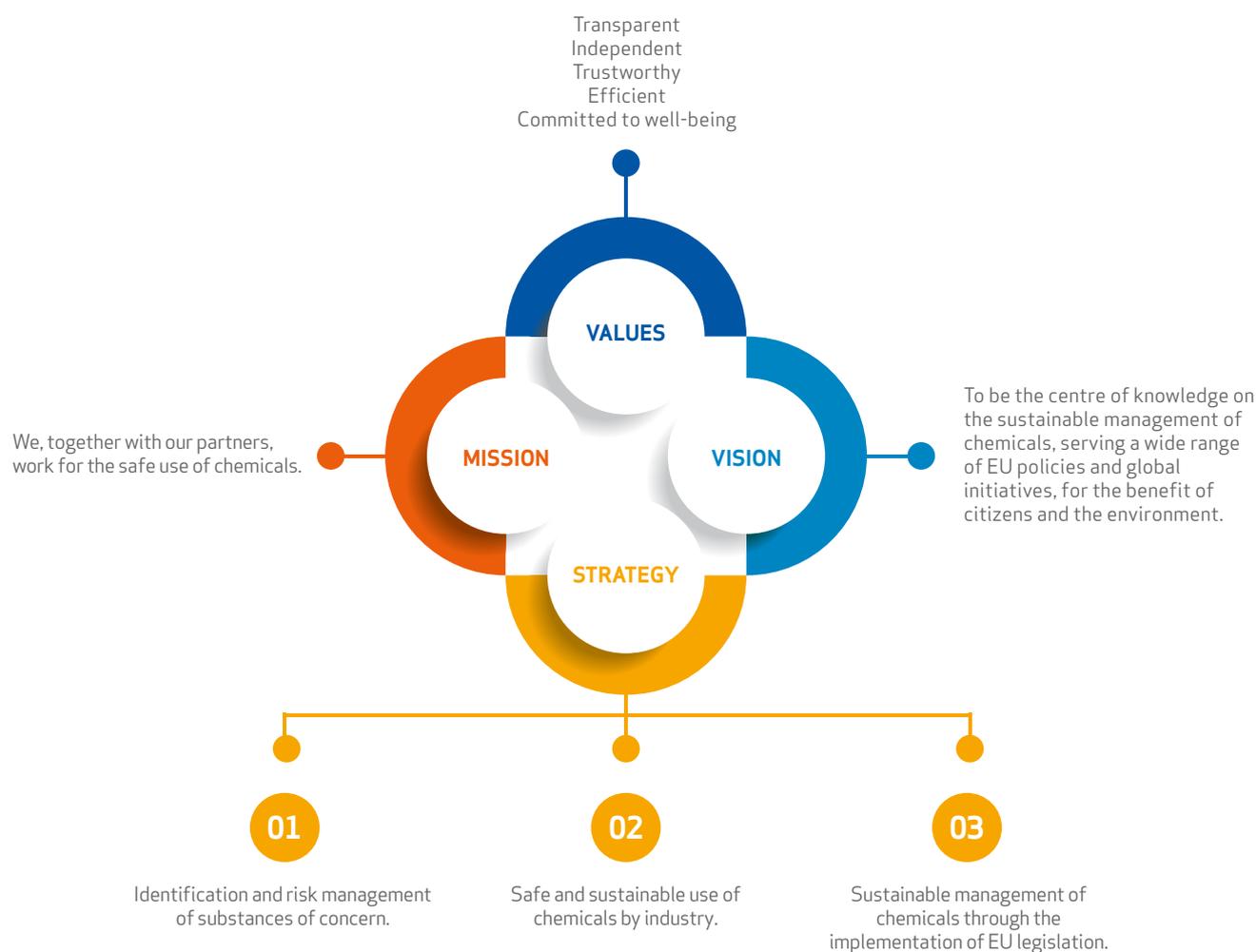


Executive summary

2019 marked the start of new political priorities with the Green Deal for Europe, the growth strategy for Europe, under the von der Leyen Commission, the start of ECHA's five-year strategic plan for improving chemical safety, preparations for the move to new premises for the Agency and the uncertainty for ECHA's stakeholders related to the withdrawal of the UK from the EU.

With valuable input from the second REACH Review¹, we have focused our priorities on where they matter most for protecting human health and preventing damage to the environment. This shaped ECHA's **new strategic plan for 2019-2023** with its three strategic priorities enabled by staff competencies and the data held by the Agency.

FIGURE 1: ECHA mission, vision, values



Under the first priority, we implement our tasks, integrating them into our work and doing so consistently. Under the second, we use our tasks to foster safer and more sustainable use of chemicals by industry. And, under the third, we ensure the consistency of our tasks with that of other EU chemicals legislation and provide scientific and technical support to international activities. Achievements in all three areas support progress towards the United Nations' sustainable development goals².

1 Commission General Report on the operation of REACH and review of certain elements, COM(2018) 116 final

2 <https://www.un.org/sustainabledevelopment/sustainable-development-goals>

They show:

- a robust baseline in identifying which substances require further work to manage the risks associated with them;
- substances for which we need more information;
- how industry is taking steps forward to ensure safe and sustainable use of chemicals; and
- where the Agency has contributed to a higher level of coherence for EU chemicals legislation.

Our reorganisation took effect in 2019 bringing processes closer together, capitalising on efficiency gains, and enabling ECHA to be more impactful³. With this, ECHA has proven to be agile and capable of undertaking major significant organisational changes. With the limited resources available to the Agency, we had to shift resources to priority work, mostly to identifying and managing the risks of substances of concern (strategic priority 1), meaning that we had fewer resources to allocate to other priority areas.

Results on strategic priorities

1. Identification and risk management of substances of concern

ECHA's screening and prioritisation work for over 21 000 substances⁴ shows good progress towards acceleration of data generation, identification of and regulatory action on chemicals of concern for human health or the environment. As of 2020, we will be able to compare the results and report on progress made with the figures in 2019 as a baseline.

The substances in the higher tonnage bands that are not yet assigned will be allocated to a specific priority group based on whether they are of priority for regulatory risk management; currently of low priority for further regulatory action; or need more data for a judgement to be made. Where further data is required, substances will undergo dossier or substance evaluation. Currently, there are around 1 500 substances registered above 100 tonnes per year that need more data before authorities can allocate them to a group⁵.

During 2019, eight more substances were identified and included in the Candidate List of substances for eventual inclusion in the Authorisation List. ECHA also recommended 18 substances for the Commission to include in the Authorisation List. With three proposals for restriction submitted by Member States and ECHA, and one restriction being adopted by the Commission, tangible progress has been made in improving risk management within the EU. Finally, the Committee for Risk Assessment (RAC) adopted 51 opinions on classification and labelling dossiers.

2. Safe and sustainable use of chemicals by industry

Establishing effective communication up and down the supply chain is critical to ensuring safe use of chemicals. ECHA has worked with key stakeholders to identify necessary improvements to the current system for providing fit-for-purpose safety information on hazardous substances and mixtures. Our work has been endorsed by key policy stakeholders and we are moving into the development phase. These changes also aim to help companies make use of this information to effectively meet their obligations under related occupational safety, health and environmental legislation.

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

The work towards this objective showed how ECHA's information, knowledge and competences on safe use of chemicals support the implementation of EU legislation. This resulted in synergies both internally when

3 See further: Workload drivers and performance indicators of ECHA's performance management model (Appendix I).

4 See further in the section 'Generating, monitoring and regulating information that matters on groups of chemicals of concern'.

5 ECHA's annual Integrated Regulatory Strategy report provides detailed information.

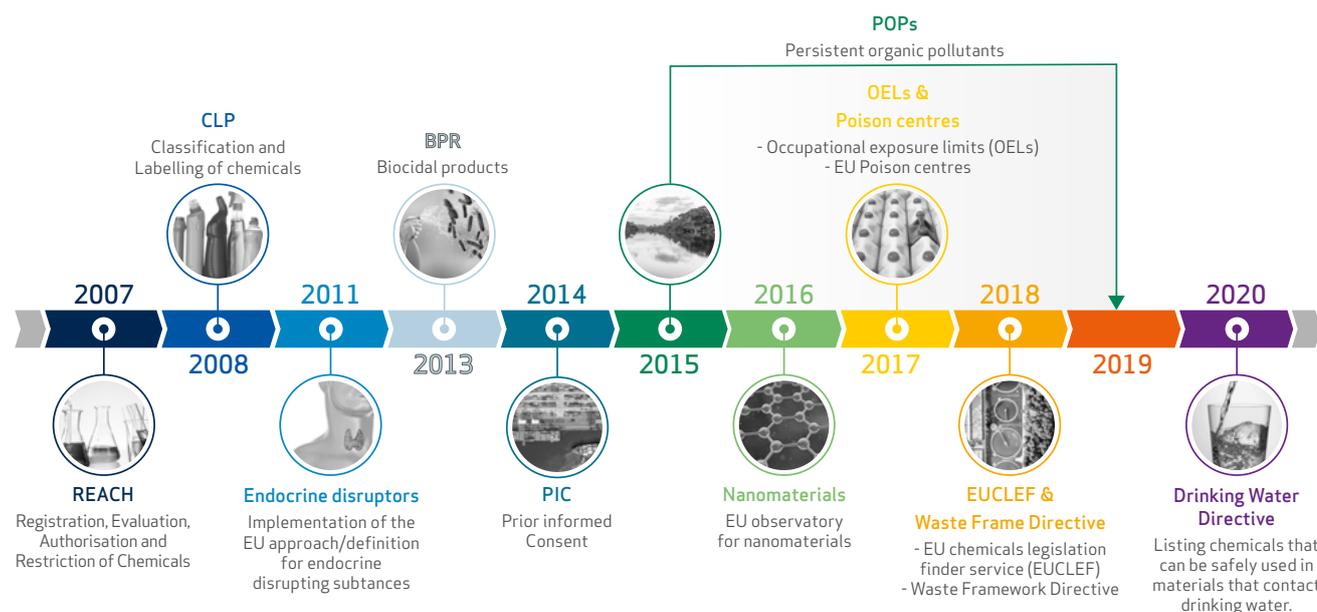
implementing new regulatory tasks and externally in cooperating with partners. By integrating new tasks into our portfolio, such as the SCIP database or preparations for assessing substances used in materials that may come into contact with drinking water, we showed that we have the competence and expertise to leverage the experience achieved through working with REACH, CLP, BPR, PIC and POPs. ECHA can apply its knowledge in new areas while re-using existing IT platforms, creating economies of scale. Long-term projects, such as sharing IUCLID-as-a-service with the European Food Safety Authority (EFSA) have started.

ECHA provided short-term support to the Consumers, Health, Agriculture and Food Executive Agency for data protection services and a peer review of common risks with the environmental agencies of the EU intensified cooperation and the exchange of good practices.

ECHA's outreach activities support sustainable chemicals management on a global level. We started developing a systematic approach for capacity building in third countries that helps them develop chemical management systems that can benefit from European chemicals management and risk assessment approaches.

Overall, we efficiently and effectively carried out our tasks under REACH, CLP, BPR, PIC and POPs together with new areas of work on poison centres, occupational exposure limits, the Waste Framework Directive, the EU Chemicals Legislation Finder and the EU Observatory on Nanomaterials.

FIGURE 2: ECHA's new areas of work during the years



For 2019, we have identified the following main **operational areas of achievements**:

- We have tackled non-compliant information on chemicals head on and recorded significant progress in generating needed hazard information. We have sped up dossier evaluation and put further measures in place to raise the percentage of the dossiers we check. We have conducted 50 % more full compliance checks⁶ of substances compared to 2018. We carried out 301 full checks covering 274 unique substances and 89 targeted checks on 64 unique substances. The full checks focused on the long-term effects of chemicals, with most

⁶ A full compliance check focuses on the most relevant information requirements for identifying substances of concern. Such checks cover as a minimum genotoxicity, repeated-dose toxicity, pre-natal developmental toxicity, reproduction toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation and bioaccumulation

carried out for properties that are important for health, such as mutagenicity and pre-natal developmental toxicity, and for the environment, such as long-term aquatic toxicity. With the Commission and ECHA's Joint Evaluation Action Plan⁷, we prepared the basis for obtaining information on substances where it is unclear whether they are safe or not.

- ECHA has taken steps to clarify how companies apply for authorisation to continue marketing and using their substances once they are listed in the Authorisation List. This includes explaining to applicants when they need to provide substitution plans and developing more consistent and concise opinions that define the boundaries of the scientific opinion making of ECHA's committees. We have started to put these opinion formats into practice and have adapted our working practices to allow a high number of authorisation applications to be processed, while ensuring proper control of risks to human health and the environment, and that substances of very high concern are substituted with safer alternatives.
- ECHA worked on four restrictions in 2019 that allow us to target how we are addressing risk to human health and the environment. There are two standout cases. Firstly, there may be smarter alternatives to microplastics that are intentionally added to some products and ultimately released into the environment in large volumes where they stay for a very long time. Secondly, the proposal to restrict hazardous chemicals in tattoo inks and permanent make-up aims to reduce the risk of cancer, as well as negative effects on fertility and skin irritation.
- In view of the delays at EU level on the implementation of the review programme for biocides active substances, ECHA has developed an action plan aiming to increase the number of dossiers submitted for peer review by the Member States. As part of this action plan, ECHA has increased the collaboration with Member States and provides them with concrete support to finalise their dossiers for decision making.

infobox

GREEN DEAL OF THE COMMISSION - ECHA'S SUPPORT

The Commission's Green Deal gives steer on how to contribute to improving air and water quality, to reduce risks of hazardous chemicals, industrial emissions, pesticides and endocrine disrupters plus a New Circular Economy Action Plan.

ECHA's knowledgebase and high quality, scientific and operational work as set out in its Strategic Plan provides a basis to support sustainable innovation that will contribute to the goals of the Green Deal. This can be in critical areas, such as circular economy, sustainability, climate change or ensuring a toxic-free environment.

In 2019, we set out how ECHA can strategically support the Commission for the Green Deal. We believe that our work can deliver synergies and efficiencies in scientific and technical tasks under various EU laws. This would not only simplify but also strengthen the legal framework by:

- bringing transparency to how the EU coherently legislates chemicals and product safety in Europe;
- evaluating the potential application of a 'one substance - one assessment' approach;
- assessing groups of similar chemicals to speed up risk management and add consistency; and
- establishing ECHA's scientific work as the basis for defining safe values for chemicals and protecting workers from cancer and other harmful effects.

ECHA can play a stronger role in promoting the competitiveness of European industry, by assuming a more robust stance on checking and controlling that chemical safety laws are followed and complied with at the EU's borders, for example, by sharing information with customs authorities.

⁷ https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en

- ECHA has formed a framework for on-boarding new tasks, such as the European Chemicals Legislation Finder and currently, for instance, the ad hoc tasks for occupational exposure limits. This framework takes into consideration how well it can do so based on existing capabilities, structures and how well new tasks can be integrated into ECHA's activities to support a more holistic approach for safer chemicals.
- The Management Board conducted a comprehensive review of its functioning and ways of working, to continue providing strategic direction and strong governance to the Agency.
- We revised the Integrated Management System Strategy and Framework to support the Agency to deliver on its strategic priorities in a more coherent way. The strategy sets high-level commitments that will direct the Agency in the coming years, as well as consolidating and integrating the different elements of ECHA's management system.

The new organisational structure introduced at the start of 2019 has increased our interconnectivity and facilitated more collaborative ways of working, shifting our focus to our existing competences in tasks where we have developed synergies over the past years. A significant amount of resources has been invested in analysing our structure and finding ways to improve it to better serve the needs of our stakeholders.

Since consumers are becoming more and more conscious of the effects that chemicals have on their everyday lives, we have developed our communications strategy to help us reach out to interested audiences and meet our stakeholders' needs with fact-based information in a relevant and easy-to-use language.

As a centre of knowledge on chemicals safety and relevant EU legislation, the strategy guides us on creating content that will be picked up by mainstream media and interested audiences, and multiplied, spreading awareness of the important work we undertake.

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