

Annual Report 2022 Executive Summary



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Executive summary

This Executive Summary provides an overview of our achievements and the challenges we faced in 2022. It summarises the information in the report, which follows the activity-based structure outlined in our Programming Document 2022-2025¹. We highlight our work's contribution to European Union (EU) priorities and share some of our key outputs from the year.

In 2022, we remained committed to fulfilling our strategic objectives and delivering on the planned activities specified in our Work Programme.

We made significant strides in identifying substances of concern that require regulatory measures, assessing around 2 000 substances across 61 groups. Overall, the Integrated Regulatory Strategy has led to around 75% of substances registered above 100 tonnes being assessed by the end of 2022, leaving around 1 000 of these high-tonnage substances still to be assessed.

This work enabled us to concentrate our compliance checks on substances where generating data would have the most impact. Once again, we exceeded our annual target of conducting 300 checks this year.

Five substances were identified as substances of very high concern and added to the Candidate List, bringing the total number of entries on the Candidate List to 224². As a result, suppliers must now communicate on their safe use, respond to consumer requests, and notify ECHA if their products contain any of these substances.

We also recommended that eight substances from the Candidate List fulfil the prioritisation criteria to be subject to authorisation requirements. If the Commission would decide to include them in the Authorisation List, companies will need to apply for authorisation to continue using the substances.

50 applications for authorisation and review reports were received for 66 uses. Our Committee for Risk Assessment (RAC) and the Committee for Socio-Economic Analysis (SEAC) adopted 36 opinions, which have been sent to the European Commission for decision making.

Following one of the actions of the Chemicals Strategy for Sustainability, the European Commission has published a Restrictions Roadmap covering ongoing and future work on restrictions under REACH. ECHA has actively contributed to the roadmap's preparation, providing input on planned restriction activities and suggesting groups of substances to be included based on regulatory needs. The roadmap provides clarity to all stakeholders on ongoing and future work on EU restrictions, and our group assessments continue to feed into this work.

In 2022, six restriction proposals were submitted throughout the year including an EU-wide restriction of per- and polyfluoroalkyl substances (PFASs) in firefighting foams. If adopted, the restriction could reduce emissions by more than 13 000 tonnes over 30 years. Additionally, five European countries have submitted a separate proposal to restrict PFASs in other applications at the start of 2023.

RAC and SEAC adopted four opinions on restriction proposals, supporting restrictions for lead in ammunition for hunting, outdoor shooting sports and fishing, polycyclic aromatic hydrocarbons

¹ https://echa.europa.eu/documents/10162/11209549/mb_39_2021_pid_2022-2025_en.pdf

² A further nine substances were added in January 2023. The current number of entries on the Candidate List is 233.

in clay targets, 2,4-dinitrotoluene, and for the flame retardant Dechlorane Plus.

RAC also adopted 40 opinions recommending a harmonised classification and labelling for substances. Following an extensive review of scientific evidence, the committee again reaffirmed that there is no justification for classifying glyphosate as a substance that causes cancer, mutagenicity, reprotoxicity, or specific target organ toxicity. As such, glyphosate's current classification as toxic to aquatic life and capable of causing serious eye damage remains.

The Biocidal Products Committee (BPC) adopted 19 opinions for active substance approval and renewal, while for Union authorisations, the positive trend continued, with 22 opinions adopted in 2022, compared to 15 in 2021. A comparative assessment of rodenticides was performed and agreed by the Committee and a first guidance on Analysis of alternatives was also developed.

Our approach for promoting alternatives to animal testing has been reviewed, with steps taken to increase the effectiveness and visibility of our efforts in supporting the uptake of alternative methods that are suitable for regulatory purposes. To achieve this, we continue to invest in our scientific and technical competences, including data management and tools that support chemicals assessment like the OECD QSAR Toolbox. We are also collaborating with the European Commission and other stakeholders to support the Commission in developing a roadmap towards the full replacement of animal testing for chemicals.

With our scientific and regulatory expertise, databases, digital tools and practical experience with chemicals regulation, we also provided support to the European Commission's Chemicals Strategy for Sustainability (CSS) throughout 2022. Our support is built around three central pillars:

- Providing technical and scientific expertise as the European Commission revises REACH and CLP, drawing on our experience of implementing these regulations for more than a decade.
- Providing input to facilitate the 'one substance, one assessment' principle, particularly regarding the potential reattribution of tasks to agencies and the future EU data platform.
- Providing advice to the European Commission on their proposal for ECHA's basic regulation.

Collaboration with our partners and sister Agencies increased in 2022. We actively engaged in initiatives under the Partnership for the Assessment of Risks from Chemicals (PARC), an EU-wide research and innovation programme focused on developing next-generation chemical risk assessment to protect health and the environment. We aim to maximise synergies and steer scientific developments that are better targeted to regulatory needs. Our grouping work on bisphenols is feeding into the PARC project on bisphenol alternatives, for example.

We have been collaborating closely with regulatory authorities, including the European Food Safety Authority (EFSA), to assess the safety of substances and develop consistent views across regulatory frameworks, including for areas such as biocides and pesticides, food contact materials, and drinking water requirements. In addition, we have partnered with the European Environment Agency (EEA) to build a joint framework of indicators that will help to track the progress and impact of the CSS implementation, using the advantage of our shared expertise in IT and communications.

In 2022, we underwent significant changes at both senior and middle management levels. With our strong management policies and quality systems in place, we were well-prepared to implement the changes smoothly, and ensure that staff were able to adapt quickly to the new leadership structure. We also welcomed our new Executive Director, *Dr Sharon McGuinness*, who joined us at the end of the year. With these changes to the management team now in place, we

are well-positioned to continue delivering on our legal mandates now and into the future.

Emerging from the pandemic, we defined and implemented a new hybrid working model for our staff and ECHA's bodies, in line with European Commission rules. The model offers the benefits and flexibility of teleworking with regular presence in the office.

While the year included many successes, we also faced several challenges.

One major issue is the inefficiency of the authorisation system, a problem that we identified already in 2021 in our *Report on the operation of REACH and CLP*³. The increase in applications for authorisation we experienced during 2022, particularly for hexavalent chromium, is expected to persist in 2023. This is exceeding the opinion-making capacity of our scientific committees, and the lack of experienced members is making the situation even worse, as it is becoming increasingly difficult to find rapporteurs to prepare fit-for-purpose opinions.

Another challenge is the low number of draft assessment reports for biocidal active substances submitted by Member States. This is detrimental to completing the evaluation of all existing active substances by the end of 2024 as required by the Biocidal Products Regulation. In line with the Active Substances Action Plan, ECHA has made efforts over the past years to support the Member States to make further progress and will continue to do so.

We also see a future challenge should the policy on 'one substance one assessment' put a requirement on agencies to fully align the opinions of different scientific committees without aligning the regulatory context first. As long as regulations contain different requirements, refer to different guidance or pose different questions to different groups of scientific experts with different timelines, it will not be possible to fully align the final outcomes.

There were also shortcomings in the dissemination of public information on chemicals during the year, with access to the information on chemicals unavailable on our website at times. We have conducted a thorough study and made solid progress, together with stakeholders, in building the new system to make data on chemicals, their properties and regulatory status more readily available. The long-term solution will improve the flow of information to stakeholders and help us to provide transparent, up-to-date and accessible data on chemicals.

With the adopted hybrid working model, we may face challenges in maintaining effectiveness, collaboration, and connectivity of staff to ECHA's mission. We recognise the importance of addressing any drawbacks from the model so that we can ensure we are able to retain and attract the best talent to support our work.

Finally, cyber security has become an important area of focus for us. With increased investment in the area, despite heightened malicious activity and the recent escalation of the geopolitical crisis, our levels of security have remained comparable to previous years, and no significant incidents have occurred. We have developed a long-term plan to maintain the delivery and high service quality of our IT operations and to address future challenges in this area.

³ https://echa.europa.eu/documents/10162/17226/operation_reach_clp_2021_en.pdf

The Agency in brief

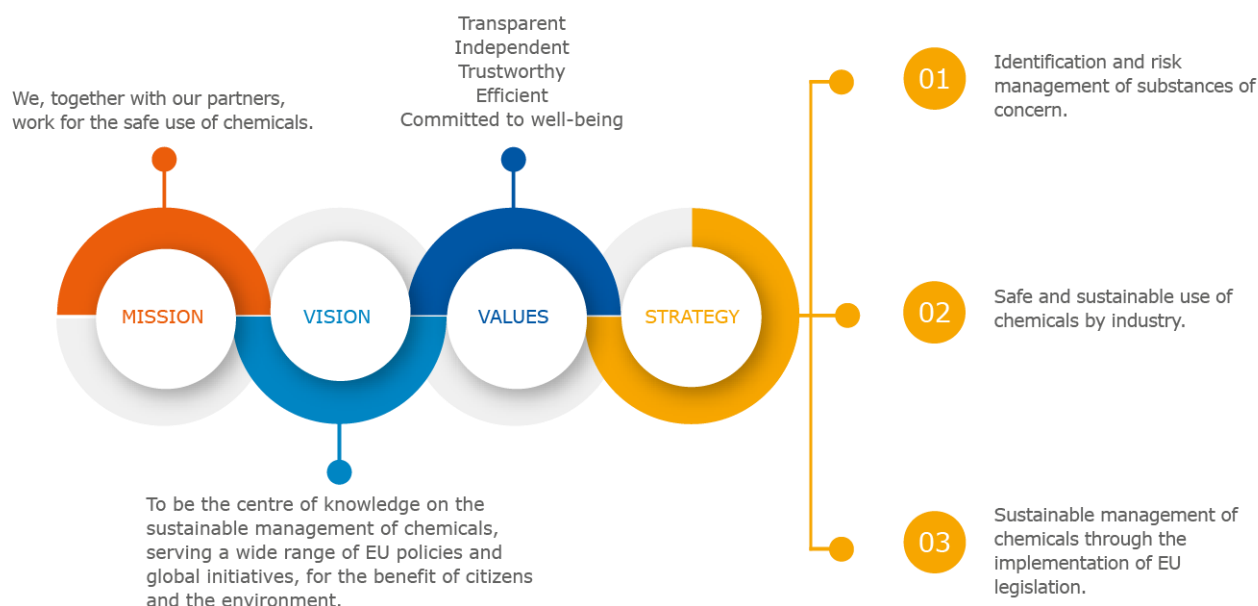
ECHA, with the aim of continuing to serve the European Union in an adequate and efficient manner, has set out three strategic priorities. They take ECHA's role as their basis, build on ECHA's competences and achieved impact, recognise the central importance of the legislation ECHA implements in the EU regulatory system, and attempt to anticipate the challenges ahead.

In line with the strategic plan 2019-2023, 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 to assist the European Commission to determine which regulatory action is needed and take the necessary action under REACH, BPR, CLP, POPs, or under other relevant legislation (Strategic Priority 1).

Strategic Priority 2 builds on the knowledge gained under Strategic Priority 1 and uses the legislative obligations of industry set out in REACH, CLP, BPR, PIC, WFD and DWD and ECHA's mandate therein, and aims to improve the knowledge and capacities of industry to take action before ECHA or other regulatory bodies do.

Finally, Strategic Priority 3 uses the data and experience gained through the implementation of ECHA's mandate to improve the consistency and integration within the EU chemicals regulatory system towards the international work on chemicals management.

By implementing its Strategic Plan and Priorities and, on an annual basis, its Work Programme, ECHA contributes to the Green Deal objectives of the EU as well as to further policy development through scientific-regulatory advice within the frame of the European Commission's requests under the Chemicals Strategy for Sustainability.



ECHA's annual Work Programme translates the Strategic Plan and Multi-annual Work Programme into concrete actions and outputs, structured around the Agency's main activities. The next section highlights the key achievements of 2022.

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