

General Report 2018 - Executive Summary



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This is an extract of ECHA's General Report 2018.

This document covers the Foreword, Legal mandate, ECHA's vision, mission and values and the Executive summary of the report.

The complete report is available in English at:

<https://echa.europa.eu/about-us/the-way-we-work/plans-and-reports>

Title: General Report 2018 - Executive Summary

Reference: ECHA-18-B-05-EN

ISBN: 978-92-9481-176-9

Cat. Number: ED-AR-19-001-EN-N

ISSN: 2467-3056

DOI: 10.2823/897174

Publ.date: April 2019

Language: EN

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Cover page © European Chemicals Agency

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General Report 2018 - Executive summary

2018 was a remarkable year for ECHA. The main developments covered in this general report will impact our work on the safe use of chemicals – today and for years to come.

As ECHA's new Executive Director Bjorn took charge of the Agency at the beginning of the year. The handover and transition went smoothly, allowing a quick induction into the complex system of ECHA's processes and structures. This was crucial ahead of the third REACH registration deadline in May, which completed the transitional regime for substances on the EU market. We now open a next chapter on the protection of human health and the environment against harmful chemicals. ECHA holds a wealth of information on chemicals. At the same time, we know that we still lack important safety information and we will need to work on this.

The Commission published the second review of the REACH Regulation in 2018. The Agency analysed all findings from the review and added the actions incumbent on it into its Work Programme 2019, as well as into its new five-year strategic plan, following a public consultation. The Management Board has provided valuable input for the drafting of this strategic plan, since the beginning of the process in 2016. The new strategic plan is based on ECHA's competences in scientific-regulatory work and IT. With its three strategic priorities, it focuses on ECHA's core regulatory tasks under REACH, CLP, BPR and PIC, as well as on its new tasks, such as the occupational exposure limits and the EU chemicals legislation finder. We are confident that it will be a compass for ECHA in the future. It will help us to navigate past the uncertainties today and overcome the challenges of the future – the new multiannual financial framework or the UK withdrawal from the EU, to name two.

We want the Agency to be prepared for the upcoming challenges, both externally, towards stakeholders' expectations, and internally. With this consideration, the Agency invested significant effort to analyse its structure and see how it can be improved to serve the new strategic plan best. The work and all the processes are now grouped around competences. We believe that this re-organisation will allow us to be more efficient in our work and take up new tasks in a more coherent way.

There are many more encouraging achievements in 2018 that the present report addresses, and we invite you to read it. The report also shows the direction of our further work – and we are very enthusiastic to address these challenges together with ECHA's staff and stakeholders.



“I found a mature and agile organisation that allowed me very rapidly to add my contribution to achieving the common goal of sustainable chemicals regulation.”

Bjorn Hansen
Executive Director

Bjorn Hansen
Executive Director

Sharon McGuinness
Chair of ECHA's Management Board

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)'.¹

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 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' (BPR).

The recast of the 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. In 2014, certain tasks related to PIC were transferred from the European Commission's Joint Research Centre (JRC) to ECHA. These legislative acts are applicable in all EU Member States (MSs) without the need for transposition into national law.

ECHA's mission, vision and values

ECHA's mission¹

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

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 and vision were renewed during 2018. The new mission and vision are effective as of January 2019.

Key achievements in 2018

Following the 10-year registration period, the end of which was marked by the successfully managed last REACH deadline in 2018, ECHA now has data on all registered substances on the EU market. Together with Member States, ECHA can now use its unique source of information on chemicals to determine which substances can be considered safe and which require further regulatory action. While the situation is significantly better than it was before REACH, it is still clear that the quality of information does not allow immediate conclusions to be made for many substances.

As such, ECHA will need to intensify its work on improving the level of compliance of the information submitted by industry. The valuable input from the European Commission's REACH Review² helped to focus ECHA's priorities where the Agency's work can have the greatest impact on protecting human health and the environment.

In developing and finalising a new strategic plan for 2019-2023, the Agency prepared for future challenges and to efficiently and effectively carry out tasks under REACH, CLP, the BPR and PIC together with work in new key areas including tasks related to poison centres, occupational exposure limits, the Waste Framework Directive, the EU Chemicals Legislation Finder and persistent organic pollutants.

OPERATIONS

- The **registration phase of REACH was completed** without causing market disruption. Companies received support for registering 28 357 dossiers and benefitted from enhanced support to prepare their registration dossiers. ECHA will look at ways to improve the level of compliance.
- Companies were able to submit their registrations by the **2018 deadline** using IT tools and support. ECHA now holds data on the most used chemicals on the EU market and can assess it together with the Member States.
- **Key data on chemicals was published**, including all the registration information submitted for the 2018 deadline, and the biocidal product assessment reports and summaries of product characteristics of authorised products. ECHA is taking steps to make further use of the data it has collected over the years.
- ECHA developed an approach to map the chemical space of substances registered under REACH to support achieving the aims of the **integrated regulatory strategy** and to increase transparency on how authorities address all substances on the EU market in a proportionate manner. This will help to achieve the World Summit on Sustainable Development 2020 goals.
- ECHA continued to focus on generating information required to clarify the long-term **effects of substances on human health and the environment**, and increased the efficiency of evaluation by addressing groups of substances. Single draft decisions are now addressed to all lead registrants of the substances in a given group. The Agency is preparing to address the lack of compliance as well as the concerns raised in the public discussions on this issue.
- ECHA was fully **transparent** to operators and stakeholders about the status of evaluation decisions through relevant updates published on the Agency's website.
- In close collaboration with Member States, chemically-related **substances registered above 100 tonnes per year were grouped** – contributing to forming a better understanding of the chemical universe and the implementation of effective and coherent regulatory action where needed.

² Commission General Report on the operation of REACH and review of certain elements, COM(2018) 116 final available at: https://ec.europa.eu/growth/sectors/chemicals/reach/review_en.

- 16 new substances were added to the **Candidate List**. Seven substances were recommended to be added to the **Authorisation List** due to the threat they pose to health and the environment. Preparations were made to take in the next wave of applications for authorisations.
- ECHA developed a record number of **restriction proposals**, some of which broke new ground, such as the proposal on microplastics.
- ECHA accelerated meaningful, informed and innovative **substitution** by improving access to its public database on chemicals, increasing the capacity of Member States and stakeholder to analyse alternatives, and enhancing networking opportunities.
- The trend for submitting **harmonised classification and labelling** dossiers has increased by approximately 50 %, mainly driven by submissions related to active substances in plant protection and biocidal products.
- The first set of tools for the harmonised notification of information on hazardous mixtures for **poison centres** were provided to industry and work progressed on the central notification portal for authorities.
- To speed up the **Biocides Review Programme**, ECHA started to provide earlier and increased support to Member States. The first Union authorisations were granted allowing companies to have their biocidal products authorised for the entire EU market with one application.
- Improved quality of regulatory information in export notifications made under PIC enabled non-EU authorities to make better-informed decisions.
- ECHA decided to proceed with building an **EU Chemicals Legislation Finder**, following the conclusions of the feasibility study conducted in the first phase of the project.
- The **EU Observatory for Nanomaterials** was further expanded with information on research and innovation.

GOVERNANCE

- A **new strategic plan** adopted by the Management Board and the **review of the organisational structure** helped the Agency prepare for future challenges. The new priorities, along with the new communications strategy under preparation, link ECHA's work closely to the UN sustainable development goals.
- ECHA's **new Executive Director** continued the solid communication streams and relationship with institutions, Member States and stakeholders of the departing Executive Director.
- **Committee's work** is successfully managed thanks to a continued high level of commitment and dedication of the members and Member State experts.
- Key enforcement projects coordinated by the **Forum** focused on obligations aimed at protecting consumers and workers, revealing that hazard information is mostly missing for chemicals sold online and that there are shortcomings in the safety information passed to workers.
- The **HelpNet** offered support so that companies could live up to their 2018 REACH registration obligations and submit their registration dossiers in time.
- The **Security Officers' Network** extended the security model for accessing ECHA's databases to individual experts involved in ECHA's committees.
- **Finance**: The mixed financing regime, a combination of fee income and EU balancing subsidy, proved particularly challenging in 2018. This was due to the unpredictability of the registration volumes stemming from the REACH registration deadline. It resulted in divergent outcomes – more fee income under REACH and less under the BPR than expected.
- A new **human resources strategy** was put in place to guide the direction of the Agency's HR development in the long term.
- The implementation of initiatives related to ECHA's **future building** progressed.