ECHA
EUROPEAN CHEMICALS AGENCY

Annual Report 2022

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List of acronyms

Acronym	Description
AD	Administrator
AST	Assistant
BEF	BPR-EN-FORCE (Forum-coordinated BPR enforcement project)
BPC	Biocidal Products Committee
BPR	Biocidal Products Regulation
BPRS	BPR Subgroup of the Forum
BREF	Best Available Techniques Reference documents
C&L	Classification and labelling
CA	Contract agent
CAD	Chemical Agents Directive 98/24/EC
CCH	Compliance check
Chesar	Chemical Safety Assessment and Reporting tool
CLH	Harmonised classification and labelling
CLP	Classification, labelling and packaging (and the respective Regulation)
CMD	Carcinogens and Mutagens Directive 2004/37/EC
COM / Commission	European Commission
CoRAP	Community rolling action plan
CSR	Chemical safety report
CSS	Chemicals Strategy for Sustainability of the Commission
CTPHT	Coal tar pitch high temperature
DG DIGIT	Directorate General for Informatics of the Commission
DG EMPL	Directorate General for Employment, Social Affairs and Inclusion of the Commission
DG GROW	Directorate General for Internal Market, Industry, Entrepreneurship and SMEs of the Commission
DG NEAR	Directorate General for Neighbourhood and Enlargement Negotiations of the Commission
DG RTD	Directorate-General for Research and Innovation of the Commission
DNA	Designated national authorities
DNEL	Derived no-effect level
DPP	Digital Product Passports
DWD	Drinking Water Directive
EAP	Environment Action Programme
ECHA	European Chemicals Agency
eChemPortal	OECD Global Portal to Information on Chemical Substances
ED	Endocrine disruptor
EEA	European Environment Agency
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EIOPA	European Insurance and Occupational Pensions Authority
EMA	European Medicines Agency
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
ERR	Exposure-risk relationship
EU	European Union
EUCLEF	European Union Chemicals Legislation Finder
EUON	European Union Observatory for Nanomaterials
EUSES	European Union System for Evaluation of Substances
Forum	Forum for Exchange of Information on Enforcement
FRA	Final regulatory action
FS	Fund source
FTE	Full-time equivalent
FWC	Framework contract
HelpNet	Network of national BPR, CLP and REACH helpdesks

Acronym	Description
HR	Human resources
ICT	Information communications technology
IED	Industrial Emissions Directive 2010/75/EU
IMS	Integrated Management System
IPA	Instrument for Pre-Accession Assistance
IRS	Integrated Regulatory Strategy
ISO	International Organisation for Standardisation
IUCLID	International Uniform Chemical Information Database
JRC	Joint Research Centre
MB	Management Board
MFF	Multiannual Financial Framework
MISA	Metals and Inorganics Sectoral Approach
MS	Member State
MSC	Member State Committee
MSCA	Member State competent authority
NAM	New approach methodologies
NeRSAP	Network of REACH SEA and Analysis of Alternatives practitioners
NONS	Notification of New Substances
Odyssey	ECHA's tool to support evaluation tasks
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational exposure limit
PAH	Polycyclic aromatic hydrocarbons
PARC	Partnership for the Assessment of Risks of Chemicals
PBT	Persistent, bioaccumulative and toxic
PCN	Poison Centre Notifications
PFAS	Per- and polyfluoroalkyl substances
PIC	Rotterdam Convention on the prior informed consent procedure (and the respective Regulation)
PMT	Persistent, mobile and toxic
POP	Persistent organic pollutant
POPRC	Persistent Organic Pollutants Review Committee
POPs	Persistent organic pollutants (and the respective Regulation)
PPORD	Product and Process Oriented Research and Development
PPP	Plant protection products
QSAR	Quantitative Structure-Activity Relationship
RAC	Committee for Risk Assessment
REACH	Registration, evaluation, authorisation and restriction of chemicals (and the respective Regulation)
REACH-IT	Central IT system providing support for REACH
REF	REACH-EN-FORCE (Forum-coordinated REACH enforcement project)
SCIP	Database for information on Substances of Concern In articles
SEAC	Committee Socio-economic Analysis Committee
SLA	Service Level Agreement
SME	Small and medium-sized enterprises
SNE	Seconded national expert
SVHC	Substance of very high concern
TA	Temporary agent
TCE	Trichloroethylene
UNEP	United Nations Environment Programme
US EPA	United States Environmental Protection Agency
UVCB	Substance of Unknown or Variable composition, Complex reaction products or Biological materials
vPvB	Very persistent and very bioaccumulative
WFD	Waste Framework Directive
WP	Work programme

Management Board analysis and assessment

The Management Board welcomes the Annual Report 2022, combining the reports prepared according to the requirements of the REACH Regulation (General Report)[1] and those of the ECHA Financial Regulation (Consolidated Annual Activity Report)[2].

We consider that this report provides a comprehensive account of the activities carried out by ECHA during 2022, the performance of the Agency against the expected inputs, outputs, outcomes and the impacts defined in the Programming Document 2022-2025[3]. It also represents a fair overview of the evolution of ECHA's budget, staffing, management, and its internal management system strategy and framework.

This assessment is based on our analysis of all parts of the report, including the activities carried out, the achievements, financial information, results of audits, ex-post evaluations and the assessment of the internal control system, as well as the risks related to ECHA's activities together with the corresponding mitigating measures.

Achievements of the year

We consider that the performance and quality of the outputs in 2022 were high.

In addition to the ongoing actions that were defined for multiple years, ECHA had defined 162 specific actions and outputs for 2022 and accomplished 151 out of these during the year. In addition, 8 actions are in progress. The three not completed actions would have required Member States' contribution or the work area was de-prioritised.

In assessing[4] the Consolidated Annual Activity Report of the Authorising Officer for 2022, we:

- Acknowledge that ECHA, as an organisation, underwent a transition in 2022, including significant changes at senior and middle management levels and implementing the new hybrid working model for ECHA staff and ECHA's bodies.

- Note that the Agency focused on delivering its core tasks and on supporting the European Commission to implement its Chemicals Strategy for Sustainability. This was in line with the direction set out by the Management Board in the Strategic Plan 2019-2023 and in its review conducted in 2021.

- Appreciate the work done to implement the Integrated Regulatory Strategy (IRS), with further progress achieved in identifying substances of concern that require regulatory measures, including assessing substances in groups. At the same time, it is necessary to analyse whether and how ECHA's IRS work contributed to initiating or accelerating the work (of the Commission, ECHA and Member States) on these substances of concern.

- Welcome the review of ECHA's activities for promoting alternatives to animal testing and the steps taken to increase the effectiveness and visibility of this work.

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[1] Article 78(a) of the REACH Regulation.
[2] Article 48 of ECHA's Financial Regulation.
[3] https://echa.europa.eu/documents/10162/13609/programming_document_2021-2024_en.pdf/
[4] Assessment pursuant to Article 48(1) of the Agency's Financial Regulation.

Based on the periodical reporting and the Annual Report 2022 prepared by the secretariat, the Board appreciates the performance of the Agency and makes the following observations[5]:

Management

- The eight recommendations the Management Board provided for 2022 as part of the assessment of the 2021 Annual Report have been implemented or are in progress.

Budgetary and financial management

- ECHA continued to rely, for its income, on fees from industry and a balancing EU contribution. Its fees have been on a decreasing trend, they fluctuated and were challenging to predict, which complicated budget planning and execution.

- Implementation of the budget, while keeping the strict segregation between several pieces of legislation or legislative area, is resulting in unnecessary administrative burden and inflexibility. This is an area of concern for the Management Board, even more in light of the new tasks being planned to be assigned to ECHA.

- The appropriations carried over from 2021 were largely implemented, with cancellations amounting to EUR 206 062, representing 2% of the total amount carried over.

- The Agency's initial budget for 2022 current year commitment appropriations amounted to c. EUR 112.0 million and was increased during the year by c. EUR 2.8 million to c. EUR 114.8 million. The final executed amount totalled EUR 113.2 million corresponding to a commitment appropriation execution rate of 98.6%, representing a slight increase of 0.2 percentage points compared to the previous year. The 2022 current year payment appropriations execution rate was 85.1%, representing a decrease of 1.1 percentage points in comparison to 2021.

Human resources management

- The Agency made use of more internal mobility to respond to the evolving needs for scientific-technical and administrative expertise in its work. This offered career enhancement opportunities and thereby contributed to motivating ECHA staff and maintaining a culture of high performance, continuous improvement and responsiveness. This remains necessary considering the new tasks expected to arrive to the Agency, for which new skills and competences will be required.

- ECHA took action to promote diversity and inclusion among its staff, and the gender balance within its (senior) management team improved.

- The Agency has again achieved a high occupancy rate of 98% for temporary agents and contract agents.

Audit and ex-post evaluation results and follow-up on recommendations

- The Board received adequate information from, and assurance provided by the Internal Audit Capability (IAC) on audits, follow-up audits and the implementation of the recommendations, as well as appropriate information from the secretariat on the two ex-

[5] Assessment pursuant to Article 48(1) of the Agency's Financial Regulation.

post evaluations.

- The European Court of Auditors adopted a positive opinion regarding the 2021 annual accounts, with no reservation or observation.

- The European Parliament, as the Discharge Authority, granted discharge to the Executive Director with respect to ECHA's 2020 budget, including the decision on the closure of the 2020 accounts. The secretariat duly provided replies to the Discharge Authority's observations and the implementation of the recommendations is on track.

- The Internal Audit Service of the Commission provided assurance on the independence of the internal audit activity.

Internal control framework and Integrated Management System

- The internal control framework remains effective and functioned as intended. Areas identified for improvement relate to areas such as risk management at all levels of decision-making, the practices with respect to ex-ante evaluations, stakeholder engagement and change management.

- While ECHA has in place a comprehensive Conflict of Interest prevention policy, ensuring that the post-employment conditions are applied in practice remains a challenge.

- ECHA's ISO 9001:2015 and 14001:2015 quality certificates were renewed and its EMAS (Eco-Management and Audit Scheme) registration maintained.

Risk management

- Appropriate measures are in place to identify, monitor and manage risks threatening the achievement of ECHA's objectives. The Secretariat regularly signalled significant risks and control issues to the Management Board, including as part of the quarterly reporting, as well as the updates to the risk register.

- The most significant risks, which persist in 2023, related to the lack of resources in Member States to contribute to Agency activities, to a peak in REACH authorisation applications and to increased and more targeted cyber-attack activities. Mitigation measures were presented to the Board and implemented.

- With respect to cyber-security, security resources increased, and a cybersecurity policy was established. A regular Information Security and IT business continuity report to the MB has been introduced.

Management Assurance

The Board takes note of the systems in place to support the Executive Director's declaration of assurance and takes note of the declaration of assurance of the Executive Director.

The Board takes note of the fact that no reservations were made.

Recommendations for the secretariat for 2023

Based on our assessment, the Management Board requests particular emphasis on the following items in 2023, without prejudice to the implementation of the Programming Document 2023-2026:

1. Work with the Management Board to align on ECHA's purpose, vision and strategic approach for 2024-2028. In this context, pay special attention to objectives, expected results and performance indicators.

2. Continue to focus on cyber security, to account for the continued high threat levels, and continue providing regular information to the Management Board.

3. Contribute to achieving steady progress in the BPR Active Substances Review Programme, through fit for purpose support to Member State competent authorities.

4. Implement the action plan to advance diversity and inclusion, including gender balance in ECHA's management team and at organisational level.

5. Continue to further refine the performance indicators and targets for the grouping of substances under the Integrated Regulatory Strategy and update the Single Programming Document as necessary.

6. Highlight to the Management Board and to EU institutions synergies and efficiencies on impact based on experience gained from implementing existing and new tasks in the portfolio of the Agency.

7. Continue to provide timely and sufficient information to the Management Board on the implementation of current tasks as well as on discussion of potential new tasks while focusing on potential benefits and risks for the Agency.

8. Continue to report regularly to the Management Board on the ECHA Committees' current and future ability to deliver the legally required high-quality regulatory outputs, in particular scientific opinions and decisions. Contribute, with independent scientific-regulatory advice, to the discussion on how to maintain the functioning of the committees, especially RAC, with a view to their current and expected future workload.

9. Put a higher focus on problems, challenges, and risks in all future reports of the Agency, to provide, if necessary, an opportunity for additional discussion and developments.

10. Regularly report to the Management Board on the progress with the measures developed in cooperation with the Commission to further develop the REACH authorisation process.

Conclusion

In assessing the Annual Report 2022, the Management Board concludes that the overall performance of ECHA is in line with the objectives included in the Agency's Programming Document 2022-2025.

Acknowledgments

The members of the Management Board thank ECHA staff, members of ECHA bodies and the Agency's partners, in particular Member States, for their commitment and valued contribution to ECHA's work in 2022.

Foreword

Dr Sharon McGuinness

Executive Director

I am pleased to present the Agency's annual report for 2022. This is my first report following my appointment as the Executive Director in 2022. This report highlights the activities and actions achieved as well as some of the challenges we faced during the year.

ECHA's mandate is wide and varied, requiring us to partner and engage with a wide range of stakeholders and organisations to deliver our work programme and legal obligations. In this regard, our committees continued to provide scientific opinions on the risk management of chemicals, spanning from the harmonisation of substance classification and labelling under CLP to the authorisation and restriction of substances under REACH.

Under CLP, we reaffirmed our position that glyphosate does not pose a cancer risk and should not be classified as a carcinogen. We also handled high volumes of authorisation applications and adopted opinions supporting restrictions for substances of concern, including Dechlorane Plus and lead used in ammunition for hunting, sports shooting, and fishing.

On biocides, we delivered on the activities outlined in our work programme and continued to provide opinions on applications for Union authorisations for biocidal products and active substance approvals. We also took steps to promote 'one substance, one assessment', partnering with the European Food Safety Authority (EFSA) to bring further coherency to hazard and risk assessments for active substances whether they are legislated as biocides, pesticides, food additives or food contact materials.

We continued to provide advice, support and tools to enable companies to comply with their regulatory obligations. In addition, we expanded the range of information available through our dissemination tools and engaged with stakeholders to help us redesign and enhance the accessibility and usability of our current system.

We have also intensified our efforts to promote the work we do on new approach methodologies (NAMs), exploring avenues towards an animal-free regulatory system in the future.

While 2022 saw us continue to deliver on our legal mandates, it also saw us take on new legislative areas such as the Drinking Water Directive. With continued developments on the Chemicals Strategy for Sustainability during the year, we worked closely with our Commission colleagues to provide advice and information across a wide range of areas including the European Common Data Platform, where we took a lead

role in drafting an implementation plan. We anticipate further legal mandates coming to us in 2023 and we will continue to work with colleagues in the Commission to ensure these can be implemented and delivered by the Agency.

Although we have made considerable progress, there have been challenges along the way. For biocides, despite our increased support, fewer draft assessment reports are still being submitted by Member States than expected. It is now clear that the legal obligation to review all existing active substances under the review programme by 2024 will not be met.

Another challenge we faced is the inefficiency of the current authorisation system under REACH. We experienced a surge in applications during 2022, specifically for hexavalent chromium, and anticipate this trend to continue into 2023 and beyond. Along with a decline in the number of experienced members within our scientific committees, these are serious concerns.

As we look to the future, partnership, agility and prioritisation will be crucial to our success. We must listen to and engage with our stakeholders more effectively to involve them in our work and ensure our mutual objectives are met. As our mandate and stakeholder expectations increase over the coming years, we will need to prioritise our efforts, not only to be efficient and effective but also to focus on delivering impactful outcomes. To achieve this, we will need to explore how technology and new scientific approaches can help us to innovate and deliver.

ECHA and I remain committed to our mission and look forward to continuing our work in 2023 and beyond. Working together with our partners and colleagues in the European Commission and Member States, as well as with a wide range of other stakeholders, we will strive to deliver safer chemicals for all Europeans and for Europe.

Finally, I would like to express my gratitude to ECHA's Management Board for their guidance and support, as well as to all ECHA staff for their hard work and commitment in achieving our objectives.

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 2022-2025[6]. 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 224[7]. 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 in clay targets, 2,4-dinitrotoluene, and for the flame retardant Dechlorane Plus.

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

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

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*[8]. 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.

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

The Agency in brief

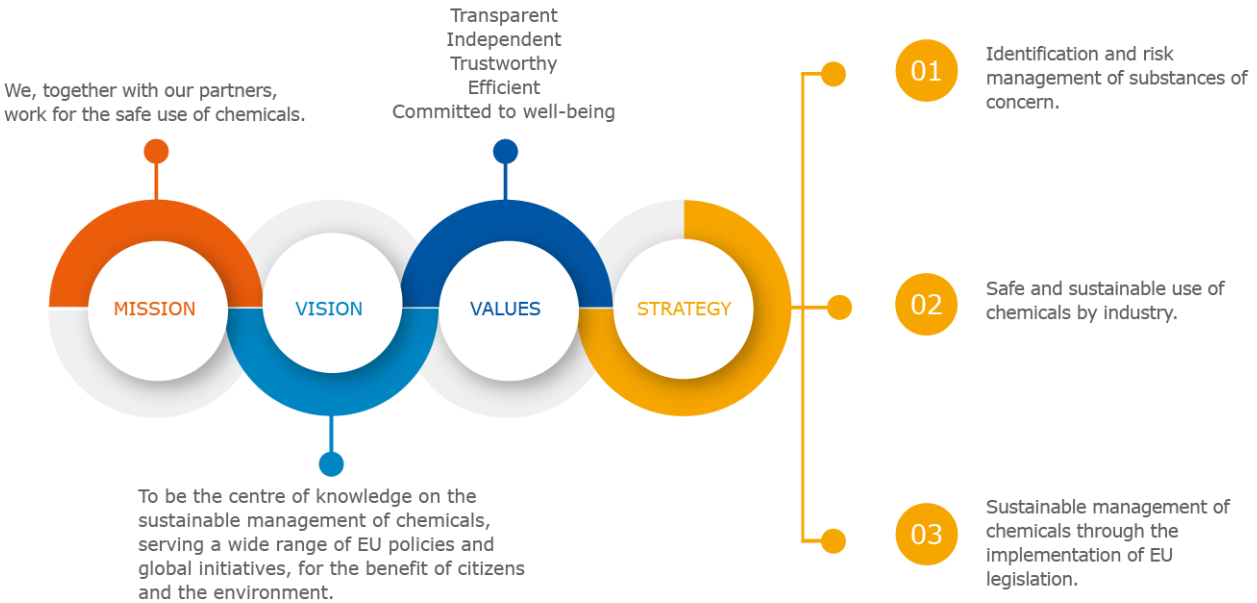
ECHA, with the aim of continuing to serve the European Union in an adequate and efficient manner, has set out three strategic priorities. They take ECHA's role as their basis, build on ECHA's competences and achieved impact, recognise the central importance of the legislation ECHA implements in the EU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

Key achievements for 2022

REACH and CLP

Registration preparation and submission

In 2022, we continued to receive and process registration dossiers, providing companies with the tools and support they need to successfully register and update their registration information.

Throughout the year, we received 13 530 registrations (including updates). To ensure the completeness of submitted information, we conducted technical completeness checks on all submitted registrations, including manually verifying certain aspects. We reached our annual target for verifying company size, checking 411 small and medium-sized enterprises (SMEs), and continued working towards reducing the time lag between submission and size confirmation for these companies.

The opportunity for companies to claim registration numbers assigned to their notifications of new substances (NONS)[9] ended in July. More than 4 700 numbers remained unclaimed, and these can no longer be used by registrants. The unclaimed registration numbers cover more than 2 800 substances, mostly registered in low volumes, and presumably abandoned by manufacturers or importers before 2008.

When the registrations were declared not valid, the substances were removed from this pool and dropped from ECHA's regulatory activities. The information from the unclaimed NONS remains available in our chemicals database but has been updated to show that the unclaimed numbers are no longer valid.

Since April 2022, only representatives have had to identify the non-EU manufacturers they represent and provide their contact details to ECHA. We released a manual to guide them on how to rearrange their REACH-IT accounts to ensure separate accounts are held for each non-EU manufacturer they represent. By October, this action had identified companies behind more than 95% of registrations by only representatives.

Initial steps have been taken to develop a future vision for REACH-IT ensuring its long-term sustainability, preparing the tool to handle submissions for the various chemical regulations currently assigned to us, and to make it agile enough to accommodate future legislation we may work on.

The latest release of IUCLID includes new features such as improved search options, better handling of datasets, and enhanced cross-referencing capabilities. Additionally, the software has been modernised and adapted to better meet the needs of different users, including those who wish to use their own IT systems to prepare and submit classification and labelling notifications through ECHA's system-to-system service.

Chesar was maintained and remains available for registrants to prepare their chemical safety reports. In parallel, work continued to develop the Chesar Platform, a new risk assessment tool that will harmonise assessments under both REACH and biocides (see Section 'Safe and sustainable use of chemicals').

In 2022, the ECHA Helpdesk received 9 500 enquiries related to regulatory or IT issues, while

[9] In 2008, ECHA assigned registration numbers to all substances notified under the Dangerous Substances Directive, for use by registrants under REACH.

national helpdesks active in the HelpNet network handled 45 000 questions. Since we now dispatch more questions to the national helpdesks, we introduced legislation-focused videoconferences where national helpdesks can present their challenges and engage in discussions with other helpdesks. The aim is to ensure consistency in responses across the EU. The majority of helpdesks participate in these videoconferences, which have resulted in even more productive collaboration than the two workshops previously organised each year.

Identification and prioritisation

In 2022, ECHA continued to assess the regulatory needs of groups of substances. Assessing substances in groups allows all the available information to be used and publishing the groups provides companies with a clearer understanding of the actions planned by regulators, which in turn will help them better prepare to replace harmful chemicals with safer alternatives.

During the year, ECHA continued its work on screening structurally similar substances in groups. The planned number of groups of substances for which the assessment of regulatory needs is carried out was 65 and we started assessments for around 2 000 substances across 61 groups[10]. Nearly 500 of the substances covered were registered above 100 tonnes per year.

In terms of assessments made during 2022, for the substances registered above 100 tonnes per year, roughly 200 were concluded as potentially needing regulatory follow-up. The Integrated Regulatory Strategy has led to around 75% of substances registered above 100 tonnes being assessed by the end of 2022. This means, around 1 000 high-tonnage substances still need to be assessed. ECHA will publish a more detailed report on the results in the course of 2023 as well as complete a review of the overall Integrated Regulatory Strategy.

We continued the practice of publishing reports on the assessment of regulatory needs (ARN) for groups of substances, making the possible regulatory actions and the progress made on grouping more transparent. During the year, we published reports for 63 groups covering around 1 600 substances. These included a group of 148 bisphenols, of which more than 30 are potential candidates for restriction because of hormonal or reprotoxic effects, and 52 hydrocarbylsiloxanes, for which restriction may be considered due to persistent and bioaccumulative properties. For a number of substances, hazards need to be clarified before risk management can be recommended.

The assessment reports are publicly available on ECHA's website in the public activities coordination tool (PACT)[11], which provides an overview of substance-specific activities that authorities are working on under REACH and CLP.

[10] 61 groups of which 10 were large (>39 members, more than double the median group size), so this is equivalent to 71 groups.
[11] https://echa.europa.eu/pact

Evaluation

The REACH Evaluation Action Plan sets targets for checking the compliance of registration dossiers submitted to ECHA. A minimum of 20% of registrations for substances registered in quantities of 100 tonnes or more per year need to be checked for compliance, with a similar percentage for substances in tonnage bands less than 100 tonnes per year. This means that all registered substances go through a grouping and screening process, and that about 30% will be checked for compliance.

In 2022, we continued to screen structurally similar substances in groups, and based on the assessments of regulatory needs, we selected 294 substances from 46 groups for compliance checks.

In total, ECHA performed 330 compliance checks in 2022. We carried out 302 full compliance checks[12] and 213 testing proposal examinations, covering 475 unique substances. These checks resulted in 459 draft decisions being issued: 277 on the compliance checks and 182 on the testing proposal examinations. We also conducted 28 targeted compliance checks[13] based on specific concerns. In 2022, a total of 421 decisions were adopted. Collaboration with the Member State competent authorities was effective and showed good alignment as only 5% of the draft decisions had to be discussed by the Member State Committee following proposals for amendment.

ECHA conducts follow-up actions to verify that any updated information provided in response to evaluation decisions addresses what was requested. In 2022, the considered requests were addressed adequately in 59% of cases. 41% remained unaddressed and these were notified to Member States for enforcement. Some of these unaddressed cases were due to delays in conducting the studies resulting from capacity constraints in laboratories that worsened during the COVID pandemic.

An analysis for 2020-2022 revealed that around 20% of completed dossier evaluation cases were being considered for further regulatory action (harmonised classification and labelling (CLH), endocrine disruptor (ED), and persistent, bioaccumulative and toxic (PBT) assessment or substance evaluation). The most frequent outcome by far was the consideration of a CLH process, particularly for reproductive toxicity concerns.

For substance evaluation, the Community rolling action plan (CoRAP) update for 2022–2024 was published in March 2022. The list was updated with 27 substances for evaluation by 10 Member States. Of these 27, four were due to be evaluated in 2022 by three Member States – two by Denmark, and one each by France and Germany[14].

For 31 substances, a conclusion was reached in substance evaluation. Some of the regulatory follow-up actions at EU level include harmonised classification and labelling for carcinogenicity (2 substances), mutagenicity (1), reproductive toxicity (2), sensitisation (4), identification as a substance of very high concern (5), and restriction (4). For 11 substances, the evaluating Member State competent authority will prepare a separate risk management option analysis to determine appropriate follow-up actions. The draft CoRAP update for 2023-2025 was referred to the Member State Committee in its December meeting.

In 2022, nine substance evaluation decisions were issued requesting data to address concerns

[12] As a minimum, full compliance checks cover genotoxicity, repeated-dose toxicity, pre-natal developmental toxicity, reproductive toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation and bioaccumulation.
[13] In a targeted compliance check, ECHA evaluates a specific part of the registration dossier based on specified concerns.
[14] 2-furaldehyde (EC 202-627-7, CAS 98-01-1) and reaction products of phosphoryl trichloride and 2- methyloxirane (EC 807-935-0, CAS 1244733-77-4) by Denmark; 1,3,4,6,7,8- hexahydro4,6,6,7,8,8- hexamethylindeno[5 ,6-c]pyran (EC 214-946-9, CAS 1222-05-5) by France; and 2-Pentanone oxime (EC 484-470-6, CAS 623-40-5) by Germany.

regarding endocrine disruption (3 substances), persistence, bioaccumulation and toxicity (PBT/vPvB) (4) and/or mutagenicity (2). Of these nine, five were adopted by the Member State Committee (four through written procedure and one in the meeting), and four were directly adopted by ECHA as no proposals for amendment were received.

Following a decision by the Board of Appeal, ECHA now takes changes to a registrant's tonnage band into account until an adopted evaluation decision is communicated to the registrant. If a registrant wants ECHA to take these changes into account, they need to inform the agency and update their dossiers after they receive a draft evaluation decision. They also have to provide evidence of the previous year's imported or manufactured volumes if they downgrade their tonnage band.

Once the adopted evaluation decision is communicated to the registrants, they must fulfil all information requirements outlined in the decision, regardless of any subsequent changes in their tonnage band or if they cease manufacture.

Infobox: Promoting alternatives

ECHA supports efforts to further reduce animal testing and promotes alternative methods for assessing hazards where available and feasible.

ECHA promotes alternatives to animal testing in three ways: focusing on groups of substances through our Integrated Regulatory Strategy, investing in international activities that promote alternatives and new approach methodologies (NAMs), and making the data we hold available.

We prioritise and group chemicals for regulatory work. This reduces the need for animal testing as tests are only requested for subsets of substances in the groups. We support companies to develop testing strategies to ensure that animal testing is only performed as a last resort and check their proposals to make sure that alternatives have been considered. Our guidance and support material helps companies understand where they can successfully replace animal tests with alternatives. We bring companies together to make sure they are sharing data and we also hold online consultations to gather information on alternatives.

Internationally, we co-manage and finance the OECD QSAR Toolbox – a tool used globally to help authorities and companies predict the toxicity of substances based on similarities in toxicological profiles and modelling. Our experts also contribute to developing OECD test guidelines in line with the requirements to refine, reduce and replace animal testing. In 2022, we made contributions to new test guidelines for skin and eye irritation and skin sensitisation that do not rely on animal testing.

We also took an active role in flagship research projects for developing new approach methodologies (NAMs) including the Partnership for the Assessment of Risks from Chemicals (PARC), the Accelerating the Pace of Chemical Risk Assessment (APCRA)[15] initiative and a project to set up a metabolic biomarker panel for toxicology (MTox700+)[16].

We have invested in making the data we hold publicly available. For example, we publish IUCLID datasets for download (the REACH Study results and pharmaceutical industry data), which help to support the development of read-across and weight-of-evidence approaches, as well as predictive models. This contributes to reducing reliance on animal testing and advancing the use of alternatives in a responsible and ethical manner.

ECHA recognises that NAMs are very relevant in the current context of policy changes, and we are committed to contributing to the scientific debate and regulatory work to accelerate the transition to an animal-free regulatory system. We are strengthening our interaction with stakeholders and work closely with the Commission and international partners to support the development and uptake of alternatives that are suitable for regulatory purposes. This work will feed into the development of a potential EU roadmap by the Commission for fully replacing animal testing in the risk assessment of industrial chemicals.

[15] https://apcra.net
[16] https://academic.oup.com/toxsci/article/186/2/208/6517515?login=true

Authorisation

Under REACH, substances of very high concern (SVHCs) on the Authorisation List need authorisation to be used or placed on the EU market after a sunset date. Authorisation can only be granted if the risks associated with using the SVHC can be adequately controlled, or if the socio-economic benefits of the substance's continued use outweigh the risks and if there are no suitable alternative substances or technologies available.

The Candidate List[17] grew to 224 entries[18] in 2022, with five new substances added. One substance used in cosmetics was found to have hormone-disrupting properties for humans, while two others used in rubbers, lubricants, and sealants were found to have negative effects on fertility. Another substance used in lubricants and greases was added due to its harmful impact on the environment as it is persistent, bioaccumulative, and toxic. And a substance used in polymers, paints, and coatings was identified as a potential cause of cancer or genetic defects.

In February, ECHA invited stakeholder feedback on its recommendation that eight more substances from the Candidate List fulfil the prioritisation criteria to be included in the Authorisation List[19]. The proposal received a significant response, with nearly 1 500 comments submitted regarding lead metal alone. Few comments were received for three substances, while the other four did not receive any comment. The Authorisation List currently includes 59 entries.

ECHA received 49 applications for authorisation for 65 uses, as well as a review report for one use. 26 further applications for authorisation for 28 uses and four review reports for four uses were submitted, but the opinion-making process for these will only start in 2023. ECHA's committees adopted 33 opinions on applications for authorisation, as well as three opinions on three review reports during the year.

The number of submitted applications is expected to continue to rise sharply, particularly for the use of hexavalent chromium in plating. With limited capacity to process applications, the opinion-making capacity of ECHA's committees will be exceeded. The inefficiency of the authorisation process was previously noted in our Report on the operation of REACH and CLP 2021[20].

A case study on the impacts of authorisation on trichloroethylene (TCE)[21] was published in February 2022, looking at the impacts of its authorisation since its addition to the Candidate List in 2010. The report found that the requirement to obtain authorisation greatly decreased the use of TCE, with its annual use declining by over 95% in the last 12 years.

In October 2022, ECHA released a report on changes in market volumes for substances subject to REACH authorisation between 2010 and 2021[22]. Based on information from registration dossiers and applications for authorisation, the report suggests that for 40% of substances subject to authorisation since 2010, no applications have been received, indicating that they are no longer being used in the EU. For the remaining substances, the market volume almost halved since 2010 to 2021.

[17] Four added in January 2022. One added in June 2022.
[18] A further nine substances were added in January 2023. The current total number of entries is 233.
[19] https://echa.europa.eu/documents/10162/0/annex_xiv_recommendation_en.pdf
[20] https://echa.europa.eu/documents/10162/17226/operation_reach_clp_2021_en.pdf
[21] https://echa.europa.eu/documents/10162/17228/report_tce_authorisation_en.pdf
[22] https://echa.europa.eu/documents/10162/2082415/change_of_tonnage_of_axiv_substances_2010_21_en.pdf

Restrictions

The Chemicals Strategy for Sustainability includes plans to potentially extend the generic approach to risk management under REACH. Until such changes are introduced into REACH, the European Commission has published a Restrictions Roadmap which sets out a plan for ongoing and future work on restrictions under REACH. ECHA has proactively participated in the roadmap's preparation. Our input has been provided on planned restriction activities and offering expert advice on Member State comments regarding the draft roadmap. We also provided estimates on the resources that will be required to develop future restriction proposals and assess them in our committees.

In 2022, six restriction proposals were submitted (two by ECHA and four by Member States).

In January, ECHA submitted a proposal to restrict the use of per- and polyfluoroalkyl substances (PFASs)[23] in firefighting foams due to their persistence and potential to cause environmental contamination, both in soil and drinking water. If adopted, this restriction could reduce emissions of PFASs into the environment by more than 13 000 tonnes over 30 years but would also cost society an estimated EUR 7 billion over the same period[24].

Furthermore, ECHA submitted a restriction proposal on medium-chain chlorinated paraffins (MCCPs) and other substances containing chloroalkanes (C14 to C17) with persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB) properties. The restriction follows a group approach that aims to reduce the risks by preventing regrettable substitution.

The four restriction proposals submitted by Member States were for creosote and creosote-related substances; bisphenols with endocrine disrupting properties for the environment and their salts; N,N-dimethylacetamide (DMAC) and 1-ethylpyrrolidin-2-one (NEP); and terphenyl, hydrogenated.

Throughout the year, ECHA's committees adopted four opinions on restriction proposals for Dechlorane Plus, 2,4-dinitrotoluene, polycyclic aromatic hydrocarbons (PAHs) in clay targets and lead in ammunition for hunting, outdoor sports shooting and fishing.

Dechlorane Plus is used as flame retardant, but its persistence and bioaccumulation are a risk to people's health and the environment. Both the Committee for Risk Assessment (RAC) and Committee for Socio-Economic Analysis (SEAC) believe that a restriction on its use would be effective in reducing risks, while SEAC also noted differences in the cost-effectiveness of the different restriction options proposed by Norway.

The committees adopted opinions to limit 2,4-dinitrotoluene – a substance found in consumer and professional products but known to cause cancer. The substance has been on the Authorisation List since 2011. They also supported a proposal to restrict polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting to prevent environmental emissions. PAHs are toxic and persistent substances, and many are known to cause cancer.

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[23] Additionally, five European countries (Denmark, Germany, the Netherlands, Norway and Sweden) submitted a separate proposal to restrict the use of all PFASs in other applications. The proposal was submitted to ECHA in January 2023 and an online information session was held in February 2023.

[24] These costs would include, among others, the price of modifying equipment for using PFAS-free foams, the cleaning of equipment to remove PFAS foam residues and the price difference between PFASs and alternative foams.

The restriction proposal submitted by ECHA on the use of lead in outdoor shooting and fishing received support from RAC and SEAC. Both committees agreed on the proposal to ban the use of lead in gunshot, bullets and in fishing tackle, with a derogation for the use of lead bullets in sports shooting ranges if appropriate risk management measures are taken to prevent the contamination of soil and water. Transitional periods for the entry into force of the conditions of the restriction ranging from 18 months to five years were proposed by RAC and SEAC to ensure that alternatives are available for those uses for which a ban is supported.

ECHA also prepared screening reports under Article 69(2)[25], finalising three during 2022 for 10 phthalates, trichloroethylene and 1-bromopropane.

ECHA also co-organised the 10th meeting of the Network of REACH SEA and Analysis of Alternatives practitioners (NeRSAP)[26] to exchange on advances and review of concepts, methods and experiences in socio-economic analysis and analysis of alternatives.

Classification and labelling

The requirement to classify, label and package products appropriately before they are placed on the market helps to keep workers and consumers informed about chemical hazards, and to protect the environment.

The hazards of a substance or mixture need to be communicated to all actors in the supply chain. Labels and safety data sheets help to alert those using the substances or mixtures to their risks and how to use them safely.

In 2022, ECHA received 46 harmonised classification and labelling dossiers – for 33 industrial chemicals and 23 new classifications were proposed for carcinogenic, mutagenic and reprotoxic (CMR) substances. 19 active substances used in biocides and plant protection products were also processed.

ECHA's Committee for Risk Assessment (RAC) continued its scientific work, adopting 40 opinions proposing to give those substances a harmonised entry throughout the EU. These included six carcinogens, three mutagens, 10 affecting reproduction and 12 causing sensitisation.

At the end of May, RAC agreed to keep glyphosate's current classification as causing serious eye damage and being toxic to aquatic life. Based on a wide-ranging review of evidence, the committee again concluded that classifying glyphosate as a carcinogen is not scientifically justified. RAC's opinion is consistent with the proposal from the four Member States assessing glyphosate: Sweden, France, Hungary and The Netherlands as well as the committee's earlier 2017 opinion.

[25] After the sunset date has passed for a substance included on the Authorisation List (Annex XIV), Article 69(2) of REACH requires ECHA to consider if the use of the substance in articles is adequately controlled and, if it isn't, prepare a restriction dossier which conforms to the requirements Annex XV.

[26] https://echa.europa.eu/support/socio-economic-analysis-in-reach/network-of-reach-sea-and-analysis-of-alternatives-practitioners

The case now moves forward to the European Food Safety Authority (EFSA) with their risk assessment expected in July 2023. After this, the European Commission will analyse the conclusions and put forward a renewal report and a draft regulation for Member States on whether glyphosate's renewal can be approved or not.

For poison centres, ECHA received and processed around 2.4 million poison centre notifications by the end of 2022. Belgium, Luxembourg, and Iceland joined the majority of EU and European Economic Area (EEA) Member States in accepting notifications through ECHA's submission portal, with only Bulgaria and Slovakia still to accept that their companies submit their notifications through ECHA's systems.

Minor changes were made to our Guidance on harmonised information relating to health emergency response[27] for poison centres in May. The update clarified obligations and options for importers and non-EU suppliers, the use of generic component identifiers and the application of the transitional period. Updates to the rules for group submissions were also added.

A meeting was also held with stakeholders in November to help them prepare for the last compliance date for mixtures for industrial use in January 2024.

Safe and sustainable use of chemicals

Our work on safe and sustainable use of chemicals has focused on providing technical and scientific support and guidance to companies. This includes assisting them in assessing chemical safety and developing chemical safety reports.

We continued development of the Chesar Platform to support both REACH and Biocides and plan to release it in 2024. The platform will help companies to perform their chemical safety assessments and generate chemical safety reports under REACH. For biocides, it will enable users to carry out environmental risks assessments for active substances and biocidal products.

A community of stakeholders has been established in 2022 with the aim to collect feedback and support the development of the Chesar Platform to fit the user needs. The community is also providing feedback on updates to the Guidance on chemical safety assessment.

Alongside this work, basic maintenance of industry-developed use maps has continued as well as support on preparing the manual for the Forum's REF-11 project on the quality of information in safety data sheets.

With regard to substitution, in June, ECHA organised a capacity building session on analysis of alternatives and substitution plans for SEAC members. ECHA also continued to provide input to the OECD's work on safe and sustainable chemistry, participating in a workshop in September.

ECHA also continued to support the European Commission in developing its criteria for safe and sustainable by design, as well as support for the Digital Product Passport and the Ecodesign Regulation.

[27] https://echa.europa.eu/documents/10162/13643/guidance_on_annex_viii_to_clp_en.pdf/412c5874-f8ec-cf52-fe1e-2fbe08fe2d11

Data management and dissemination

ECHA's dissemination platform, that makes information on chemicals publicly available, experienced a number of issues in 2022. During the year, we surveyed and interviewed more than 1 500 stakeholders to gather their requirements for a new dissemination system. Stability of the platform is a significant concern, but they also highlighted the need for better navigation and search functionality. As we move forward with the redesign and upgrade, we plan to continue gathering feedback from stakeholders in the years to come.

Steps were taken to enhance data availability throughout the year. In April, the pharmaceutical industry made previously unpublished data on 19 chemicals, tested to develop medicines, available as IUCLID datasets. The information can be used to develop predictive computational testing models and promote alternative test methods to replace animal studies.

REACH study results were refreshed in August, with 654 new substances added since September 2021. They contain non-confidential substance data submitted to ECHA under REACH from studies related to physical-chemical properties, environmental fate and pathways, and ecotoxicology and toxicological information. Making these available is another step forward towards improving safety data sheets and developing alternative methods.

Further developments were deployed for the Data Extractor and the Text Analytics search engine, as well as the first official release of the Data Uploader, all tools which will allow users to easily convert and manage their chemicals data in IUCLID format.

Under the European Commission's Chemical Strategy for Sustainability, ECHA co-led a subgroup[28] with Directorate-General Environment to develop a draft implementation plan for an EU common data platform on chemicals.

The idea is to create access to more comprehensive data and information on chemicals held by EU agencies and the European Commission as part of their tasks. This will ease the sharing, access, and dissemination of data from ECHA, the European Medicines Agency (EMA), European Environment Agency (EEA), the European Food Safety Authority (EFSA) and the Joint Research Centre (JRC) and will also support the needs of regulatory authorities, companies, academia and the public.

Biocides

Biocidal products protect people, animals, and goods by controlling harmful organisms, including pests and microorganisms. They contain active substances that need to be approved before the biocidal product can be authorised. Member States assess the applications for approval of active substances and for Union authorisation of products, and ECHA's Biocidal Products Committee (BPC) forms scientific opinions on these assessments. The committee's opinions serve as a basis for the European Commission to decide on whether or not to approve the active substances or grant the Union authorisations.

In 2022, the BPC adopted 19 opinions for active substance approvals within the review programme, maintaining the levels seen in the previous year (18 opinions in 2021), which is below the targets set to make significant progress in the review programme based on the initial plans of Member States. For Union authorisations[29], a positive trend continued, with the number

[28] Participants from the European Food Safety Authority (EFSA), European Medicines Agency (EMA), European Environment Agency (EEA), the Joint Research Centre, and Directorate-Generals RTD, SANTE and GROW.
[29] The procedure through which companies can apply for permission to place their biocidal products on the market throughout the EU, without needing specific national authorisations.

of BPC opinions on Union authorisation increasing to 22 this year (15 in 2021 and 9 in 2020).

It has become evident that the obligation in the Biocidal Products Regulation of reviewing all existing active substances[30] by 2024 will not be achieved, as Member States are submitting fewer draft assessment reports than expected. ECHA will continue to offer support to Member States to complete as many substance assessments as possible. Specific support is also provided on the assessment of endocrine disrupting properties, which has been particularly challenging in the evaluation of active substances in several Member State dossiers.

Throughout the year, the BPC provided opinions on various challenging cases that were pending, such as the approval of sulphur dioxide and ozone. Many biocidal active substances can also be used as pesticides, food additives, or components in food contact materials and, as such, are also regulated under other EU legislative frameworks. In collaboration with the European Food Safety Authority (EFSA), we make substantial efforts to align our perspectives in the context of the 'one substance, one assessment' concept as a key aspect of the Chemical Strategy for Sustainability. Despite these efforts, it was not possible to achieve full alignment in the case of sulfur dioxide[31], and a broader alignment of EU chemicals regulation requirements, approaches and decision-making procedures will be needed to fully achieve the 'one substance one assessment' concept. In the meantime, the efforts will continue with the aim to bring about harmonisation and coherence in hazard and risk assessments to the extent possible.

Another example of the groundwork in 'one substance, one assessment' is our collaboration with EFSA to develop joint guidance on the impact of water treatment processes on active substance residues in drinking water, which is expected to be concluded in 2023.

Another area of significant progress is the development of a specific guidance on the assessment of alternatives to active substances meeting the exclusion and substitution criteria, the *Guidance for applicants and Member States*[32] that was adopted by the BPC in its December meeting. The guidance is based on pilot cases: in June, the BPC found that there are no suitable alternatives currently available for hexaflumuron for use as an insecticide, acaricide and in products to control arthropods. Due to its persistence, bioaccumulation, and toxicity, this active substance meets the exclusion criteria, which means its approval is only possible on the grounds of protection of public health, as there are currently no alternatives.

Later in the year, the committee carried out a comparative assessment for anticoagulant rodenticides, looking at both chemical and non-chemical alternatives. The committee found that mechanical traps are suitable for controlling indoor mice infestations, but that their effectiveness is uncertain for other uses and for controlling other rodents like rats.

In September, we took a step forward in developing guidance for assessing the risk to pollinators, by publishing a scientific report on the biodiversity, ecology, and sensitivity of pollinators other than bees to biocides[33]. The report thoroughly explains the ecology of four insect groups that together cover the majority of flower-visiting pollinators. The findings showed that certain species can be just as sensitive, or even more so, to some active substances compared to

[30] Active substances which were on the market in biocidal products on 14 May 2000.
[31] https://echa.europa.eu/documents/10162/763823/joint_echa_efsa_comparison_evaluations_en.pdf/9805dc77-9434-6ae1-0267-fa68ecb3b9c2?t=1671533934305
[32] https://echa.europa.eu/documents/10162/1276600/guidance_analysis_alternatives_biocides_en.pdf/10646cd2-8ec9-36a8-2f00-201fcc49c43e
[33] https://echa.europa.eu/documents/10162/17231/nbp_report_en.pdf/7ea8718e-2d64-141e-9f23-3c9207dcd824

honeybees. However, due to limited knowledge on the variability of sensitivity, further research is necessary to fill data gaps on the species' ecological traits before a proper assessment of the risk posed by biocidal products can be conducted.

Environmental Directives and International Conventions

Prior informed consent

In April 2022, 22 chemicals were added to the Prior Informed Consent (PIC) Regulation, including the first substance-in-substance entry for substances containing benzene as a constituent in concentrations equal or greater than 0.1% weight-by-weight. The update started to apply in July, while the necessary changes to ePIC – ECHA's IT system for PIC implementation – were in place since April 2022 already.

In 2022, ECHA processed 10 071 export notifications – an approximate 6% decrease compared to the previous year. The workload for explicit consent requests increased by around 10% compared to 2021, while waiver-related tasks stabilised. Our workload on PIC also increased with the receipt in 2022 of 11 new access to document requests – seven of which were completed by the end of the year[34].

Our October report on the exchange of information under PIC highlighted a 23% increase in export notifications during 2020-21, compared to 2018-19. The notifications contain information on where the chemicals are exported, their uses and hazardous properties, as well as how to safely store, transport, use and dispose them. The EU must provide these export notifications to authorities in non-EU importing countries before the chemicals can be exported.

In 2022, we drafted seven new final regulatory action (FRA) notifications and provided them to the European Commission. We also revised five existing FRAs. These notifications inform Parties to the Rotterdam Convention[35] that the use of certain chemicals has been banned or severely restricted in the EU and are a first step towards the possible inclusion of these chemicals in the global convention.

In December, we published our report looking back at the trade in chemicals exported from and imported to the EU under PIC in 2021. The report showed a significant increase in reported trade volumes of PIC chemicals, in large part due to the change in status of the United Kingdom (UK) from an EU to a non-EU country. No longer considered internal market trade, exports and imports between the EU and UK are now reported under PIC.

The UK also contributed considerably to increases of imports to the EU in 2021. The total amount of PIC chemicals that came into the EU in 2021 was around 883 000 tonnes, a 120% increase compared to 2020 figures. Around one third of this volume came from the UK.

In November, data on chemicals subject to PIC, export and import notifications, explicit consents and waivers, and lists of designated national authorities were all fully integrated into ECHA's dissemination platform. Searching PIC data has been streamlined with each PIC dataset having

[34] The four ongoing requests were closed in early 2023.
[35] http://www.pic.int/

its own custom search functionality and available for bulk download.

ECHA continued throughout the year to provide support to the European Commission, not only in *ad hoc* discussions with EU and non-EU authorities, but also in reporting, international cooperation (particularly participation at the Rotterdam Convention Conference of the Parties meeting in June) and policy implementation and development through meetings with designated national authorities and providing input on possible improvements to PIC legislation.

Persistent organic pollutants

Exposure to persistent organic pollutants (POPs) can have various severe adverse health effects. For instance, they may lead to conditions such as cancer and birth defects. To tackle these concerns, the Stockholm Convention was set up as a global treaty to address the negative impact that these biodegradable resistant chemicals have on human health and the environment.

The EU enforces the Stockholm Convention through the POPs Regulation, tasking ECHA with, for example, identifying and proposing new POPs within the EU.

The draft risk management evaluation for methoxychlor, an organochlorine pesticide used as an insecticide, was adopted in January. ECHA played a supportive role in the process, assisting the European Commission in drafting the risk management evaluation and the substance was recommended for inclusion in the Stockholm Convention by the Persistent Organic Pollutants Review Committee (POPRC).

In its role of providing technical and scientific support, ECHA assisted the European Commission and Member States in preparing and reviewing the draft risk profile for chlorpyrifos and draft risk management evaluations for Dechlorane Plus and UV-328. ECHA's committees adopted opinions on the restriction proposal for Dechlorane Plus, that supported the risk management evaluation of the substance in the POPRC.

In May, we launched consultations looking for relevant information to support draft risk management evaluations for Dechlorane Plus and UV-328, and to invited comments on the draft risk profiles for chlorpyrifos, chlorinated paraffins and long chain perfluorocarboxylic acids (LC-PFCAs). The risk management evaluations for each of these substances were adopted by the POPRC in September, with both substances recommended for listing under the Stockholm Convention.

In November, ECHA released a Union Overview report[36] and individual reports for each Member State[37], detailing the implementation of the POPs Regulation in the EU. The reports provide information on various aspects of POPs, such as manufacturing, market placement, stockpiling, enforcement actions and releases of POPs into the environment.

[36] https://echa.europa.eu/documents/10162/16596982/pops_union_overview_report_en.pdf/0995480d-5f55-4f08-999c-339395c93482
[37] https://echa.europa.eu/planning-and-reporting

Waste Framework Directive

Data on products containing substances of very high concern (SVHCs) is collected in ECHA's SCIP database[38]. This information is made available throughout the product's lifecycle, including when it becomes waste. This aims to help waste operators improve their recycling practices so they can prevent harmful substances from re-entering the market. It may also help consumers make more informed and sustainable purchasing choices. All of this supports the goals of a circular economy.

In 2022, companies across the EU had successfully submitted almost 10 million notifications (including updates) to the database. The data collected increases knowledge about which harmful chemicals are present in supply chains and can help companies to phase them out.

Throughout the year, ECHA continued to improve the way information is displayed in the database, stabilising the system, and providing help to stakeholders through support documents and events. ECHA also made progress in developing reports that would allow this information to be used for regulatory purposes, specifically for the restriction process.

A survey was launched in March to collect ideas from users on how to further enhance the database, and a workshop was held with waste operators who gave feedback on their use of SCIP data.

In May, this was followed up by an evaluation[39] of SCIP, assessing the extent to which objectives have been achieved and performing an assessment of the costs incurred. The results will help in assessing the future needs and determine priority areas for the database, albeit several of the shortcomings identified would require amendments to the legal text (for example, mandatory information requirements).

New service releases for IUCLID brought improvements that also benefitted SCIP users. The IUCLID validation assistant was aligned with official Candidate List updates, and further fixes helped to increase confidentiality when managing SCIP data and avoid duplications of submitted data.

Drinking Water Directive

The revised Drinking Water Directive came into effect at the start of 2021. The recast gave ECHA a new role in setting up and managing lists of chemicals that can be safely used in materials that come into contact with drinking water. The aim of the directive is to improve people's access to safe drinking water, protect them from contamination and to ensure that safety and hygiene standards for companies are harmonised throughout the EU.

Member States notified their existing national lists to ECHA in July 2021. These covered around 2 300 substances. ECHA compiled them into draft European positive lists for the different materials that come into contact with water – organic, cement, metal and enamel, ceramic, or other inorganic materials.

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[38] SCIP is the database for information on Substances of Concern In articles as such or in complex objects (Products) established under the Waste Framework Directive (WFD).
[39] https://echa.europa.eu/documents/10162/6205986/scip_evaluation_report_en.pdf

Throughout 2022, the Agency has been verifying the lists. ECHA will recommend an expiry date for each entry taking the hazardous properties of the substances and any related risk assessments into account. Once the lists have been verified, they will be sent to the European Commission which will decide on their adoption and set the expiry dates by 12 January 2025 at the latest, and most likely earlier than that.

Companies that want their substances to remain on the lists must send a review application to ECHA before the relevant expiry date. To guide them, we have been drafting guidance, which will be made available in 2024.

ECHA's Committee for Risk Assessment (RAC) will adopt opinions on the applications and send them to the European Commission, which will then decide whether to keep the entries, amend them or remove them from the lists.

Support to 8th Environment Action Programme

The 8th Environment Action Programme is a joint initiative for implementing the European Green Deal. The programme set objectives to support a green recovery in Europe and ensure a transition toward minimising pollution and reversing climate change. It enshrines EU environmental and climate objectives into law, as well as mechanisms to monitor progress.

Together with the European Environment Agency (EEA), we have provided technical support to the European Commission in developing a framework of chemical indicators that will help to monitor the effectiveness of the Chemicals Strategy for Sustainability (CSS).

Based on the data we hold, we developed prototype algorithms for two impact indicators:

1. progress in regulating high tonnage substances under REACH and CLP; and

2. economic growth on the EU chemicals markets using substances with different levels of concern.

A third indicator related to the rate at which substances with different levels of concern are identified is under development.

In collaboration with the EEA, ECHA is developing a common report with joint messages on EU progress towards the policy objectives of the CSS. The report will accompany the CSS indicator dashboard, which is expected to be published in early 2024.

Other tasks

EU Observatory for Nanomaterials

The European Union Observatory for Nanomaterials (EUON)[40] gathers information about nanomaterials on the EU market and generates new data by commissioning market studies.

During 2022, three literature studies were outsourced, and their results published. The first predicted growth in volume and value of the EU nanomaterial market between 2021-25. Such growth is being driven by technological advancement and public demand for functional, lightweight, and state-of-the-art products that are affordable. While EU and national public funding is an enabler for continued development, the current regulatory landscape does not

[40] EUON development is financed by a separate contribution agreement with the European Commission.

allow products containing nanomaterials to be commercialised easily. A strict regulatory regime does, however, increase public trust in nanomaterial products.

The second study assessed potential health and environmental effects of graphene, its derivatives and other 2D materials, recommending for doses and exposure scenarios to be considered when risks are identified. The study also called for more research efforts to assess the toxicity and ecotoxicity of graphene-based materials using OECD test guidelines and ISO documentary standards.

The third study provided information on the state-of-the-art, the existing gaps, and the research needs of the degradation, biodegradation, and persistence of nanomaterials. The study also pointed out the need for a common definition for 'safe-by-design' – the process of including safety at the earliest stage of product development – to increase the societal acceptance of nanomaterials.

NanoData – the knowledgebase on nanosciences and technologies – was given a facelift to improve the user experience. Data and statistics on different products, research projects, publications, patents and organisations can now be visualised using built-in charts and graphs, and easily filtered by sector and location. It can also be downloaded in bulk.

The EUON website was also refreshed with new and updated content on the use of nanomaterials in medicine, the environment, cosmetics, and more topics related to safety.

Views from different experts were also published throughout the year in the Nanopinion[41]. These guest columns covered topics including how nanomaterials can bypass the blood-brain-barrier, challenges in developing models to characterise exposure to nanomaterials, and how nanowire-based devices can detect cancer.

EU Chemicals Legislation Finder

In 2022, the European Union Chemicals Legislation Finder (EUCLEF)[42] continued to offer up-to-date information to users on how their substances are regulated across 56 pieces of chemicals legislation. The finder is integrated into our chemicals database and is available free of charge. Users can search it for information on the laws that apply to their substances and check which obligations they have.

The scope of EUCLEF was updated to cover new regulations concerning medical devices that replaced repealed directives. Among the updates was the fifth list of indicative occupational exposure limits values, completing the finder's coverage of EU lists for OELs.

The user friendliness of the EUCLEF web pages and the finder's visibility have been further improved, based on the feedback from the strategic assessment carried out in 2021.

Efforts were also made to promote the dedicated EUCLEF Helpdesk, which users can contact if they need help in clarifying which chemicals legislation applies to their business.

[41] The Nanopinion is a platform where EUON invites views ranging from policy makers and authorities to industry and civil society on their work and areas of interest related to nanomaterials and nanotechnology.
[42] EUCLEF is funded by the EU Programme for Competitiveness of Enterprises and Small and Medium-sized Enterprises (COSME). ECHA maintains and develops EUCLEF through a contribution agreement with the European Commission.

Support to occupational health legislation

Occupational exposure limits (OELs) are values set by authorities at EU and national levels that help employers protect their workers' health from possible risks when using chemicals at work and limit exposure to harmful chemicals in the air of a workplace. In 2022, ECHA's Committee for Risk Assessment (RAC) adopted four opinions on the evaluation of OELs for isoprene, 1,4-dioxane, cobalt and inorganic compounds, and polycyclic aromatic hydrocarbons.

Isoprene is an intermediate used in the rubber industry and in the chemical industry to produce polymers. It is also produced and emitted naturally by many species of trees, accounting for around one third of all hydrocarbons released into the atmosphere.

While there are no studies directly assessing isoprene's cancer risk to humans, there is some evidence of an increased cancer incidence in exposed humans within the rubber industry. Animal tests have also indicated genotoxic carcinogenicity. Since it is difficult to derive an exposure-risk relationship from animal data that accurately reflects the cancer risk in humans, RAC set an OEL within the statistical range of total internal isoprene levels at 8.5 mg/m^3 (3 parts per million (ppm)).

1,4-dioxane is used as a solvent in industrial settings. It has a harmonised classification under the CLP Regulation as a category 1B carcinogen, which means it is presumed to have cancer potential for humans. After repeated dose exposure, the main organs affected are the respiratory tract (particularly the nasal cavity), liver and kidney. Based on systemic effects in the kidney, RAC proposed an OEL of 7.3 mg/m^3 (2 ppm). This would also protect workers from nasal irritation effects and the effects found in the liver.

Cobalt and its inorganic compounds are considered carcinogenic without a threshold, and no human data is available to set a limit value or derive a dose response. To estimate lung cancer risks of cobalt, RAC adopted a sublinear approach using animal data, and an exposure limit of 0.5 µg cobalt/m3 was identified as the breakpoint for the dose-response.

For polycyclic aromatic hydrocarbons (PAHs), RAC agreed on a cancer exposure-risk relationship (ERR) based on benzo-a-pyrene. Once the Working Party on Chemicals of DG-EMPL's Advisory Committee on Safety and health (WPC-ACSH) recommends an OEL based on this ERR, a corresponding biological limit value can be set.

In November, ECHA released a scoping study[43] evaluating workplace exposure to welding fumes. The study found a diverse array of health effects. Some were acute, like asthma or pneumonia, caused by irritation to the gases or exposure to fumes containing certain metals. Others were chronic – lung cancer, occupational asthma, chronic obstructive pulmonary disease (COPD), and pneumosiderosis (welder's lung). The presence of manganese in some fumes also caused some neurological effects.

Five new requests for setting occupational exposure limits were received under the 2022 contribution agreement with the Commission – four single chemicals and a group[44]. RAC opinions for these will be adopted by February 2024.

[43] https://echa.europa.eu/documents/10162/7399806/report_welding_fumes_en.pdf/45d744a8-da00-7ebe-3890-0a4cded3bf7d

[44] 1,2,3-trichloropropane (EC 202-486-1, CAS 96-18-4); 1,2-dichloropropane (EC 201-152-2, CAS 78-87-5); glycidyl methacrylate (EC 203-441-9, CAS 106-91-2); chloroprene (EC 204-818-0, CAS 126-99-8); and a group of nitrosamines (EC -, CAS -).

Instrument for Pre-Accession Assistance (IPA)

With a view to readying to align to EU chemicals legislation, the gaps and needs of Albania, Bosnia and Herzegovina, Kosovo, North Macedonia, and Türkiye were assessed[45].

The outsourced studies identified shortcomings in institutional capacity and infrastructure, and generated national action plans to ready the five candidates and pre-candidates for enacting EU chemicals laws. The findings showed that the countries would need more financial, human and IT resources to be able to successfully implement and enforce the REACH, CLP, BPR, PIC and POPs regulations.

To overcome such challenges, the study recommends for their national authorities to strengthen cooperation with academia, increase communications activities and dedicate more resources to IT. Under a signed IPA agreement, ECHA will continue supporting this work by providing training on enforcement, risk assessment, and IT security and tools.

In June, Ukraine and Moldovia were granted candidate status in the context of EU membership. ECHA will play a role in supporting them to align their legal frameworks for chemicals management with that of the EU.

Also that month, ECHA took part in the yearly informal meeting between EU agencies working with pre-accession and European neighbourhood programmes in Budapest. Hosted at the EU Agency for Law Enforcement Training (CEPOL), the meeting was an opportunity to discuss important issues of common interest and exchange experiences.

Support to other legislation

In April, the Commission proposed revisions to the Industrial Emissions Directive aiming to cut down environmental emissions from some of Europe's key industries. The revision would formalise the role ECHA has taken in this area in drawing up best available technique reference documents (BREFs) for different sectors.

It would also require ECHA to contribute further to a methodology for on-site risk assessment to manage (through an inventory) input chemicals and their resulting emissions. This would require continued input to the Joint Research Centre and the Sevilla process from ECHA's databases to generate a list of hazardous substances potentially used in sectors, characterising sectoral use of the substances, and defining best practice for using the safest alternatives on the market. ECHA would also provide other technical support for revising the BREFs.

This is work that the Agency has done in the past, but if the proposals are adopted, then ECHA will be formally resourced and expected to contribute on a systematic basis from 2024 onwards.

ECHA took part in a kick-off meeting aimed at revising the BREF for surface treatment of metals and plastics in June. This sector plays a major role in extending the life of metals, particularly in the aerospace, automotive and construction industries, but has an environmental impact particularly for energy and water consumption. The revision of the BREF would strengthen environmental management systems that are essential for minimising such impacts.

[45] https://echa.europa.eu/about-us/partners-and-networks/international-cooperation/support-to-eu-external-relations-policies/activities-under-ipa/2020-2022?panel=study-visit#study-visit

IUCLID for EFSA

The EU's regulation on transparency and sustainability of risk assessment in the food chain requires applicants to provide plant protection product dossiers to the European Food Safety Authority (EFSA) in IUCLID format.

ECHA and EFSA have a service level agreement in place for EFSA to use IUCLID to carry out its regulatory tasks on plant protection products.

In March 2022, IUCLID was rolled out for use by EFSA to handle active substance applications and product authorisations for plant protection products. IUCLID has been configured and modified to handle the submission and dissemination of plant protection product dossiers. This is an example of the central role IUCLID can have as a tool for chemicals data management across legislation. The use of additional data tools, such as Text Analytics and Data extractor is being further explored.

The suitability of IUCLID for other food regulated products, including food contact materials is also being explored. Cooperation between ECHA and EFSA will continue to define the necessary support, resources and IT solutions for these cases.

Partnership for the Assessment of Risks of Chemicals (PARC)

The Partnership for the Assessment of Risks of Chemicals (PARC)[46] is an EU-wide research and innovation programme that seeks to develop next-generation chemical risk assessment that protects health and the environment. ECHA is actively participating, for example, with our grouping work contributing to the PARC project on bisphenol alternatives.

To avoid situations where one hazardous bisphenol is replaced with another that may be equally harmful, ECHA and the Member States have assessed 148 bisphenols as a group. Assessing the effects of bisphenol A alternatives and mixtures is one of PARC's projects that aims to address data gaps for prioritised substances of concern.

With some alternatives being low tonnage substances, data under REACH is lacking. As such, the first step in the project was to select further bisphenols for data generation. A list of alternatives to bisphenol A was compiled and ECHA provided valuable feedback on their regulatory relevance for testing, based on our experience with the grouping work and other criteria such as potential for substitution.

In June, a workshop was held with Member States and research partners to discuss the possible alternatives and the results will be used to refine the project and close data gaps for selected alternatives.

In the future, we will continue to give our regulatory expertise on other PARC projects, and the partnership will also serve as a platform for developing new approach methodologies for different areas, such as neurotoxicity, endocrine disruption or immunotoxicity.

[46] The partnership builds on the work undertaken as part of the European Joint Programme on human biomonitoring HBM4EU, which came to an end in summer 2022, expanding the scope to cover the assessment of environmental risks.

Governance and enablers

Forum

In October 2022, ECHA published the results of a pilot enforcement project on substances recovered from waste[47], which found that more than a quarter of recovered substances checked were in breach of REACH registration requirements.

The project also found that while safety data sheets were, in most cases, being provided with recovered substances and mixtures, some lacked crucial information specifically on substance identity. Based on the findings, the Enforcement Forum recommended that waste operators placing recovered substances on the market should contact their customers to gain a better understanding of how the substances were being used. Authorities enforcing REACH and the Waste Framework Directive, respectively, were also encouraged to strengthen their cooperation.

The results from the EU-wide enforcement project (REF-9) controlling REACH authorisation requirements for substances of very high concern (SVHCs) on the Authorisation List were delayed until early 2023. Inspections for this project began later than scheduled due to COVID-19 and were extended due to these delays.

Inspections for the second biocides enforcement project (BEF-2) checking the compliance of biocidal products and the use of approved active substances began in January and continued throughout 2022. The project will specifically check the compliance of disinfectants that have been widely used during the COVID-19 pandemic. A workshop for national coordinators of the project was held in June 2022, and the results are expected in 2023.

The Forum also held its yearly open session with stakeholders in November. Among the topics discussed were market surveillance for REACH compliance for textile products, difficulties in enforcing the restriction of lead ammunition in wetlands, and analytical methodologies for checking the regulatory compliance of absorbent hygiene products.

[47] https://echa.europa.eu/-/one-in-four-substances-recovered-from-waste-non-compliant-with-reach

Management

Governance and Management Board

Management Board

The Management Board provides strategic direction and governance to ECHA to enable the Agency to deliver on its mission and vision and meet the expectations of its stakeholders. In 2022, the Management Board guided the Agency through a leadership transition and re-appointed its Chair, Paul Krajnik, and Deputy-Chair, Claudia Dumitru, for second terms of office of two years.

Following the retirement of ECHA's previous Executive Director in March 2022, the Management Board appointed an Acting Executive Director to provide stability for ECHA and ensure the effective implementation of the 2022 Work Programme until the future Executive Director could take office. Dr Sharon McGuinness started as the new Executive Director on 1 December 2022, following her selection by the Management Board in June. She appeared before the European Parliament and answered questions from its members prior to her appointment.

The Management Board adopted all statutorily required documents in line with the applicable rules and regulations. They carried out the annual appraisal exercise of the former Executive Directors and set objectives for the probationary period of Dr Sharon McGuinness. They also confirmed the Legally Qualified Member of the Board of Appeal in her functions and conducted the annual appraisal exercise of all Board of Appeal members.

The Management Board regularly discussed significant risk and control issues, including information security and IT business continuity, as a standard agenda item.

Communications

ECHA is committed to ensuring the safe use of chemicals, and communication plays a critical role in achieving this. Clear, accurate and accessible information is crucial for ensuring that the information we share is understood by our stakeholders, and that companies can meet their obligations under EU law. Effective communication is therefore a vital part of our mission.

ECHA had a successful 2022, with a total of 21 news releases and numerous updates on our website covering important topics from the year such as the re-evaluation of glyphosate's hazard classification, the proposed restriction on lead in ammunition, our grouping approach on risk management for 300 harmful chemicals, and the results of an enforcement project on substances recovered from waste. These activities resulted in an 18% increase in media coverage compared to 2021, totalling more than 4 800 clippings during the year. Additionally, general media coverage rose from 58% to 80%.

Our website visits have remained steady compared to 2021 figures, with nearly 13 million visits during 2022. We also experienced growth in our social media channels, with a 20% increase in followers on LinkedIn (52 400), 37.7% on Twitter (20 500) and 5.2% on Facebook (10 780). Our videos on YouTube also received more than 500 000 views during the year.

In May 2022, ECHA collaborated with four sister agencies[48] to launch a joint Instagram channel

[48] The European Centre for Disease Prevention and Control (ECDC), the European Environmental Agency (EEA), the European Food Safety Authority (EFSA), and the European Medicines Agency (EMA).

called 'One Health One Environment', which covers topics related to health and the environment. The channel saw significant growth, gaining 8 100 new followers by the end of the year.

Internally, ECHA's focus has been on preparing for the launch of our revamped intranet platform, ECHAnet. The platform was redesigned to improve how staff connect, collaborate, and communicate, as well as to provide easier access to information and resources that staff need for their work. The platform was successfully launched at the start of 2023.

Financial management

The Agency's budget is managed in line with rules and regulations as well as principles of economy, efficiency and effectiveness, to support the delivery of ECHA's Work Programme. In 2022, the budget was successfully executed to a high degree and the Agency received a clean financial audit report.

ECHA effectively managed its financing in 2022, closely monitoring fee income development and reaching a 99% commitment rate and 85% payment rate, surpassing the targets set. The European Court of Auditors gave a clean audit opinion on ECHA's annual accounts for 2021 and their first audit mission on the financial year 2022 concluded without any preliminary findings.

The initial budgetary payment appropriations for expenditure in 2022 was EUR 112.7 million, including EUR 0.8 million for 'Other Tasks'. The final expenditure need in the second amending budget in September was EUR 117.0 million, including EUR 2.4 million for 'Other Tasks'. The budget increase was due to positive fee income development and advancing certain IT projects that has initially been expected in 2023. Despite the financial challenges of fee income uncertainty and high inflation, ECHA effectively used its funds and received a clean audit opinion from the European Court of Auditors for its financial and procurement operations.

ECHA continued working towards a sustainable and predictable fee income model and a simpler budget structure. We submitted a fee options analysis to the Commission in 2021 and responded to follow-up questions throughout the year to support the development of a new financing model.

Details on ECHA's budget information and management in 2022 can be found in Appendix II.

Human resources management

ECHA embraced a cautious return to the office in 2022, starting in March with a gradual approach and ending with the implementation of new hybrid working rules in October 2022. The new rules promote flexibility and staff empowerment while maintaining social cohesion and collaboration through regular weekly presence at the office. ECHA continued to implement its 2019-2023 Human Resources (HR) Strategy and had a high rate of filled establishment plan posts (98%) with low Temporary Agent turnover (3%). We also launched a number of successful initiatives to support staff wellbeing and development.

With the new rules on hybrid working and working time, we followed the example set by the Commission in guiding staff back to the office. Through a measured approach, guidance and communication, we ensured that the benefits of teleworking were combined with regular in-office presence.

The HR Strategy continued to advance with a focus on internal mobility, an agile culture and staff competence development. Our competence mapping process was reviewed, and management development programmes were implemented for middle and senior management. To motivate employees and build skill sets, we introduced new initiatives including mentoring and coaching. The Diversity and Inclusion Working Group at ECHA continued its efforts to raise awareness and promote diversity and inclusion. In 2022, the group successfully introduced the

ECHA Charter on Diversity and Inclusion and published it online[49]. An action plan was put into effect to bring more visibility to the Charter's objectives, including aiming to achieve gender balance in the management team. One example of the action plan's implementation was the hosting of an internal event for ECHA staff, which aimed to increase the visibility of our female managers. This event sparked increased interest among female colleagues in pursuing managerial positions.

The Commission initiated a comprehensive inter-Agency benchmarking process, and as part of this process, we carried out a job screening exercise to determine the number of posts working on administrative tasks versus operational duties. The objective is to guarantee adequate staffing in operational areas.

Corporate resources management

During 2022, despite facing challenges related to prolonged implications of the pandemic and the war of aggression against Ukraine, the Agency managed to ensure effective business continuity, and continued to monitor the geopolitical situation closely with local authorities. As restrictions related to the pandemic were lifted, various services, including restaurant, reception, travel, and accommodation services, as well as several on-site events, resumed.

After a gap of more than two years, the Agency also resumed in-person meetings of its official bodies. We successfully organised meeting services for all events and official meetings, with 674 meetings held, and 37 500 participants joining online through Webex. Additionally, we hosted approximately 4 000 visitors to our premises in 2022.

The Agency also resumed staff travel, with a decrease in business-related travel compared to 2019, due to environmental considerations. Approximately 200 staff missions took place. In support of addressing the European energy crisis, the Agency also took additional steps to reduce its energy consumption, for example, by adjusting the office temperature.

Environmental and sustainability management

To sustainably use resources and maintain sound environmental practices, ECHA has integrated environmental management into its system. In 2022, the Agency achieved its EU Eco-Management and Audit Scheme (EMAS) registration, which is a top-tier management instrument created by the Commission to help companies and organisations evaluate, report and enhance their environmental performance. This accomplishment is crucial to realising our vision of becoming an Agency with net-zero greenhouse gas emissions, as stated in our climate neutrality pledge.

ECHA’s Environmental Management Work Programme outlines our goals, actions, and objectives for reducing the consumption of natural resources, cutting down waste, and minimising our carbon footprint. In 2022, we successfully achieved our targets for reducing CO2 emissions from both business travel and building operations, surpassing the expectations set in the 2020-2022 programme. This was made possible with the collective effort of all ECHA staff, who resumed their travel and returned to the office in April 2022 after the pandemic.

[49] https://echa.europa.eu/documents/10162/17100/echa_charter_on_diversity_and_inclusion_en.pdf/3ca93100-fc9d-09fb-2732-9c699a5ddb93

Environmental Objectives 2020-22 (Benchmark Year: 2019)	Result in 2022 (Benchmark Year: 2019)	Achievement
Building CO_2 emissions reduction of 20%[50]	69% decrease	Exceeded
Travel (meeting participants) CO_2 emissions reduction of 75%	77% decrease	Exceeded
Travel (staff missions) CO_2 emissions reduction of 50%	81% decrease	Exceeded

In November 2022, the 2023-2025 Environmental Management Work Programme was approved, building upon the successes of the previous programme. This new work programme focuses on further reducing ECHA's carbon footprint and implementing sustainable practices in our activities. Additionally, ECHA's environmental management system (EMS) underwent successful audits in May 2022, achieving its EU Eco-Management and Audit Scheme (EMAS) registration, and passing an ISO 14001 surveillance audit.

IT Resources management

The Agency established goals for the 'ECHA IT 3.0 Journey' project, with a focus on improving IT systems and strengthening security measures. The aim is to improve ECHA's overall technology infrastructure to ensure that it is adaptive, agile and secure.

ECHA's IT operation has a strong reputation for its delivery capabilities and high service quality. However, to maintain its success and ensure it is future proof, we introduced a multi-year IT 3.0 transformation journey during 2022. The journey is an integrated part of our work, guided by business demand and the Agency's priorities, and not 'IT for the sake of IT'. The objective is to improve the resilience and scalability of our IT portfolio, moving it from a 'well-oiled machinery' towards a more adaptive, agile and integrated operation. In doing so, we aim to make it more efficient, more cost effective and more capable to deliver through a refined architecture and the use of new technologies.

The Information Systems Directorate has undergone several small but impactful changes, laying the foundation for the harmonisation of DevOps[51] practices and a more agile way of working. Additionally, a dedicated programme has been established to manage migration to the Public Cloud.

ECHA has been proactive in ensuring the security of its systems and information by increasing security resources, establishing a cybersecurity policy, and intensifying awareness. Despite the recent escalation of the geopolitical crisis and an increase in malicious activity, no significant incidents have occurred, and the level of security has remained comparable to previous years.

In November, ECHA held its first IT Days, which was an open event attracting 130 participants from 20 countries to Helsinki. The event brought together representatives from various technology companies and consultancies, as well as some of our sister agencies like EMA and EFSA. The purpose of the event was to provide participants with insight into ECHA's IT landscape and to learn from case studies presented by ECHA and other organisations.

[50] Based on the latest available emissions factors for district heating (2021).
[51] DevOps is a method that integrates and automates the work of software development (Dev) and IT operations (Ops).

Litigation, appeals and complaints

Based on REACH and the Biocidal Products Regulation, certain ECHA decisions can be appealed to the Board of Appeal. The EU courts decide on legal remedies against ECHA's decisions which cannot be appealed before the Board of Appeal, or decisions taken by the Board of Appeal. In 2022, the European Court of Justice and the General Court delivered 12 judgments and orders where ECHA acted either as a defendant, respondent, or an intervener in support of the Commission.

Cases before the EU Courts

Overall, the judgments were favourable to ECHA and to the Commission which ECHA supported, except for a judgment annulling a harmonised classification for titanium dioxide. This case is under appeal.

Particular judgments from the General Court include:

- Confirmation that substances that are persistent, mobile and toxic (PMT) may be identified as substances of very high concern (SVHCs) under Article 57(f) of REACH. In this case, the General Court dismissed in its entirety an action brought against ECHA's decision to identify a number of substances as SVHCs which, in the environment, dissociate to form the substance 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propanoate (HFPO-DA). These substances are sometimes referred to as GenX, the name of the technology in which they are used. They are part of a larger family of chemicals known as PFAS or "forever chemicals" because they persist in the environment for decades.[52]

- Annulling the harmonised classification of titanium dioxide as a category 2 carcinogenic substance, by inhalation in certain powder forms, introduced by Commission Delegated Regulation (EU) 2020/217. ECHA intervened in support of the Commission in this case, together with a number of Member States. This judgment is under appeal.[53]

- Dismissing an action seeking the annulment of a Commission Regulation restricting the use of lead in gunshot in or around wetlands (Commission Regulation (EU) 2021/57). ECHA intervened in support of the Commission.[54]

- Upholding the decision of the Commission not to approve silver zeolite and silver copper zeolite for use as biocidal active substances. It confirmed the interpretation of ECHA and the Swedish evaluating competent authority that to show efficacy of an active substance to be used for treating articles, the efficacy has to be proven in the context of the use conditions of the said article and on the materials of the article that will be treated with the substance (a tier 2 efficacy test). Demonstrating efficacy of the active substance itself (a tier 1 test) is not enough.[55]

Before the Court of Justice, four cases concerned appeals against General Court judgments dismissing actions for damages against the Commission for having unlawfully classified the substance coal tar pitch high temperature (CTPHT). The Court dismissed the actions for damages on the basis that the Commission's conduct did not constitute a sufficiently serious breach of a

[52] Judgment of 23 February 2022, Chemours Netherlands B.V. v ECHA, case T-636/19, EU:T:2022:86.
[53] Judgment of 23 November 2022, CWS Powder Coatings v Commission, case T-279/20, Billions Europe & Others v Commission, case T-283/20 and Brillux and Daw v Commission, case T-288/20, EU:T:2022:725. Appeals by France C-71/23 P and by the Commission C-82/23 P.
[54] Judgment of 21 December 2022, Firearms United Network and Others v Commission, case T-187/21, EU:T:2022:848.
[55] Judgment of 16 November 2022, Sciessent v Commission, case T-122/20 and case T-123/20, EU:T:2022:712.

rule of law and the unlawful classification of CTPHT appeared to be excusable.[56]

In another case, the Court of Justice dismissed in its entirety the appeal brought against the judgments of the General Court which confirmed the Commission's decision not to approve the biocidal active substance PHMB in product types 1, 5 and 6, and to approve that substance in product types 2 and 4 for limited uses only, on the basis of unacceptable risk to human health and the environment.[57]

Cases before the Board of Appeal

The Board of Appeal adopted 11 decisions in appeal cases brought against ECHA's decisions. In those decisions, the Board of Appeal addressed aspects of ECHA's processes including the following:

- As regards the information requirements for degradation (Section 9.2. of Annex IX of the REACH Regulation), the Board of Appeal found that the obligation to provide the standard information required under Column 1 does not depend on whether the chemical safety assessment indicates a need for that information. Column 2 is a trigger for degradation testing which is further or additional to the standard information requirements.[58]

- As regards the information requirements for developmental toxicity, the Board of Appeal reiterated that a pre-natal developmental toxicity study (PNDT) in a second species is a standard information requirement at Annex X and cannot be adapted on the basis of Column 2 of Annex IX.[59]

- As regards the requirements for read-across adaptations (Section 1.5. of Annex XI of the REACH Regulation), the Board of Appeal held that, for an adaptation to be acceptable, it is sufficient to show that the properties of two substances are likely, and not certain, to be similar or follow a regular pattern. Whether this requirement is fulfilled must be determined in a case-by-case assessment of all relevant factors.[60]

- As regards the dossier evaluation process, the Board of Appeal confirmed that a follow-up decision under Article 42(1) of the REACH Regulation does not need to set a deadline for the registrants concerned to provide the information required by the initial compliance check decision.[61]

- As regards the substance evaluation process, the Board of Appeal concluded in one case that the Larval Amphibian Growth and Development Assay (LAGDA) test can be suitable to examine a concern related to the thyroid mode of action. Agency's request was based on a concern that the substance diuron may be an endocrine disruptor in the environment.[62]

In three other cases, the Board of Appeal also clarified the requirements for asking further information. It held that demonstrating a potential risk (hazard and exposure) includes an examination of whether there is potential exposure to a substance irrespective of the controls in place. Furthermore, both harmonised classification and self-classification under the CLP

[56] Judgment of 16 June 2022, SGL Carbon SE and Others v Commission, case C-65/21 P, Química del Nalón v Commission, case C-73/21 P, Deza v Commission, case C-74/21 P and Bilbaína de Alquitranes v Commission, case C-75/21 P, EU:C:2022:470
[57] Judgment of 10 November 2022, Laboratoire Pareva v Commission and Others, case C-702/21 P, EU:C:2022:870.
[58] Decision of the Board of Appeal of 27 September 2022, Albemarle Europe, case A-005-2021.
[59] Decision of the Board of Appeal of 31 October 2022, Croda EU, case A-011-2021.
[60] Decision of the Board of Appeal of 23 August 2022, Celanese Production Germany, case A-004-2021.
[61] Idem.
[62] Decision of the Board of Appeal of 10 May 2022, Lanxess Deutschland and Schirm, case A-002-2021.

Regulation can lead to improved risk management measures.[63]

In the same cases, the Board of Appeal also held that compliance check and substance evaluation can run in parallel, and that the Agency is not required to wait for information to be produced under a compliance check before requesting further information under a substance evaluation.[64]

Administrative complaints and European Ombudsman

The Agency received 17 external administrative complaints in 2022. The topics included i.a. seven complaints related to Biocides namely Union authorisations, active substance approvals and processing of Article 95 applications. Most of these were however either misunderstandings or not in ECHA's competence or related to an IT issue. The corrective actions included e.g. proceeding with an Article 95 inclusion as the conditions were met and correcting the status of the active substance on ECHA's webpage. ECHA also clarified its role in the Union authorisation process and provided explanations. Other complaints concerned dossier evaluation leading to corrective action not to automatically exclude a registrant from random selection, the SCIP database which were outside ECHA's competence, data sharing, access to documents, additional C&L activities and ECHA's IT Tools. Within the integrated management system of the Agency, all complaints have been analysed and followed up resulting in corrective actions, where appropriate.

This year, the Ombudsman received a complaint[65] alleging procedural irregularities due to a misalignment with the position of EFSA's experts. The Ombudsman examined how ECHA communicated on the risk assessment of the active substance sulphur dioxide. She concluded that ECHA considered the arguments raised by the stakeholders in an open discussion and that the Agency provided sufficient explanations to the complainant as to why its assessment differed from the one conducted by EFSA. The Ombudsman also observed that it is not in her mandate to examine the merits of scientific evaluations and that disagreement among experts does not mean that the scientific assessment as such is manifestly flawed. The Ombudsman therefore decided that there were no grounds to inquire further into the complaint and closed the case.

The lesson taken was that by registering and handling complaints in a timely manner according to ECHA's Code of Good Administrative Behaviour, the Agency may avoid scrutiny from the European Ombudsman.

[63] Decision of the Board of Appeal of 22 March 2022, Campine, case A-003 2020, Decision of the Board of Appeal of 22 March 2022, Tribotecc, case A-004-2020 and Decision of the Board of Appeal of 22 March 2022, S. Goldmann, case A-005-2020.
[64] Idem
[65] Decision of 14 October 2022, NN, case 1485/2022/MIG

Audits and evaluations

Internal Audit Service

The Internal Audit Service (IAS) did not conduct a specific audit during the year.

Internal Audit Capability

The Internal Audit Capacity (IAC) conducted two assurance audits with the objective of assessing and providing reasonable assurance on the regularity and the quality of internal control systems applied as well as efficiency and effectiveness of the operations.

The first assignment '*Review of the Agency's IT Security Governance Framework*' was conducted by an external service provider and resulted in two medium/important recommendations on a comprehensive security risk assessment and security awareness.

The second audit covered the '*Stakeholder relationship management activities*', resulting in two very important recommendations:

- Update the ECHA Communications strategy if ECHA's main strategy is reviewed and monitor achievement of strategic stakeholder management objectives;
- Further develop a proactive stakeholder engagement methodology;

  Ensure coordination and holistic view of the stakeholder activities across ECHA.

and two important recommendations:

- Identify, classify and prioritise stakeholders, collect their needs, expectations and feedback systematically.
- Enhance systematic involvement of stakeholders to the development of IT services and products;

  Define and monitor trends of Key Performance Indicators (KPIs) on user satisfaction on IT services and products.

The audit also identified some improvement areas, classified as desirable, including a recommendation to continue to strive for mutual understanding on the role and mandate of the RAC and SEAC committee observers, following comments raised by them about participation, transparency and good administration.

The Agency follows up these recommendations with corresponding actions.

For earlier audits, the Internal Audit Capability conducted three follow-up audits to verify the implementation of the action plans, concluding that one very important and five important actions are still being implemented.

European Court of Auditors

In their statement of assurance[66], the European Court of Auditors (ECA) concluded that the accounts of the Agency for the financial year 2021 present fairly, in all material respects the financial position of the Agency at 31 December 2021, the results of its operations, its cash flows, and the changes in net assets for the year then ended, in accordance with its Financial Regulation and with accounting rules adopted by the Commission's accounting officer.

The revenue and payments underlying the accounts for the year were also legal in all material aspects.

The Court did not make any observations regarding the financial year 2021 and there are no observations open from previous years either.

Follow-up of observations from the discharge authority

For the discharge 2021, the Secretariat of the European Parliament Committee on Budgetary Control asked all EU Decentralised Agencies for a follow-up report to the 2020 budgetary discharge to be submitted by 16 September 2022.

The report[67] provides an overview of the relevant observations and recommendations from the European Parliament Resolution[68] of 4 May 2022 on discharge in respect of the implementation of the budget of ECHA for the financial year 2020, together with the measures ECHA has taken in light of these. It is to be noted that no comments accompanied the Council's Recommendation[69] of 16 February 2022 on the discharge of the Agency for the financial year 2020.

On 4 May 2022, the European Parliament also adopted the resolution on discharge in respect of the implementation of the budget of the EU agencies for the financial year 2020: performance, financial management and control (2021/2157(DEC)). This resolution is a horizontal report containing recommendations and observations that accompanied the individual 2020 discharge reports for each of the Agencies and Joint Undertakings. The follow-up actions to these recommendations, where a collective response was prepared by the EU Agencies Network, is presented in a separate report being prepared by the Agency holding the Chairing role of the EU Agencies' Network. ECHA has contributed to this report by providing information in relation to its own actions.

In summary, there were 10 recommendations from the European Parliament, out of which four have been completed.

[66] https://www.eca.europa.eu/lists/ecadocuments/agencies_2021/agencies_2021_en.pdf
[67] European Chemicals Agency report on the follow-up to the 2020 budgetary discharge
[68] https://www.europarl.europa.eu/doceo/document/TA-9-2022-0174_EN.pdf
[69] https://data.consilium.europa.eu/doc/document/ST-6003-2022-ADD-1/en/pdf

Ex-ante and ex-post evaluations

In 2022, ECHA performed the following two ex-post evaluations[70].

The first was an *ex-post evaluation of the SCIP database*[71], that had two main objectives. Firstly, to assess the extent to which the objectives of the implementation of the SCIP database have been met and whether ECHA's duty in setting up and maintaining it has been fulfilled. The second objective was to perform a historical cost assessment and use the results to forecast SCIP-related expenditures in the future. The results are used to determine priority areas of development for the future of the database.

The second was an *ex-post evaluation of ECHA's financial model*, including its REACH/CLP and Biocides fee income trends, and their predictability and stability throughout the years. A comparison with other agencies' models is also covered to allow for conclusions on the proportionality of ECHA's model. The costs, risks and benefits associated with the model for ECHA and its main stakeholders are also captured in the analysis. The results of the ex-post evaluation may be used to support the Commission's proposal for an ECHA Basic Regulation.

The follow-up of the evaluations performed in previous years showed that most of the recommendations on the ex-post evaluations, such as those concerning the *EU Chemicals Legislation Finder (EUCLEF), the EU Observatory for Nanomaterials (EUON), Cloud services and Portal Dashboard for national enforcement authorities (PD-NEA) and Portal Dashboard for Member State competent authorities (PD-MSCA)* have been implemented.

The follow up of the ex-post evaluation on the functioning of *ECHA's Integrated Management System* (performed in 2019) showed progress in areas such as further integration of internal control and quality, simplification of IMS processes, aiming to ensure proportionality between costs, risks and benefits at process level and promotion of staff empowerment.

[70] Evaluations follow the criteria and methodology as stipulated in the Better Regulation guidelines http://ec.europa.eu/smart-regulation/guidelines/tool_42_en.htm

[71] https://echa.europa.eu/documents/10162/6205986/scip_evaluation_report_en.pdf/2c677149-e876-f2b1-0ba7-3daca0a419ef?t=1665556373094

Internal control – system effectiveness

Risk management

Risk management is an integral part of ECHA's Integrated Management System. The risks, that were identified as possibly jeopardising the achievement of the objectives defined in the Programming Document, were followed up regularly and a more detailed assessment was carried out every four months during the year.

For most risks, the levels remained relatively stable and no critical risks materialised during the year. Regular updates were given to the Management Board and specific reporting was set up to follow the IT security related risks.

Transparency, accountability and integrity

Throughout 2022, the Agency lived up to its values of transparency and independence, ensuring continued public and stakeholder trust in the impartiality and objectivity of ECHA's work.

The decision-making processes of the Agency are designed to be clear, open and to ensure a balanced outcome based on a reasoned scientific approach. Information on the intentions of ECHA and the Member States – for example, to look into substances or create dossiers – is available online, so companies have access to the data they need to make informed business decisions.

Accredited stakeholder organisations may participate in scientific meetings as observers, except where confidential business information requires sessions to be closed. This gives them a chance to witness the debate and decision-making process and, where appropriate, express their views. Where consultations take place, the comments received are discussed and addressed. The reflections, minority opinions and conclusions of ECHA's scientific committees are recorded in opinions and minutes, and these are published online.

ECHA maintains the world's largest regulatory database on chemicals. The database provides transparent information on the chemicals used in Europe today in three layers: a simple Infocard aimed at consumers, a more detailed Brief Profile for professionals and the non-confidential source data submitted by industry to ECHA.

During 2022, over 600 new substances have been added to the REACH study results – a collection of non-confidential substance data submitted to ECHA under REACH. The data contains results from studies related to physical-chemical properties, environmental fate and pathways, and ecotoxicology and toxicological information.

Prevention of conflicts of interest

Policy update

Based on a thorough risk assessment of its activities, the Agency has identified the processes and sub-processes that require conflicts of interest to be managed. Conflict of interest checks are performed for more than 30 processes, sub-processes or process steps, including the main operational processes of the Agency.

In all of these processes, a review of the annual declarations of interest is performed by the process owner each time a task is assigned to a staff member, while for some sensitive processes this is complemented with a case-specific declaration of no interest by the staff member.

If there is a potential conflict, the case is assigned to a different staff member. The approach is documented in detailed work instructions and guidance is available for those managing the interests to help them deal with individual cases. As a result, no cases of actual conflicts of interest affecting the output of the Agency were identified in 2022.

For the ECHA bodies, all members are assessed against the generic exclusion criteria agreed upon by the Management Board, at the time of their appointment. Once they take up their function, their annual declarations of interest are reviewed by the respective Chair and published on ECHA's website.

Before each meeting of an ECHA body, specific declarations for items on the agenda are collected and documented in publicly available minutes together with the mitigating measures imposed. As most of the members of ECHA's bodies are Member State public officials, the majority of the conflicts of interest declared by the members concerned involvement in preparing dossiers submitted by their Member State competent authority. In all such cases, the members concerned were considered to not be in a position to participate in the voting on such dossiers.

During 2022, ECHA introduced a new electronic tool for collecting and reviewing the annual declarations of interest of the external experts contributing to the Agency's work, providing further assurance to the process.

Post-employment

Members of staff must notify new occupational activities for the first two years after leaving the service of the Agency. ECHA can forbid the new activity or impose conditions.

In 2022, 27 staff members left ECHA: 9 of them went to work for another EU institution, body or Agency. One staff member moved to a national public administration or international organisation. Five staff members moved to the private sector or started self-employment and, in three of these cases, the Agency deemed it necessary to impose specific conditions due to the nature of the occupational activity or the role of the individual within their new occupation.

In the remaining 12 cases, ECHA has not (yet) been informed about a new occupational activity, as the departure was due to unemployment after resignation, retirement or permanent invalidity. Two of these cases concerned the retirement of a member of senior management.

An overview of the post-employment decisions of all former senior managers is published on ECHA's website, including their names, date of departure, positions, their foreseen new occupational activities, and the outcomes of ECHA's assessments[72].

ECHA has been following the latest developments in this area, including the EU Ombudsman and European Court of Auditors' recommendations to ensure its policies, including on post-employment, remain up to date.

No breaches of trust or disciplinary procedure were initiated for conflict of interest management.

[72] https://echa.europa.eu/documents/10162/13559/post-employment_senior_managers_en.pdf/8567fc1f-1631-05fe-eceb-8817a0e110d1

Conflict of Interest Advisory Committee

The Conflict of Interest Advisory Committee (CoIAC) is an advisory body in the context of ECHA's Procedure on Prevention and Management of potential conflicts of interest. The Committee is available to the Management Board, the Committees, the Forum and the Executive Director for advice on matters related to potential conflicts of interest of ECHA staff or members of the Agency's bodies.

No changes occurred in the composition of the CoIAC in 2022. The Committee comprises three members: Ms Judite Dipane, appointed by the Management Board of ECHA, Mr Julio Bacio Terracino from the OECD ethics department, appointed as an external expert, and Ms Minna Heikkilä, Head of ECHA's Legal Affairs Unit as Chairperson.

On 21 November 2022, the CoIAC convened for its annual meeting where it took note and exchanged on the activities of the European Ombudsman in 'revolving doors' cases. No individual advice was requested from the CoIAC in 2022.

Ex-post controls

In line with the Procedure on Prevention and Management of potential Conflicts of Interest, ECHA must annually undertake ex-post controls to guarantee the effectiveness of the procedure.

A sample check on 36 annual declarations submitted by the members of the ECHA Committee for Socio-Economic Analysis revealed that all of them were in place, updated during the last year, publicly available and sufficiently complete. For the Chair and Deputy Chair of the Committee, the latest version, although available to their managers and the secretariat, was not published on the website. For one declaration, a clerical error was detected and addressed.

In addition, ex-post reviews were carried out during the internal audits of the meetings' management process and the stakeholder management process. Based on sample checks it was confirmed that the secretariats of the Member State Committee, Committee for Risk Assessment and the Biocidal Products Committee Working Groups systematically collect declarations of interest from all members once a year. Access rights to collaboration tools were removed when memberships are no longer valid.

Fraud prevention

By design, the Agency's internal control systems contain fraud prevention, with an emphasis on critical areas such as financial transactions, procurement and selections.

ECHA's Code of Good Administrative Behaviour[73] is well communicated to all staff members. Management Board decision 30/2009 of 23 April 2009 stipulates the terms and conditions for internal investigations in relation to the prevention of fraud, corruption, and any illegal activity detrimental to the Communities' interests.

Guidelines for whistleblowers were first adopted in 2015 and updated in September 2018. Through these guidelines, ECHA ensures that its employees can always highlight any action which goes against the public interest.

[73] https://echa.europa.eu/documents/10162/13559/code_of_good_administrative_behaviour_en.pdf/a4aa94f7-f631-43d6-8c28-77a10a0d0720

The ECHA Anti-Fraud Strategy[74] was revised by the ECHA Management Board in December 2022 and includes a focus on maintaining and further developing the anti-fraud culture in the Agency and regularly reviewing key policies and procedures.

Data protection

The Data Protection Officer is an independent function within the Agency, who advises the units on compliance with privacy laws and regulations. He keeps the required records of processing operations centrally and acts as the liaison with the European Data Protection Supervisor.

In 2022, the focus areas of support concerned contractual arrangements for IT solutions procured by the Agency, including an update of the contractual arrangements with the Commission's service provider for IT services, DG DIGIT. Actions have also been taken in the context of two data protection related complaints and four personal data breaches that occurred in ECHA and involving ECHA staff and/or stakeholders.

As required, these cases were recorded and reported, and appropriate mitigating measures were agreed with process owners to avoid repeats in the future.

Security and business continuity

During 2022, separate training sessions for service providers in ECHA's premises as well as numerous unit/directorate fire-safety and evacuation walkthroughs were organised. The Emergency Rescue Plan was updated and communicated to the Helsinki Rescue Authorities. ECHA's emergency procedures were audited as part of the EMAS verification of ECHA's environmental statement. Radiation safety training was organised for ECHA's Radiation Safety Officer by the Finnish certified training organisation. The roles and responsibilities of parties involved in ECHA's business continuity activities, and the organisation of ECHA security, was streamlined and updated in 2022 to better reflect the needs of the organisation. Finally, the Agency received two requests for support from the EU Agencies Security Network related to security management. The Corporate Services Unit provided input to a request on travel risk management services and provided advice to another Agency about technical support on security scanning devices.

Pervasive large-scale and long-term teleworking resulted in a higher workload for the security function of the Agency. In addition, some new contractors were onboarded, and teleworking related arrangements had to be put in place as a priority. Furthermore, significant efforts were put into introducing new channels of awareness raising for ECHA staff.

ECHA organised the 19th Security Officers Network (SON)[75] annual meeting on 5 December 2022, where the topics of the new Identity Management Tool, recent developments and real-world security breach scenarios were presented and discussed.

[74] https://echa.europa.eu/documents/10162/10709201/final_mb_47_2022_annex1_anti-fraud-strategy_2023-2026_en.pdf/c42eb6f4-1d61-5be9-83a4-3f4af5ee6b4e

[75] Composed of nominated security officers from Member State competent authorities, mandated national institutions, designated national authorities, the European Commission and chemicals industry, and chaired by ECHA.

Compliance and performance of ECHA under the Integrated Management System Strategy and Framework

The purpose of this assessment is to give reasonable assurance that ECHA's management system is functioning, continuously improved, and that the objectives set out in Article 30 of the ECHA Financial Regulation are met, namely: (I) effectiveness, efficiency and economy of operations; (ii) reliability of reporting; (iii) safeguarding of assets and information; (iv) prevention, detection, correction and follow-up of fraud and irregularities; and (v) adequate management of risks relating to the legality and regularity of the underlying transactions.

The reference for the assessment is ECHA's Integrated Management System Strategy and Framework[76] which supplements the financial regulation and aligns with the principles and guidelines set out by the European Commission (in the areas of internal control and programming) and with the ISO 9001:2015 and ISO 14001:2015 standards.

For 2022, the assessment confirms that the IMS is effective and functioning as intended. All directors and most middle managers agree that management commits to the core principles. Also, most of the detailed components are fully present and functioning (9 out of 12), while areas identified for improvement are not considered major, or critical, deficiencies of the whole IMS or about the objectives of Article 30 of the ECHA Financial Regulation.

Areas for attention remain in areas such as risk management at all decision-making levels, the practices related to ex ante evaluations, stakeholder engagement and change management. In some of these areas, improvement work is ongoing.

In terms of costing the controls, the Agency follows the definition in the General Financial Regulation[77] of the EU, according to which 'control' means *'any measure taken to provide reasonable assurance regarding the effectiveness, efficiency and economy of operations, the reliability of reporting, the safeguarding of assets and information, the prevention and detection and correction of fraud and irregularities and their follow-up, and the adequate management of the risks relating to the legality and regularity of the underlying transactions, taking into account the multiannual character of programmes as well as the nature of the payments concerned'*.

Controls may involve various checks, as well as the implementation of any policies and procedures to achieve the objectives. Based on an approximation of the resources deployed in the units responsible for governance, human resources and financial management, as well as the average salary costs, the cost of controls as a percentage of the total budget are estimated to be around 3.7%.

The summary from the internal controls assessment as per the principles and characteristics of each component is as follows:

Component	Conclusion
Governance	
Mission and vision	ECHA's mission and vision are clearly defined and communicated. The level of convergence sees a declining tendency towards the end of the current strategy cycle.

[76] ECHA's Integrated Management System Strategy and Framework (POL-001): https://echa.europa.eu/documents/10162/0/pol_0001_man_system_strategy_en.pdf/db8ac28f-868b-0da5-8bba-6bc595f4ea5a?t=1632298260973

[77] Financial Regulation applicable to the general budget of the Union: https://op.europa.eu/en/publication-detail/-/publication/e9488da5-d66f-11e8-9424-01aa75ed71a1

Component	Conclusion
Ethical and organisational values	The principle is present and functioning. ECHA is perceived as a transparent organisation. Continued attention on ethics and organisational values remains necessary.
Management responsibility	The Integrated management system is functioning, and management committed. The ambition for some objectives is not achieved in full. As part of the strategy development the commitments and principles could be reviewed.
Human Resources	Commitment is demonstrated to enhance staff competence and assess performance in an objective, equal and transparent way. The ratio of females in management remains a point for attention, as does the impact of the working time rules and feedback on the performance management culture.
Stakeholders and partners engagement	All elements for stakeholder relationship management in place and ECHA committed to its stakeholders. The approach needs to be updated, aligned with strategy, and better structured.
Strategy, planning and risk management	
Priorities planning and resource allocation	ECHA demonstrates commitment to objectives, priorities, and activity-based resource allocation. The implementation of the next strategy should be used to foster a focus on defined priorities and objectives.
Risk management	The corporate level risk exercise is well established as part of the annual planning exercise. Process-level risk management is less structured, and controls are partly perceived as disproportionate. Different indications exist for the cost-benefit ratio of horizontal functions. No overall analysis is available.
Operations and operational structure	
Activity management	The activity and process management enables synergies. Efforts were made in 2022 to define the outcomes, expected performance, efficiency, and impact of activities. ECHA's supplier management practices are adequate.
Information and data management	ECHA aims at effective, efficient, integrated information, communication, and data solutions. The level of IT has remained adequate, despite the increased number of security threats. The perceived low efficiency of the IT systems by the Heads of Units needs further consideration.
Change management	ECHA overall responds to changes flexibly whilst ensuring continuity of operations. Specific consideration should be paid to the negative views of Heads of Unit on some aspects of ECHA's agility in responding to changes.

Component	Conclusion
Evaluation and improvement	
Performance management	The structures ensure reliability of reporting, as well as accuracy, completeness, and timeliness of data. The adequacy of corporate metrics will need to be addressed. Attention is required to ensure that ex-ante and ex-post evaluations are risk-based. Assessments performed for new projects may not always contain full consideration of options with their respective risks, costs, and benefits.
Assessments, audits, and evaluations	ECHA has adequate tools at its disposal to oversee the effectiveness, adequacy, and suitability of the Agency's Integrated Management System through assessments, audits, and evaluations.

Strategy for efficiency gains

The ECHA Integrated Management System Strategy and Framework aims to align our processes with our strategic priorities. It seeks to achieve efficiency and effectiveness through performance-based governance that considers risks and control measures. The focus is on smart production, not just increased production.

We are making progress in implementing our integrated regulatory strategy. Our grouping approach has matured, and respective processes are being further developed. There are also ongoing discussions at EU level to improve risk management activities, including the authorisation and restriction processes.

As an IT-focused Agency, we understand the crucial role that technology plays in enabling our regulatory work. By having all data available in digital format, we ensure accessibility and automation in its processing, enabling us to handle a high volume of submissions, meet legally binding deadlines, perform automated checks on dossiers and automate the dissemination of the data.

Therefore, we at ECHA will continue to invest in IT tools to drive efficiencies for all stakeholders, including companies with regulatory obligations to submit data to us, authorities using the data and for any future roles we may have in chemicals regulation.

To ensure ECHA's IT remains future-proof, we launched a multiyear IT 3.0 transformation journey. This evolution will transform our IT into a more adaptive, integrated, and agile IT development and operations model while high quality, security standards and efficiency. The IT 3.0 journey is not limited to technology advancements, but also includes changes in the way we operate, work and collaborate within ECHA, as well as with stakeholders and partners. As a result, some aspects of the transformation will be cultural in nature.

Concrete achievements in 2022 include the development of the new tools to support the Planning and reporting of the agency, that are more user-friendly, provide better reporting capabilities and save time for the whole staff of the agency. At the same time the reporting dimensions have been revised to better reflect the Agency Work Programme and allowing better linking of the Agency level objectives and those of individual staff members.

Furthermore, a new application to facilitate the budget preparation and its implementation was developed. The tool is designed to take into account the specific needs stemming from the complex budget structure and requirement to manage the REACH/CLP, Biocides and Environmental directives and international conventions separately.

The recently developed applications are also built on the same technology, facilitating sharing metadata and providing integrated reporting features. An initiative for developing a new workflow circulation tool, which will integrate a qualified electronic signature feature (EU sign), also commenced.

In 2022, ECHA also started an infrastructure capacity optimisation exercise to minimise any excess capacity in the IT infrastructure. The short-term goal is to reduce the excess capacity and to improve applications in terms of performance and required computing resources. The longer term goal is then also to optimise the infrastructure capacity in view of using more public cloud based solutions. The results from the second half of the year show, that ECHA was able to reduce the usage (both CPU i.e. processors and RAM i.e. memory) by roughly 25%.

Review of the elements supporting assurance - assessment by management

The Authorising Officer performed an assessment of the effectiveness and efficiency of the internal control system, acknowledging that the system, based on ECHA's Integrated Management Strategy and Framework, is functioning well.

The assessment considered a broad range of input[78] and will feed into the Management Review 2023, where senior management of the Agency gets together to reflect on the strengths, weaknesses, risks and opportunities of the management system.

Based on this retrospective assessment, the Senior Management agrees on the priorities and actions to take in 2023.

No significant weaknesses that may have a potential impact on the declaration of assurance of the Authorising Officer were identified and reported in any of the relevant parts as set out in the present report.

[78] Surveys, interviews, reports, audit and ex-post evaluation results, non-conformities, complaints, improvement proposals, risks, opportunities, and other sources of information.

Declaration of assurance by the Authorising Officer

I, the undersigned,

Dr Sharon McGuinness

Executive Director of the European Chemicals Agency

In my capacity as Authorising Officer,

Declare that the information contained in this report gives a true and fair view,

State that I have reasonable assurance that the resources assigned to the activities described in this report have been used for their intended purpose and in accordance with the principles of sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions,

This reasonable assurance is based on my own judgement and on the information at my disposal, such as the results of the self-assessment, ex post controls, the work of the Internal Audit Capability, the recommendations of the Internal Audit Service and the lessons learnt from the reports of the Court of Auditors[79] for years prior to the year of this declaration,

Confirm that I am not aware of anything not reported here which could harm the interests of the Agency.

Done at Helsinki, on 27 March 2023

signed

Dr Sharon McGuinness

Executive Director

[79] With regard to the implementation of EU legislation and the fee regulations under the Agency's remit, this assurance has to be limited to the field of competences of the Agency. Since ECHA's mandate does not include controls or inspections at national level, it cannot be confirmed that only registered or authorised substances and products, for which a fee has been paid to the Agency, are circulating on the EU market.

Statement of the managers in charge of risk management and internal control

We, the undersigned,

Shay O'MALLEY	and	**Frank BÜCHLER**
Director of Resources		Head of Unit Governance, Strategy and Relations

In our capacities as manager in charge of risk management and internal control, we declare that in accordance with ECHA's Internal Control Framework, we have reported our advice and recommendations on the overall state of internal control in the Agency to the Executive Director.

We hereby certify that the information provided in the present Annual Report and in its annexes is, to the best of our knowledge, accurate, reliable and complete.

Done at Helsinki, on 16 March 2023

signed		*signed*
Shay O'MALLEY	and	**Frank BÜCHLER**
Director of Resources		Head of Unit Governance, Strategy and Relations

Appendices

Appendix I - Actions, outputs and indicators

Table A. Actions and outputs

Main actions and outputs specified in the Work Programme 2022[80]
1.1 Registration dossier preparation
✅ Update of ECHA's IT tools and support materials in line with regulatory developments, such as the amendment of the REACH information annexes [Joint Action Plan Actions 5 and 6]. [2022, 2023] [CSS relevant]
✅ Follow-up on actions taken to support and promote the Commission's implementing regulation on dossier updates [REACH Review Action 1]. Review the effectiveness and efficiency of the task and decide on further measures. [2022, 2023]
✅ Handle disputes on data sharing. [2022, 2023]
✅ As part of the development of a registration obligation for certain polymers, support Commission in establishing guidelines for identification of polymers and set conditions for grouping polymers into one registration including provisions for data sharing. [2022, 2023] [CSS relevant]
✅ Ensure progressive maintenance of IUCLID to incorporate (international) regulatory requirements (e.g. adaptations to new requirements following the amendment of REACH Annexes, other technical and scientific progress under REACH and CLP such as the PCN format or requirements from our OECD international partners). [2022, 2023]
✅ Maintain version 3 of Chesar so that it remains available to registrants as the mainstream tool for preparing chemical safety reports (CSRs) under REACH, providing support to ensure new CSRs are generated with an appropriate level of quality and updated where relevant. [2022, 2023] [REACH Review Action 1] [REACH Review Action 3].
✅ In parallel, continue developing the Chesar platform, a new risk assessment tool which harmonises assessments under both REACH and biocides, including the establishment of a scientific governance for the methodologies used by the tool. This development will ultimately replace version 3 of Chesar. [2022, 2023]
✅ Further work with the DG ENV contractor in support of the study on use and exposure related registration requirements. [2022, 2023] [CSS relevant]
✅ Support to the subsequent Impact Assessment and legislative phase. [2022, 2023] [CSS relevant]
✅ Contribute to OECD activities related to further development of alternatives and integration of regulatory relevant alternatives in the OECD test guidelines. [2022, 2023]
✅ Continue contributing to the efforts at international level[1] together with US EPA and Health Canada to further investigate the use new alternative methods in regulatory processes (jointly with activity 1.3). [2022]
✅ Promote alternatives to animal test methods through the development and maintenance of the OECD QSAR Toolbox, e.g. by extending its applicability and facilitating its use with IUCLID data (jointly with activity 1.3). [2022, 2023]
1.2 Dossier submission
✅ Process the continuous flow of registration dossiers (new and updates). Perform completeness checks, including manual verifications of the chemical safety report; and assess confidentiality requests. [2022, 2023] [REACH Review Action 1]
✅ Continue and further develop actions to clarify the status of inactive or incompliant registrations by mechanisms such as revocation and invalidation of registration decisions. [2022, 2023]
✅ Process PPORD notifications and monitoring high level indications for innovation and new kind of substances. [2022, 2023]

[80] (✅) achieved; (⏩) ongoing; (⛔) not achieved

✓ As part of the development of a registration obligation for certain polymers, support the Commission on the development of a registration process, including definition and assessment of polymer substances, actual registration and following regulatory activities, and start preparations for the necessary changes in relevant IT tools [2022, 2023] [CSS relevant]
✓ Prepare the report from the Forum pilot project on recovered substances exempted from REACH registration and guide for enforcement based on the experience gathered in that project. [2022]
1.3 Identification and prioritisation
✓ Continue the development and efficient use of computational tools on the scientific data analysis platform to generate groups and summarise the available hazard and use information to accelerate the assessment and the compilation and publication of the assessment outcomes. [2022]
✓ Continue making efficient use of the experience and tools developed to support the work on groups to support the preparation of the impact assessment for the revision of the REACH and CLP Regulations. [2022]
✓ Implement the actions of ECHA's action plan that was developed in response to the audit carried out by the Commissions Internal Audit Service on the integrated regulatory strategy: screening, evaluation and regulatory management option analysis in ECHA in 2021. [2022]
✓ To support reaching the goals of the integrated regulatory strategy, continue the development of approaches and tools to support a coherent assessment of regulatory needs and the work across different regulatory processes (such as common templates across the processes, support to the read across for regulatory purposes). Pilot the generation and assessment of groups, which contain only lower tonnage substances, in line with the approach developed in 2021. Refine the approach for implementation from 2023 onwards. [2022]
✓ Further develop high throughput new approach methodologies (NAM) in cooperation with ECHA's international partners. Explore how alternative methods can be used to support the assessment of groups, including those which contain only lower tonnage substances. Following the finalisation of the collaborative project of Tier 2 (in vitro assays and modelling), Tier 2 (NAM enhanced in vivo short-term verification studies) will be initiated followed by preparation for Tier 3 (NAM enhanced in-vivo longer-term regulatory studies). [2022] [REACH Review Action 2]
✓ Augment the registration data with external sources containing in vivo and in vitro (eco)toxicological information, results from predictive models and chemical safety data exchanged with other authorities (e.g. Canada, US EPA). [2021, 2022]
✓ PBT Expert Group: Support the Commission in developing the criteria for the new hazard classes for PBT/vPvB and PMT/vPvM to be included in the CLP Regulation. [CSS relevant]
✓ Continue monitoring updates of hazard and risk assessment in registration dossiers and subsequent risk management of metals and inorganics as a follow up to MISA. [2022] [REACH Review Actions 1, 14]
⏩ Continue the work with industrial sectors to address in particular petroleum and coal stream substances and metal UVCBs. [2022]
1.4 Evaluation
✓ Complete the examination of testing proposals included in the registrations from the 2018 deadline by 1 June 2022 and any new testing proposals within the legal deadlines. [2022, 2023] [REACH Review Action 2]
✓ Ensure, together with Member States, that substance evaluation contributes in an effective manner to the implementation of the integrated regulatory strategy. This entails updating the CORAP with substances for which substance evaluation is the most appropriate tool to generate further hazard information, in line with the outcome of screening and prioritisation based on the grouping approach; it may result in a lower number of substance evaluation cases comparing to previous years, as data relevant for regulatory risk management could be generated to a large extent through compliance check. Applying compliance check in parallel with substance evaluation will be considered where appropriate. [2022, 2023] [REACH Review Action 2, Joint Action Plan Action 10]
✓ Ensure together with the Member States that the substance evaluation is concluded as fast as possible to enable initiating appropriate regulatory risk management measures; the aim is to reduce the number of substance evaluation cases currently opened. [2022, 2023]
✓ Report on the progress made in evaluation as part of the report on the Integrated Regulatory Strategy and publish the updated recommendations to registrants stemming from evaluation. [2022, 2023] [REACH Review Action 2]
✓ Contribute to the Caracal sub-groups and other fora in support of the Commission in their policy activities, such as the amendment of the REACH information annexes in accordance with the REACH Evaluation Joint Action Plan [Joint Action Plan Actions 5 and 6]

1.5 Authorisation
Continue to work with the Commission and to support the analysis of all possible options and the respective consequences of possible changes to the authorisation process, the potential revision of the authorisation and restriction titles of REACH including the related initiatives, as described in Section 'Restrictions'. Provide specific analysis related to the efficacy and efficiency of the authorisation system and the implications of new concepts, such as essential uses. [2022, 2023] [CSS relevant]
Carry out market research to estimate the substitution effort taken and the likely number of applications to be received to plan well the opinion making process. [2022, 2023]
Develop further the analysis of alternatives activities under the Network of REACH SEA and Analysis of Alternatives Practitioners (NeRSAP) and hold one or two meetings to improve the knowledge and skills of European applied economists, providing analysis in regulatory settings for restrictions or in applications for authorisation. Hosting NeRSAP in 2022[2]. Joint activity between restrictions and applications for authorisation. [2022, 2023]
Provide web-based training to interested stakeholders on analysis of alternatives and informed substitution from substances subject to regulatory risk management. Joint activity between applications for authorisation and restrictions as well as Biocidal Products Regulation supporting substitution of substances of concern [2022, 2023] [REACH Review Action 5]
Provide timely notes on methodological questions, including socio-economic issues. [2022, 2023]
Provide timely and transparent support to applicants and authorisation holders through a streamlined process, including teleconference-based information sessions, updated information documented in, for instance, updates of the Guidance document, practical guide, application formats, 'reference' DNELs and dose-response relationships of substances. [2022, 2023]
1.6 Restrictions
Submit fit-for-purpose restriction proposals or restriction reports to address the identified concerns for (groups of) substances, as requested by the Commission, or for substances of very high concern used in articles, addressing the specific aspects of groups of substances where appropriate. [2022, 2023] [CCS relevant]
Provide web-based training to interested stakeholders on analysis of alternatives and informed substitution from substances subject to regulatory risk management. Joint activity between applications for authorisation and restrictions as well as Biocidal Products Regulation supporting substitution. [2022, 2023]
Develop further the analysis of alternatives activities under the Network of REACH SEA and Analysis of Alternatives Practitioners (NeRSAP) and hold one or two meetings to improve the knowledge and skills of European applied economists, providing analysis in regulatory settings for restrictions or in applications for authorisation. Hosting NeRSAP in 2022[4]. Joint activity between applications for authorisation and restrictions. [2022, 2023]
Further investigate and develop methodologies related to socio-economic analysis to create a fit-for-purpose tool box; in particular in the context of the OECD. This comprises the valuation of various health and environmental endpoints, lessons from regulatory risk management cases in different OECD member countries as well as other qualitative or partially quantitative methods (as e.g. multi-criteria analysis). The Agency should ensure the Commission's Better Regulation guidelines for evaluations and impact assessment are taken into account for the preparation of restriction dossiers [2022, 2023]
Based on initial work carried out in 2021 further develop a data strategy that would allow for 1) identifying high-risk uses of substances in the EU, and 2) facilitate ex-post evaluation of the most relevant impacts of restrictions/authorisations. One first step in this direction would be to find ways of receiving accurate information on substance uses in the EU single market. [2022, 2023] [CSS relevant]
1.7 Classification and Labelling
Process incoming CLH dossiers and the continued trend of mostly industrial chemicals from the outcome of screening and prioritisation based on the grouping approach but still a high number of PPP and Biocides dossiers resulting from the joint Commission, EFSA and ECHA efforts to encourage timely submission of dossiers. [2022, 2023]
Provide scientific and technical support to the Commission in its implementation of the Chemicals Strategy for Sustainability in the context of the revisions of the CLP regulation. [2022] [CSS relevant]
Maintain standard formats and tools: product categorisation system, poison centre notification (PCN) format and Unique Formula Identifier (UFI) generator. [2022, 2023]
Revise guidance for the poison centres notifications following the experience gained with the first years of implementation. [2022]

Maintenance of the notification portal and system-to-system submission channel and alignment with IUCLID. [2022, 2023]
Continue the promotion of the PCN activities with duty holders, in preparation for the next compliance date for mixtures with industrial uses, and with consumers. [2022, 2023]
1.8 Safe and sustainable use of chemicals
Provide inputs in relation to the reporting and characterisation of hazardous properties in the context of chemical risk assessment, in particular for complex substances such as UVCB and metals. Carry out further work on the use and exposure reporting for metals (relevant also to our ECHA's work on identification and prioritisation). [2022]
Develop requirements and specifications for improved article service life assessment and reporting in IUCLID and Chesar, whilst working in parallel on potential methods to distinguish between high and low release potential in article service life (relevant also to ECHA's work on identification and prioritisation). [2022]
Provide basic maintenance and dissemination of industry-developed use maps. [2022]
Organise capacity building session(s) on analysis of alternatives for committee members in SEAC and BPR and relevant stakeholders drawing upon the practical guide as well as internal and external expertise. [2022, 2023]
Potential support to the Commission in the development of Safe and Sustainable by Design methodologies, to enable the implementation of these criteria by designers/producers of products.
In the context of the Sustainable Products Initiative, potential support on the design and implementation of the Digital Product Passport concept, (depending on the role of topics such as tracking of hazardous substances and the management of chemical risk and safe use advice by DPP duty holders). Clarification of the potential role of REACH/CLP supply chain mechanisms in relation to the DPP concept.
Develop and take into use an IT solution to search the potential alternatives covered in the analysis of alternatives of application for authorisation. [2022]
Produce a practical guide on analysis of alternatives to be released on ECHA website to support capacity building of relevant stakeholders. [2022]
Work further on the strategy to support a safer use of chemical substances in articles, including any specific questions arriving via the Commission in relation to the development and implementation of the Circular Economy policy [2022, 2023]
Help Member States and other stakeholders in the organisation of substitution collaborative supply chain workshops. [2022, 2023] [REACH Review Action 5]
1.9 Data management and dissemination
Further develop and maintain ECHA's data integration platform as a single data provider for all data needs of internal regulatory processes and dissemination. [2022, 2023]
Promote the common usage of data by interested parties, in cooperation with other EU agencies, particularly EFSA, aiming for a higher level of consistency and preparing the ground for the future EU data platform on chemicals. [2022, 2023]
Continue to provide data analysis services as a response to internal and external with a priority to support the Commission's work on the CSS various actions including the review of REACH and CLP. [2022]
Contribute with data provision to the EU Warning System on new psychoactive substances implemented by EMCDDA. [2022, 2023]
Continue the development of tools to search, extract and analyse data in registration dossiers and make these tools available to other authorities and industry [2022, 2023].
Develop tools and methodologies to convert legacy toxicity data to IUCLID harmonised templates and collaborate with other Authorities and industry to migrate legacy toxicity databases [2022, 2023].
Develop data analysis algorithms, including chemoinformatics approaches, to support the generation of substance groups and their assessment [2022, 2023].
Maintain the automated Chemical Universe engine [2022, 2023].
Complete the development of the public SCIP and the improvements of the PIC dissemination solution [2022].
Maintain the current Dissemination platform operational and prepare its transition to a new Data availability system [2022, 2023].
Initiate work on a new, expandable Data availability system to make publicly available data received under different chemicals regulations and promote transparency of regulatory activities. [2022, 2023] [CSS relevant]. Further develop IUCLID as a key building block of the EU data platform on chemicals as mentioned in the CSS, bearing in mind the OECD intentions for a Global Chemicals Knowledge Base. [2022, 2023]

✓ Maintain and further develop the OECD Global Portal to Information on Chemical Substances (eChemPortal). Maintain the synchronisation of the eChemPortal with ECHA's dissemination website. [2022, 2023]
2. Biocides
✓ Revision of the opinion forming process aimed at expanding the capacity to handle a significant increase of assessment submissions. [2022]
✓ Support the Member State competent authorities in the preparation of complementary BPC opinions on the endocrine-disrupting properties of active substances evaluated before June 2018 following the request by the Commission: 6 opinions are foreseen for 2022. [2022]
✓ Support the Member State competent authorities in the preparation of BPC opinions on the early review of already approved active substances (according to Article 15) following the adoption of the endocrine-disrupting criteria. The Commission has requested the opinion on three substances to be provided in 2022. [2022]
✓ Development of a guidance and reporting template for the analysis of alternatives under the BPR for applicants, MSCAs and third parties. [2022]
✓ Develop the Chesar platform, a new tool combining EUSES and CHESAR to harmonise assessments under both REACH and BPR (see REACH Activity 1.1) that was started in 2020 is foreseen to continue until 2022. [2022]
✓ Support the Commission before the EU Courts in the proceedings related to biocides approvals.
⏩ Develop further the IT support tools (in particular ECHA Interact) to facilitate the work of Member States competent authorities during the peer review and opinion-forming for active substances and Union authorisation. [2022]
3.1 Prior Informed Consent
✓ Process a continuously increasing number of notifications and related tasks such as stakeholder support. [2022, 2023]
✓ Produce and publish the third biannual report on the exchange of information under the PIC Regulation. [2022]
✓ Provide scientific and technical support to the Commission in notifying the Rotterdam Convention Secretariat. [2022, 2023]
✓ Support the Commission in their participation to the second part of the 10th Conference of the Parties to the Rotterdam Convention [2022], the regular meetings of the designated national authorities and the international capacity building activities. [2022, 2023]
✓ Based on the outcome of the stakeholders' consultation on PIC dissemination, adapt PIC data publication to ECHA's dissemination portal and performing the necessary technological upgrades. [2022]
✓ Maintain ePIC and further develop it to increase the efficiency of the process by facilitating the work of DNAs, exporters, Commission and ECHA secretariat. [2022, 2023]
⏩ Taking in consideration the continuous increase in the workload, review current PIC regulatory procedures and related ECHA tasks, in dialogue with Commission and DNAs, striving to clarify stakeholders' roles and identify ECHA's priority tasks in order to potentiate the highest impact of ECHA's contribution and the increase in overall efficiency of PIC regulatory procedures. [2022]
3.2 Persistent organic pollutants
✓ Support to the Commission with nominating a new EU proposal for inclusion in the Stockholm Convention, and with the on-going work to list new substances as POPs. [2022, 2023]
✓ The compilation and publication of a Union Overview report based on the Member States reports on the implementation of the POP regulation, which will be submitted to ECHA. [2022]
3.3 Waste Framework Directive
✓ Provide support to duty holders to allow EU suppliers of articles to submit the required information to ECHA. [2022]
✓ Collect feedback from "waste treatment operators" and consumers on the use of the SCIP data published via ECHA's dissemination portal. [2022]
✓ Stabilisation of the notification portal and system-to-system submission channel of SCIP notifications in alignment with IUCLID, and of the dissemination of SCIP database information. [2022]
3.4 Drinking Water Directive
⏩ Draft the information requirements for and the risk assessment methods used in preparing the applications. [2022]

3.5 Support to the 8th Environment Action Programme of the EU
✓ Develop prototype implementations for the indicators based on ECHA's data as agreed with COM and EEA. Based on the prototypes seek input from stakeholders and finalise the indicator specifications. [2022] [CSS relevant]
✓ Together with EEA facilitate the overall development of the monitoring framework and provide input for possible upcoming reporting needs. [2022, 2023] [CSS relevant]
4.1 EU Observatory for Nanomaterials
✓ Further improvements to the EUON website following the customer insight project and improve integration with data from REACH dossiers. [2022]
✓ Continue to fulfil specific data gaps in the public knowledge about nanomaterials via the commissioning of external studies. [2022, 2023]
✓ Continue to promote the EUON via different channels to increase its outreach to a wide variety of audiences. [2022, 2023]
✓ Perform a technology upgrade to the NanoData knowledge base. [2022]
⏩ Update the data hosted on the NanoData knowledge base, following completion of the relevant data update contract with DG RTD. [2022]
4.2 EU Chemicals Legislation Finder
✓ Continue to operate EUCLEF and maintain updated the pieces of legislation in the scope of the service. [2022, 2023]
✓ Continue to promote EUCLEF via different channels to increase the utility of the service for its target audiences. [2022, 2023]
✓ Run the corresponding helpdesk. [2022, 2023]
✓ Initiate steps for the establishment of a new Data Service Provisioning Framework Contract for EUCLEF. [2022, 2023]
4.3 Support to occupational health legislation
✓ At the Commission's request and based on a service level agreement, RAC issues opinions, based on the preparatory work by the secretariat. The Commission uses the RAC opinion in its procedure to propose occupational exposure limit (OEL) values for adoption into the Carcinogens and Mutagens Directive 2004/37/EC (CMD) or the Chemical Agents Directive 98/24/EC (CAD). [2022, 2023]
4.4 Instrument for Pre-Accession Assistance (IPA)
✓ Addressing gaps identified in the national action plans such as focusing on building capacity on enforcement, risk assessment, IUCLID and IT tools as well as provide support to the alignment of national fees with the principles in the EU regulations and transparency measures
✓ Agreement on a new IPA III project with DG NEAR to support the improvements needed in candidate countries to implement the tasks under the EU regulations and Directives within ECHA's mandate.
4.5 Support to other legislation
✓ Sustaining active input to the review of the Best Available Techniques Reference documents (BREF) under the Industrial Emissions Directive. [2022, 2023]
✓ At Commission request, provide input to the revision of the Industrial Emissions Directive. [2022]
✓ Continue supporting the Commission services in implementing the chemicals related parts of the ecolabel, eco-design and green public procurement schemes. [2022, 2023]
✓ Contribute to EFSA's work to re-evaluate the risks related to plasticisers used in food contact materials, in particular, by identifying, grouping and prioritising substances for further work and development of the holistic assessment of the exposure from different uses. [2022]
4.6 IUCLID for EFSA
✓ Assess applicability of IUCLID to other food regulated products (e.g. Food Contact Materials and synergies with Drinking Water Directive). [2022, 2023]
✓ Continued cooperation with EFSA on the use of IUCLID as building block for the future EU Open Data Platform on Chemicals. [2022]
✓ Continued cooperation with EFSA in the definition of IT architecture and level of support required by EFSA to perform its regulatory work. Estimate resources and compensation mechanisms. Execution of the Service Level Agreement for implementation of additional scope and regular service accordingly. [2022, 2023]
5.1 Support to Forum
✓ Prepare the guide for enforcement of REACH, CLP and BPR in internet sales of chemicals based on experience from the eighth Forum-coordinated REACH enforcement project (REF-8) as well as a

workshop for accredited stakeholder organisations to discuss the recommendations from the project. [2022]
✓ Support inspectors during the operational phase and prepare the report from the tenth Forum-coordinated REACH enforcement project (REF-10), on REACH and POP restrictions on hazardous substances in various mixtures and articles, and support inspectors during implementation phase. [2022, 2023]
✓ Continue preparing, executing and reporting on Forum-coordinated REACH enforcement projects described in other sections of this document. In particular select the subject of twelfth Forum-coordinated enforcement project (REF-12). [2022]
✓ Continue establishing best practice in enforcement by testing enforcement approaches by running Forum pilot projects and maintaining the Forum and BPRS Manual of Conclusions on practical enforcement issues. [2022, 2023]
✓ Continue to examine enforcement proposals and deliver advice on enforceability of restrictions and revise the process for delivering Forum advice. [2022, 2023]
✓ Continue to support efficient and timely enforcement of ECHA decisions, such as non-compliance with ECHA's dossier evaluation decisions. Make best use of data and expertise to maintain interlinks between ECHA regulatory processes and national enforcement. [2021, 2022]
✓ Continue to support enforcement authorities by developing and delivering training programmes for national trainers and inspectors. [2022, 2023]
⊖ Harmonise practice for reporting on national enforcement activities and, if possible, start the pilot exercise in annual reporting of national enforcement activities to ECHA with the volunteering Member States. [2022, 2023] [REACH Review Action 13]
5.2 Board of Appeal
✓ Process and decide on appeals following decisions of the Agency related in particular to dossier evaluation and substance evaluation, as well as decisions adopted under the BPR. [2022, 2023]
✓ Adopt procedural decisions in appeal cases (e.g. on applications to intervene), as needed. [2022, 2023]
✓ Publish a robust body of high-quality decisions online, thereby facilitating proper implementation of REACH and BPR, and strengthening the trust of different ECHA stakeholders in that regard. [2022, 2023]
✓ Provide clear, accurate and timely communication to the parties in appeal proceedings and to the interested public in relation to appeal process. [2022, 2023]
⏩ With a view of continuous efforts to improve the policy on prevention of (potential) conflicts of interest situations, preparation and adoption of a code of conduct applicable to the members of the Board of Appeal who are Agency staff members. [2022]
5.3 Management
✓ Support the Management Board in performing its duties, through the preparation of plenary and working group meetings and the administration of all relevant procedures, with a view to further clarifying ECHA's role in regulatory implementation vis-à-vis other involved stakeholders and provide strategic steer to implementation. [2022, 2023]
✓ Support the Management Board in the selection and appointment of ECHA's new Executive Director [2022], and prepare the Management Board's review of ECHA's mission, vision and strategy for the next strategy cycle as of 2024. [2023]
✓ Onboard the new Executive Director in office and support the management transition, accompanied by communication and stakeholder engagement activities. [2022]
✓ Prepare and coordinate the activities of the senior management team, including management strategies, decisions, delegations and policies. Support the senior management team in continuing the change process towards one-ECHA operation. [2022, 2023]
✓ Coordinate the portfolio of ECHA contributions to the Chemicals Strategy and new tasks, to ensure relevance and consistency of the input provided. Ensure full utilisation of ECHA's competences, knowledge, as well as data held, to provide expert advice and support the efficient on-boarding of other pieces of legislation and policy areas related to the safe use of chemicals. [2022, 2023] [CSS relevant]
✓ Support strategic alignment with Member States' priorities on policies relevant to ECHA's mandate. [2022, 2023]
✓ Develop the Agency's relationship with institutional (policy) stakeholders of the European Parliament and the Commission. [2022, 2023]
✓ Seek synergies and align, where appropriate, on strategic and/or work programme level with peer agencies working in the area of health and environmental protection. [2022, 2023]
✓ Steer relationships with peer agencies on strategic matters, including active participation and leadership of the EU Agencies' Network. [2022, 2023]

Coordinate the Agency's international activities. [2022, 2023]
Maintain and develop further ECHA's integrated management and internal control systems to support ECHA operations while successfully maintaining relevant ISO standards [2022, 2023]
Perform audits and evaluations in line with the annual audit plan, and act on the feedback generated. [2022, 2023]
Together with partners and in line with the Commission request ECHA will provide technical and scientific support to the implementation of the capacity building project, which is managed by UNEP, in four African countries. [2022] [CSS relevant]
5.4 ICT
Plan and prepare the establishment of replacement framework contracts for Portals (Dissemination, Website, EUON, eChemportal, Interact Portal and EUCLEF) [2022], for Management Information Systems and Enterprise Content Management, (Dynamic Case, Odyssey, Assessment Tool, Collaboration & Consultation modules, FIMS, Budget tool, PPO, PMR, ELM and others) [2023], and for Managed IT Workplace Services (laptops, screens, mobile phones and other personal equipment) [2023]
Continue to evolve the workplace service to ensure an appropriate service for ECHA staff, adjusting to the demands of a more mobile workforce, post COVID-19. [2022, 2023]
Managing and maintaining IT security on ECHA infrastructure, systems and data while worldwide IT threats are continuously increasing, becoming more sophisticated and are more difficult to remediate. Ensuring appropriate security remains in place for new hybrid work practices. Implementing and adapting practices according to the Cybersecurity and Information Security Regulations. [2022, 2023]
Implement the targets agreed in Enterprise Architecture 2020-2023 and IT Master Plan. [2022, 2023]
Prepare the roadmap for the future of the ICT infrastructure services, including an analysis of the use of public cloud as an approach to be more cost efficient. [2022, 2023]
Plan and initiate the refresh of end-of-life administrative tooling (PMR, PPO, EasySign, Budget tool, IMS etc…) IT architecture. [2022, 2023]
Ensure that services can continue to be run at the required level of quality, in an efficient and cost-effective manner, by continuously investing in evolving the tools and practices. [2022, 2023] [REACH Review Action 15]
5.5 Financial resources
Prepare the Agency's budget and manage its implementation, including budget amendments and transfers, revenue collection and cash management, procurement and contracting, financial accounting and reporting. [2022, 2023]
Continue regular exchange with Commission partner services, including reporting on actual budget implementation, communicating revenue and expenditure estimates for the future and discussing ways of handling any shortfall or surplus during the budget year. [2022, 2023]
Support the European Commission in identifying alternative options for ensuring sustainable financial model for ECHA in particular with a view to the Multiannual Financial Framework of the EU (2021-2027). [2022, 2023] [REACH Review Action 15(1)]
Monitor and report on transfer of fees to Member States and prepare updates to the related transfer amounts per country. [2022, 2023]
Implement further efficiency measures, including automation, further digitalisation and financial process re-engineering as part of the financial management information system development. [2022, 2023]
5.6 Human resources
Implement ECHA's human resources strategy to continue to ensure high-quality services to staff and optimal use of its human resources. [2022, 2023]
Provide relevant competence development activities to ensure continuous capacity-building of staff and support more flexible deployment of staff. [2022, 2023]
Ensure efficient allocation of resources by providing sufficient staffing to the identified priority areas. [2022]
Support the Agency staff in adapting to the new ways of working. [2022]
Conduct the job screening exercise as part of a wider inter-Agency benchmarking exercise initiated by the Commission. [2022, 2023]
Maintain positive relations and dialogue with ECHA's Staff Committee, the European School of Helsinki and other key stakeholders. [2022, 2023]

✓ Conduct necessary management development actions to ensure a high level of people management by ECHA and to maintain a healthy working culture throughout the Agency. [2022, 2023]
✓ Implement the agreed action plan to advance gender balance in ECHA's management team and at organisational level. [2022, 2023]
✓ Provide a report by Q1/2022 on the allocation of the Agency's human resources to the activities of the Agency with due consideration of the tasks of the Agency to be maintained, revised or phased out, and with a view to assess the future resources needs of the Agency and the approach of the Agency to activity-based budgeting. [2022] [CSS relevant]
5.7 Corporate services
✓ Ensure operations under the responsibility of Corporate Services continue to run smoothly and investigate alternative modes of facilities services delivery, while striving to maintain/improve quality while reducing building and other service-related costs and environmental impact. [2022, 2023]
✓ Implement further efficiency measures and improvements in services delivery models. [2022, 2023]
✓ Facilitate the planned hybrid working environment, taking account of the facilities at the Agency's disposal. [2022, 2023]
✓ Identify and propose the Agency's 3-year environmental programme objectives (2023-2025 inclusive). [2022, 2023]

Table B. Indicators

Work Programme 2022 workload drivers and performance indicators	type	estimate	actual
1.1 Registration dossier preparation			
Effective working time for processing inquiries	Performance	0.3 person days/inquiry	0.23 person days/inquiry
Inquiries received and concluded	Output	4 200	4 827
1.2 Dossier submission			
Number of PPORD notifications received	Input	340	203
Number of C&L notifications received	Input	33 500	27 800
Number of Registration dossiers received (incl. updates)	Input	15 000	13 530
Number of SME companies verified for their status	Output	400	411
Effective working time for processing a registration dossier (first submission)	Performance	0.50 – 0.60 person days	0.45 person days
Registrations stopped for manual verification at technical completeness check	Input	5 550	4 667
Number of registrations failing first technical completeness check	Output	1 500	958
Share of registration dossiers over 100 tonnes in the database that has passed the enhanced technical completeness check	Outcome	62%	58%
1.3 Identification and prioritisation			
Number of substances registered above 100 t/y for which a conclusion on potential regulatory follow up was drawn	Outcome	300	c. 200
Number of groups of substances for which the assessment of regulatory needs is carried out	Outcome	65	61[81]

[81] 61 groups of which 10 were large (>39 members, more than double the median group size), so this is equivalent to 71 groups.

Work Programme 2022 workload drivers and performance indicators	type	estimate	actual
1.4 Evaluation			
Compliance checks concluded: draft decisions or no action[82]	Output	300	302
Final decisions on dossier evaluation (testing proposals and compliance checks)	Output	300	421
Number of substances for which a conclusion was reached in the follow-up to dossier evaluation	Outcome	200	363
Substance evaluation final decisions issued	Output	15	9
Number of substances for which a conclusion was reached in substance evaluation	Outcome	25	31
1.5 Authorisation			
Number of new entries in the Candidate List	Output	15	5
Recommendation for inclusion of substances in the authorisation list	Output	-	8
Number of downstream user notifications of authorised uses of SVHCs	Outcome	3 000	3 560
Number of RAC and SEAC opinions adopted on applications for authorisation (number of uses)	Output	30	36
Effective working time of ECHA staff per opinion	Performance	38-46 person days	45.5 person days
Applications and review reports for authorisation received (number of uses)	Input	55	66
1.6 Restrictions			
Number of RAC and SEAC opinions on restriction proposals	Output	2	4
Restriction proposals 69(1) or reports developed under Article 69(2)	Output	4	5
Effective working time of ECHA staff per opinion (ECHA dossier)	Performance	240-290 person days	225 person days
Effective working time of ECHA staff per opinion (Member State dossier)	Performance	Approx. 200 person days	179 person days
1.7 Classification and labelling			
Number of RAC opinions on proposals for harmonised classification and labelling	Output	60	45
Decisions made on requests to use alternative (Article 24)	Output	40	16
Effective working time for processing RAC opinions	Performance	45-55 person days	51.59 person days
Proposals for harmonised classification and labelling	Input	50	45
Poison centre notifications received and made available to Appointed Bodies and Poison Centres	Output	1.6 million	2.4 million
Poison centre notifications viewed by national authorities in the PCN central database	Outcome	10 000	12 036
1.9 Data management and dissemination			
Number of user page views for published information on chemicals	Outcome	50 million	32 million
Description and number of data requests	Outcome	Internal: 60 External: 30	Internal: 69 External: 27

[82] The estimate reflects the number of substances that will be checked for compliance. The overall number of dossiers concerned by that compliance check depends on the number of companies having registered jointly. It can vary significantly depending on whether the substance is a commodity or a specialty.

Work Programme 2022 workload drivers and performance indicators	type	estimate	actual
Average time taken for publication (days)	Performance	3	125[83]
2. Biocides			
Number of BPC opinions on active substances approval	Output	30	18
Number of BPC opinions on the renewal of active substances approval	Output	2	1
Number of BPC opinions on Article 15, Article 38 and Article 75(1)(g) requests	Output	20	15
Number of BPC opinions on Union authorisations of biocidal products	Output	30	22
Number of BPC opinions on Union authorisations (same biocidal products, administrative and minor changes)	Output	48	36
Support actions on evaluation of Active substance approvals	Output	10	12
Support actions on evaluation of Union authorisation applications	Output	3	8
3.1 Prior Informed Consent (PIC)			
Scientific and technical support provided to the Commission, EU and non-EU DNAs	Output	3 800	3 800
Support provided to PIC duty holders (importers and exporters)	Output	450	230
Export notifications processed (validated, rejected, resubmissions)	Output	14 500	10 071
Share of notifications validated/accepted by ECHA	Outcome	90%	92%
3.2 Persistent organic pollutants			
Number of scientific dossiers drafted for the identification of new substances as Persistent Organic Pollutants	Output	1	1
Support provided to various stakeholders	Output	50	20
Scientific and technical support provided to the Commission, EU and non-EU CAs.	Output	10	16
3.3 Waste Framework Directive			
Successful SCIP notifications received (incl. updates)	Input	17 million	9.9 million
4.1 EU Observatory for Nanomaterials			
All traffic to EUON websites	Input	100 000	132 197
4.2 EU Chemicals Legislation Finder			
Number of data updates on EUCLEF pieces of legislation	Output	4-6	4
All traffic to EUCLEF pages[84]	Input	250 000	310 452
4.3 Support to occupational health legislation			
Number of OEL requests received under SLA[85]	Output	5	5
Number of RAC opinions on OELs completed	Output	4	4

[83] Due to the agreed five-month processing halt, and corresponding processing backlog queues, while the IUCLID format changed.

[84] Traffic aggregated for all the EUCLEF pages, including EUCLEF main landing page, Information for Chemicals (EUCLEF subset) and EUCLEF Legislation Lists for substances.

[85] Request for five substances to provide 1 scoping study and 4 OEL opinions.

Work Programme 2022 workload drivers and performance indicators	type	estimate	actual
5.1 Support to Forum			
Number of enforcement trainers trained by the Forum	Output	200[86]	667[87]
5.2 Board of Appeal			
Appeals submitted under REACH	Input	17	10
Appeals submitted under BPR	Input	2	2
Appeals concluded under REACH	Output	14	10
Appeals concluded under BPR	Output	2	1
5.3 Management			
Areas where audits and evaluations results (including prevention of conflicts of interest and fraud) have been taken into account in future strategic decisions	Intermediate impact	4	4
Combined neutral and positive feedback monitored in media publications	Outcome	>90%	87%
Website unique visitors/traffic to the web content	Outcome	4.1 million	4.9 million
5.4 ICT			
Average availability of key systems	Outcome	>98%	99.9%
High impact security incidents	Outcome	Max. 3	0
5.5 Financial resources			
Level of budget implementation: commitment rate and cancelled carry-over rate	Performance	Min. 95%, max. 5% respectively	99% and 2% respectively
Processing of payments within legal deadlines	Performance	No less than 99%	99.6%
5.6 Human resources			
Percentage of Establishment Plan posts filled	Performance	95%	98%
Turnover of Temporary Agents	Performance	<5%	3%
Turnover of Contract Agents	Performance	<10%	2%
5.7 Corporate services			
Reduction in building C02 emissions (benchmark 2019)	Outcome	Reduction by 20%	Reduction by 69%[88]
Reduction in travel related (meeting participants) CO2 emissions (benchmark 2019)	outcome	Reduction by 75%	Reduction by 77%[89]
Reduction in travel related (staff missions) CO2 emissions (benchmark 2019)	outcome	Reduction by 50%	Reduction by 81%[90]

[86] The estimate covers REACH, CLP and BPR trainers and inspectors trained on-site in ECHA as well as those trained during an online training event.
[87] This comprises of 55 participants who attended physically and 612 remote participants. This covers both the REACH and BPR trainings.
[88] The latest available emissions factors were used for the calculation.
[89] Post-COVID travel for staff missions and meeting participants resumed in April 2022.

Appendix II - Budget implementation reports and statistics on financial management

Budget overview

The initially budgeted total payment appropriations for the Agency's expenditure in 2022, as concluded by the Management Board in December 2021, amounted to EUR 112.7 million, which included c. EUR 0.8 million for the separately budgeted Other tasks ("Contribution Agreements and SLAs" in the table below), and the final total expenditure, concluded in the amending budget in September 2022, amounted to EUR 117.0 million. The primary reason for this net budget increase during the year was the positive evolution of fee income on both REACH/CLP and Biocides areas, which enabled advancing some of the IT investments planned for 2023 and accommodating higher than anticipated costs related to the significant inflation increase. In addition, the budget for the Other tasks was increased by EUR 1.6 million.

Revenue	Initial voted budget	Amending budgets	Final voted budged
Total revenue	112 660 846	4 320 894	116 981 740
Expenditure	**Initial voted budget**	**Amending budgets**	**Final voted budged**
Commitment appropriations	112 764 403	4 425 380	117 189 783
Payment appropriations	112 660 846	4 320 894	116 981 740

Revenue

The budget funding of ECHA in 2022 consisted of the following (amounts in EUR):

Description	Initial voted Budget 2022	Budget Amendments 2022	Final voted Budget 2022	Entitlements established 2022	Revenue received 2022
Fees and charges from Registrations & Updates	22 865 083	3 900 037	26 765 120	29 721 895	29 721 895
Fees and charges from Authorisations	2 793 000	200 000	2 993 000	2 781 556	2 781 556
Fees SME Administration	950 000	-	950 000	790 581	790 581
Fees and charges from CLP	171 950	(100 000)	71 950	69 400	69 400
Fees and charges from Appeals	-	-	-	34 081	34 081
Total REACH Fees & Charges Income	26 780 033	4 000 037	30 780 070	33 397 513	33 397 513
Fees relating to Biocidal Active Substances	414 005	(87 000)	327 005	167 400	167 400
Fees for Union Authorisation of Biocidal products	1 003 206	2 252 157	3 255 363	4 407 200	4 407 200
Miscellaneous fees	1 826 689	87 000	1 913 689	2 182 020	2 182 020
Fees and charges from Appeals	-	-	-	-	-
Total BPR Fee & Charges Income	3 243 900	2 252 157	5 496 057	6 756 620	6 756 620
REACH EU Contribution	66 722 055	(2 500 000)	64 222 055	64 222 055	64 222 055
BPR EU Contribution	8 100 000	(1 000 000)	7 100 000	7 100 000	7 100 000
ENV EU Contribution	4 727 000	-	4 727 000	4 727 001	4 727 001
EFTA Contribution - REACH	1 610 075	-	1 610 075	1 610 075	1 610 075
EFTA Contribution - BPR	203 310	-	203 310	203 310	203 310
Confederation of Switzerland Contribution - BPR	371 790	(58 680)	313 110	313 110	313 110
EFTA Contribution - ENV	117 971	-	117 971	117 972	117 972
Total EU and other Contributions	81 852 201	(3 558 680)	78 293 521	78 293 523	78 293 523

Description	Initial voted Budget 2022	Budget Amendments 2022	Final voted Budget 2022	Entitlements established 2022	Revenue received 2022
Contribution Agreement EUON	-	-	-	609 000	609 000
Contribution Agreement EUCLEF	-	-	-	1 519 000	1 519 000
Contribution Agreement IPA	-	-	-	641 348	641 348
Contribution Agreement OELs	-	975 000	975 000	975 000	975 000
SLA with EFSA	784 712	652 380	1 437 092	1 437 092	1 437 092
Total Contribution Agreements and SLAs	784 712	1 627 380	2 412 092	5 181 440	5 181 440
Total Other income-miscellaneous	-	-	-	107 607	74 178
Total	**112 660 846**	**4 320 894**	**116 981 740**	**123 736 703**	**123 703 274**

REACH/CLP Revenue

A) REACH/CLP fees and charges

ECHA is financed through fees paid by industry and by an EU balancing contribution, in accordance with the REACH Regulation (No 1907/2006). The fees and charges collected by ECHA are determined by the REACH Fee Regulation and by the decisions of the Management Board.

Due to the one-off nature of REACH fees and their dependence on strategic decisions of the chemical industry players, there is high uncertainty as to their amount and timing.

The budgetary revenue from REACH fees and charges in 2022, in terms of cash received, amounted to EUR 33.36 million (EUR 27.06 million in 2021). In addition, EUR 0.03 million (EUR 0.07 million in 2021) was recorded in relation to REACH appeal fees[91] giving a total of fees and charges of EUR 33.40 million (EUR 27.13 million in 2021).

During 2022, ECHA cashed in a total of EUR 29.7 million from REACH Registrations and Updates fees (EUR 24.7 million in 2021). Furthermore, the Agency collected EUR 2.78 million from Applications for Authorisation (EUR 1.1 million in 2021) and EUR 0.07 million from CLP fees in 2022 (EUR 0.09 million in 2021). The additional registration fee income that was generated through the SME company size verification process (which is included in the REACH registrations and updates income) amounted to EUR 0.52 million in 2022 (EUR 0.72 million in 2021). On top of the additional registration fees, the Agency generated EUR 0.79 million in administrative charges (EUR 1.18 million in 2021) levied on companies who were not eligible for the already received rebates.

B) REACH/CLP contributions from the General Budget of the EU:

During 2022, the Agency received an EU balancing contribution for REACH/CLP of EUR 64.22 million (EUR 61.91 million in 2021) and a European Free Trade Association (EFTA) contribution of EUR 1.61 million (EUR 1.68 million in 2021).

BPR Revenue

A) BPR fees and charges

In accordance with the Biocidal Products Regulation (BPR, No 528/2012), ECHA is financed through fees paid by industry and a balancing EU contribution. The biocide fees and charges

[91] Income from appeal fees is recognised by ECHA only when a case has been decided and the Board of Appeal rules that the fee should not be refunded to the applicant.

collected by ECHA are determined by the Biocidal Products Regulation, the Fees and Charges Regulation (No 564/2013) and by the decisions of the Management Board. The budgetary revenue from BPR fees and charges for 2022, in terms of cash received, amounted to EUR 6.76 million (EUR 3.07 million in 2021). The significant increase in the collected BPR fee income relates primarily to the significantly higher number of Union Authorisation applications, for single products and for product family, that were received in 2022 (42 applications in 2022) compared to 2021 (8 applications in 2021).

B) BPR contributions from the General Budget of the EU

During 2022, the Agency received an EU balancing contribution of EUR 7.10 million (EUR 10.05 million in 2021) and an EFTA contribution of EUR 0.20 million (EUR 0.28 million in 2021). In addition, the Agency received a contribution from the Confederation of Switzerland of EUR 0.31 million (EUR 0.46 million in 2021).

Environmental directives and international conventions Revenue

In accordance with the Prior Informed Consent (PIC) Regulation (EU) No 649/2012, Persistent Organic Pollutants (POPs) Regulation (EU)2019/2021, Waste Framework Directive (SCIP) (EU) 2018/851 amending Directive 2008/98/EC, the revised Drinking Water Directive (DWD) Directive (EU) 2020/2184, and the 8th Environment Action Programme (8th EAP), ECHA is fully financed through an EU contribution for these activities. In 2022, the EU contribution amounted to EUR 1.16 million for PIC (EUR 1.16 million in 2021), EUR 0.20 million for POPs (EUR 0.22 million in 2021), EUR 1.49 million for SCIP (EUR 2.20 million in 2021), EUR 1.52 million for DWD (EUR 1.69 million in 2021), and EUR 0.33 million for 8th EAP totalling EUR 4.73 million, (EUR 5.29 million in 2021). Furthermore, in 2022, the Agency received for the first time an EFTA contribution of EUR 0.12 million in total for the above tasks

Other tasks (Contribution and Service Level Agreements)

The Agency has signed contribution agreements with the European Commission to implement the European Union Observatory for Nanomaterials (EUON) and the European Union Chemicals Legislation Finder (EUCLEF), as well as for work with respect to the Instrument for Pre-Accession Assistance (IPA). ECHA has also signed a Service Level Agreement with the European Commission to provide opinions for occupational exposure limits (OELs). Additionally, the Agency signed a Service Level Agreement with the European Food Safety Authority (EFSA) for developing and implementing IUCLID software solution for plant protection products. In 2022, ECHA received an amount of EUR 5.18 million in aggregate for these tasks (EUR 4.35 million in 2021).

Other miscellaneous income

The table below shows other miscellaneous income received in 2022 (amounts in EUR).

Description	Entitlements established 2022	Revenue received 2022
Legal recoveries	65 918	32 489
Late interest income	11 299	11 299
Recoveries from other EU agencies	28 728	28 728
Other recoveries	1 662	1 662
Miscellaneous income	107 607	74 178

Fee Invoicing

ECHA uses a separate system for invoicing the fees, which records the invoices raised and the payments received in the central accounting system monthly.

A) REACH Fees and Charges

The total net invoiced REACH fees and charges amounted to EUR 33.02 million in 2022 (EUR 26.63 million in 2021 and EUR 28.64 million in 2020). The table below depicts the breakdown of the net invoiced REACH fees during the years 2020-2022.

REACH	2022		2021		2020	
Description	No of Invoices	EUR	No of Invoices	EUR	No of Invoices	EUR
Invoices issued	6 579	35 011 416	6 588	28 295 673	7 383	31 360 367
Credit Notes	494	(1 628 744)	215	(1 161 459)	257	(1 857 253)
Unpaid	111	(364 332)	118	(505 526)	154	(867 424)
Considered paid	17	(842)	29	(488)	18	(274)
Net Invoiced		33 017 498		26 628 200		28 635 416
Write offs	13	(238 488)	29	(458 573)	-	-

On 31 December 2022, the amount to be recovered for REACH fees and charges, before any year-end accounting adjustments, stood at EUR 1.95 million relating to 290 open invoices (On 31 December 2021, the amount to be recovered for REACH fees and charges, before any year end Accounting adjustment, stood at EUR 2.41 million relating to 376 open invoices).

B) BPR Fees and Charges

The total net invoiced BPR fees amounted to EUR 6.80 million in 2022 (EUR 3.00 million in 2021). The table below depicts the breakdown of the net invoiced BPR fees during the years 2022-2022.

BPR	2022		2021		2020	
Description	No of Invoices	EUR	No of Invoices	EUR	No of Invoices	EUR
Invoices issued	1 201	8 232 100	730	3 383 700	1 126	3 350 000
Credit Notes	103	(1 347000)	39	(363 700)	67	(518 800)
Unpaid	37	(81 400)	14	(13 700)	23	(230 500)
Considered paid	3	(95)	2	(110)	2	(25)
Net Invoiced		6 803 605		3 006 190		2 600 675

On 31 December 2022, the amount to be recovered for Biocidal product fees and charges before any year end accounting adjustments, stood at EUR 0.10 million relating to 18 open invoices (On 31 December 2021, the amount to be recovered for BPR fees and charges, before any year end Accounting adjustment, stood at EUR 0.05 million relating to 39 open invoices).

Expenditure

ECHA's expenditure budget consists of commitment appropriations (CA) and payment appropriations (PA). The initial CAs totalled EUR 112.0 million and the initial PAs totalled EUR 111.9 million, while the figure concluded in the final budget is EUR 114.8 million for CAs and EUR 114.6 million for PAs. These commitment and payment appropriations consist of C1 funds.

Budget expenditure includes payments made during the year and the carry-over of budgetary appropriations. The following paragraphs and the tables provided in the Statistics on Financial Management and Budget (Expenditure) summarise the execution of appropriations per title while a more detailed breakdown is provided in Appendix I.

Changes and implementation of the of the commitment appropriations for the current year (C1)

The initially adopted budget for the Agency in 2022 was EUR 112.0 million and the overall net increase during the year, including 20 transfers and two amending budgets, was EUR 2.8 million, to arrive at EUR 114.8 million as the final budget.

The main reason for the increase in the budget was the positive fee income development, which allowed, for instance, accelerating some IT investments initially planned for 2023.

The final executed amount totalled EUR 113.2 million corresponding to an execution rate of 98.6% for the appropriations.

Carry over of appropriations to 2023

The commitment and payment appropriations carried over to 2023 totals EUR 15.5 million, corresponding to 13.7% of the committed amount.

The carry-over of staff related expenditure, budgeted in Title 1, was insignificant and mainly relates to the commitments for trainings and interim services.

In Title 2, covering the Agency's infrastructure, the carry over totalled EUR 1.8 million, stemming mainly from commitments related to ECHA's IT services.

The operational expenditure required to implement the Work Programme for the different regulations is budgeted in Title 3 for REACH and CLP, in Title 4 for Biocides and in Title 5 for the Environmental Directives and International Conventions (PIC, POPs, Waste Framework Directive (SCIP), Drinking Water Directive and the 8th Environment Action Programme). The carry over in operational titles totalled EUR 13.6 million and is mostly related to IT projects.

The relatively high level of carry overs stems from the contracting cycle caused largely by the uncertainty in the fee income. In the past years, ECHA has had to wait late in the year before signing the contracts to make sure sufficient funds will be available, and at the same time, has had to sometimes frontload certain projects when the income has exceeded the estimates. This had led to a situation where, during the first part of the year, the focus has been on implementing the projects carried over and new projects are only commenced during the second half and sometimes even during the last quarter of the year.

Implementation of the appropriations carried over from previous year (C8)

The amount carried over from 2021 totalled EUR 13.2 million and the finally executed amount was EUR 13.0 million, corresponding to 98%. The cancelled 2% relates mostly to IT projects in Title 2 and lower than anticipated costs for legal services related to collection of administrative charges.

Late interest payments

During 2022, ECHA did not pay late interest for commercial invoices.

Procurement procedures

In 2022, in implementing its budget, ECHA signed 333 contracts and purchase orders. Following the return to the normal operations of the Agency on its premises, the number of catering and travel agency orders, through the electronic ordering tools of the relevant framework contracts (FWC), got closer to the pre-Covid 19 years.

Out of the 333 signed contracts, 275 were specific contracts and orders under FWC, and 58 were contracts resulting from tendering procedures.

Out of the 58 contracts following procurement, ECHA concluded 2 new FWCs for printing as a service and for ex-post evaluations; and joined 3 inter-institutional FWCs, one for IT services (Benchmarking, Advisory and Consultancy Services in Information and Communication Technology – BEACON Lot 2); and two for HR (EIOPA-OP-139-2022 for the assessment of management skills and OC/EFSA/AMU/2021/03 - Lot 1 for the delivery of tailored training courses/sessions on the specific steps of the SR process). A total of 19 contracts were signed following negotiated procedures without prior publication based on the relevant rules of the Financial Regulation (Annex 1–11.1), 10 of which refer to legal services; 7 for technical reasons for subscriptions to a scientific database and professional journals, as well as for a parking garage related to the lease agreement, as well as two FWC ceiling increases had been foreseen in the specifications of the original procurement procedure.

In 2022, the performance of the suppliers of the Agency was satisfactory overall and in accordance with the terms of the contracts, with very few exceptions, which were successfully addressed by ECHA. The contractual arrangements implemented in 2020 to tackle the consequences of the COVID-19 pandemic on the contracts (such as reduced presence on-site, reduced volumes of services, etc) were discontinued in 2022.

Preliminary market consultation in the form of questionnaires to be filled up by potential tenderers has become an established practice in ECHA before launching procurement. The Agency also arranged an ECHA IT days event to reach out to potential IT service providers.

Green Public Procurement (GPP) continued to be a priority and an integral part of the Agency's management system.

The annual list of contractors is published by ECHA by 30 June of each year for the previous year on ECHA's website[92].

Acts of delegation and sub delegation

For the purposes of the budget implementation, and in line with Article 41(1) of ECHA's Financial Regulation, the Executive Director as the Authorising Officer of the Agency has delegated financial powers to the directors for the budget lines which they are responsible for, in line with their activities.

In accordance with Article 41(2), the directors have further sub-delegated financial powers to the heads of unit of their directorates.

For efficiency reasons, the Executive Director has also delegated financial powers to authorise payments below EUR 6 000 to staff in the Finance Unit.

[92] https://echa.europa.eu/view-article/-/journal_content/title/annual-list-of-awarded-contracts

Statistics on Financial Management and Budget (Expenditure)

Budget 2022: Breakdown and changes in commitment appropriations and implementation of the appropriations for the current year (C1) per Title93 (EUR)

Title	Description	Budget 2022 (1)	Transfers / amendments (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (6)/(5)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
A-1	STAFF	76 977 340	-833 249	76 144 091	75 359 404	99.0%	76 144 091	75 162 697	98.7%	196 707	0.3%	784 687
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	14 953 313	566 235	15 519 548	15 441 082	99.5%	15 519 548	13 684 856	88.2%	1 756 227	11.4%	78 466
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	15 925 468	2 221 019	18 146 487	17 565 751	96.8%	17 938 444	7 232 692	40.3%	10 124 968	57.6%	580 736
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	2 009 792	800 673	2 810 465	2 695 134	95.9%	2 810 465	765 270	27.2%	1 929 864	71.6%	115 331
B0-5	OPERATIONAL EXPENDITURE - ENVIRONMENTAL DIRECTIVES AND INTERNATIONAL CONVENTIONS	2 113 778	43 322	2 157 100	2 125 619	98.5%	2 157 100	606 331	28.1%	1 519 288	71.5%	31 481
		111 979 691	**2 798 000**	**114 777 691**	**113 186 990**	**98.6%**	**114 569 648**	**97 451 845**	**85.1%**	**15 527 055**	**13.7%**	**1 590 701**

[93] Note: As ECHA operates with both differentiated (multi-annual) and non-differentiated (annual) budget lines, the funds reserved for commitments (commitment appropriations) do not equal the funds reserved for payments (payment appropriations). The results for the administrative titles 1 and 2 are combined for all three regulations.

Budget 2022: Breakdown and changes in commitment appropriations and implementation of the appropriations for the current year (C1) per Regulation and Title (EUR)

REACH/CLP

Title	Description	Budget 2022 (1)	Transfers / amendments (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (6)/(5)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
A-1	STAFF	66 639 683	-884 007	65 505 676	64 789 505	98.9%	65 505 676	64 620 969	98.6%	168 536	0.3%	716 171
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	12 650 569	267 511	13 168 080	13 100 534	99.5%	13 168 080	11 615 551	88.2%	1 484 983	11.3%	67 546
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	15 925 468	2 221 019	18 146 487	17 565 751	96.8%	17 938 444	7 232 692	40.3%	10 124 968	57.6%	580 736
		95 215 720	**1 604 523**	**96 820 243**	**95 455 789**	**98.6%**	**96 612 200**	**83 469 212**	**86.4%**	**11 778 487**	**12.3%**	**1 364 454**

BIOCIDES

Title	Description	Budget 2022 (1)	Transfers / amendments (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (6)/(5)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
A-1	STAFF	8 204 518.00	356 755.00	8 561 273.00	8 505 326.75	0.99	8 561 273.00	8 485 155.51	0.99	20 171.24	0.00	55 946.25
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	1 704 690.00	36 049.00	1 740 739.00	1 732 659.69	1.00	1 740 739.00	1 531 812.62	0.88	200 847.07	0.12	8 079.31
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	2 009 792.00	800 673.00	2 810 465.00	2 695 133.98	0.96	2 810 465.00	765 269.59	0.27	1 929 864.39	0.72	115 331.02
		11 919 000.00	**1 193 477.00**	**13 112 477.00**	**12 933 120.42**	**0.99**	**13 112 477.00**	**10 782 237.72**	**0.82**	**2 150 882.70**	**0.17**	**179 356.58**

ENVIRONMENTAL DIRECTIVES AND INTERNATIONAL CONVENTIONS

Title	Description	Budget 2022 (1)	Transfers / amendments (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (6)/(5)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
A-1	STAFF	2 133 139.00	-55 997.00	2 077 142.00	2 064 572.85	0.99	2 077 142.00	2 056 572.32	0.99	8 000.53	0.00	12 569.15
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	598 054.00	12 675.00	610 729.00	607 889.01	1.00	610 729.00	537 492.65	0.88	70 396.36	0.12	2 839.99
B0-5	OPERATIONAL EXPENDITURE - ENVIRONMENTAL DIRECTIVES AND INTERNATIONAL CONVENTIONS	2 113 778.00	43 322.00	2 157 100.00	2 125 618.60	0.99	2 157 100.00	606 330.63	0.28	1 519 287.97	0.71	31 481.40
		4 844 971.00	**0.00**	**4 844 971.00**	**4 798 080.46**	**0.99**	**4 844 971.00**	**3 200 395.60**	**0.66**	**1 597 684.86**	**0.33**	**46 890.54**

Budget 2022: Implementation of differentiated appropriations (EUR)

Budget line		Available commitment appropriations	Commitments made	%	Available payment appropriations	Payments made	%
B3-111	Substance evaluation and Rapporteurs (Multiannual)	781 057	780 758	100%	440 364	440 017	100%
B3-801	Cooperation with international organisations for IT programs	400 000	400 000	100%	532 650	532 650	100%
Total		**1 181 057**	**1 180 758**	**100%**	**973 014**	**972 667**	**100%**

Out of the total available commitment appropriations, EUR 998 254 was stemming from commitments made in earlier financial years. The available commitment appropriations for 2022 totalled EUR 1 181 057 out of which EUR 1 180 758 (100%) were committed.

Budget 2022: Implementation of assigned revenue (C4, C5, R0) (EUR)

Title	Description	FS	Commitments Appropriations	Commitments Established	Com%	Payments Appropriations	Payments Executed	Pay%	Carried over commitment appropriations	Carried over payment appropriations
A-1	STAFF	C4	28 728	0	0%	28 728	0	0%	28 728	28 728
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	C4	11 299	0	0%	11 299	0	0%	11 299	11 299
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	C4	33 043	0	0%	33 043	0	0%	33 043	33 043
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	C4	852	0		852	0	0%	852	852
		C4	**73 922**	**0**	**0%**	**73 922**	**0**	**0%**	**73 922**	**73 922**

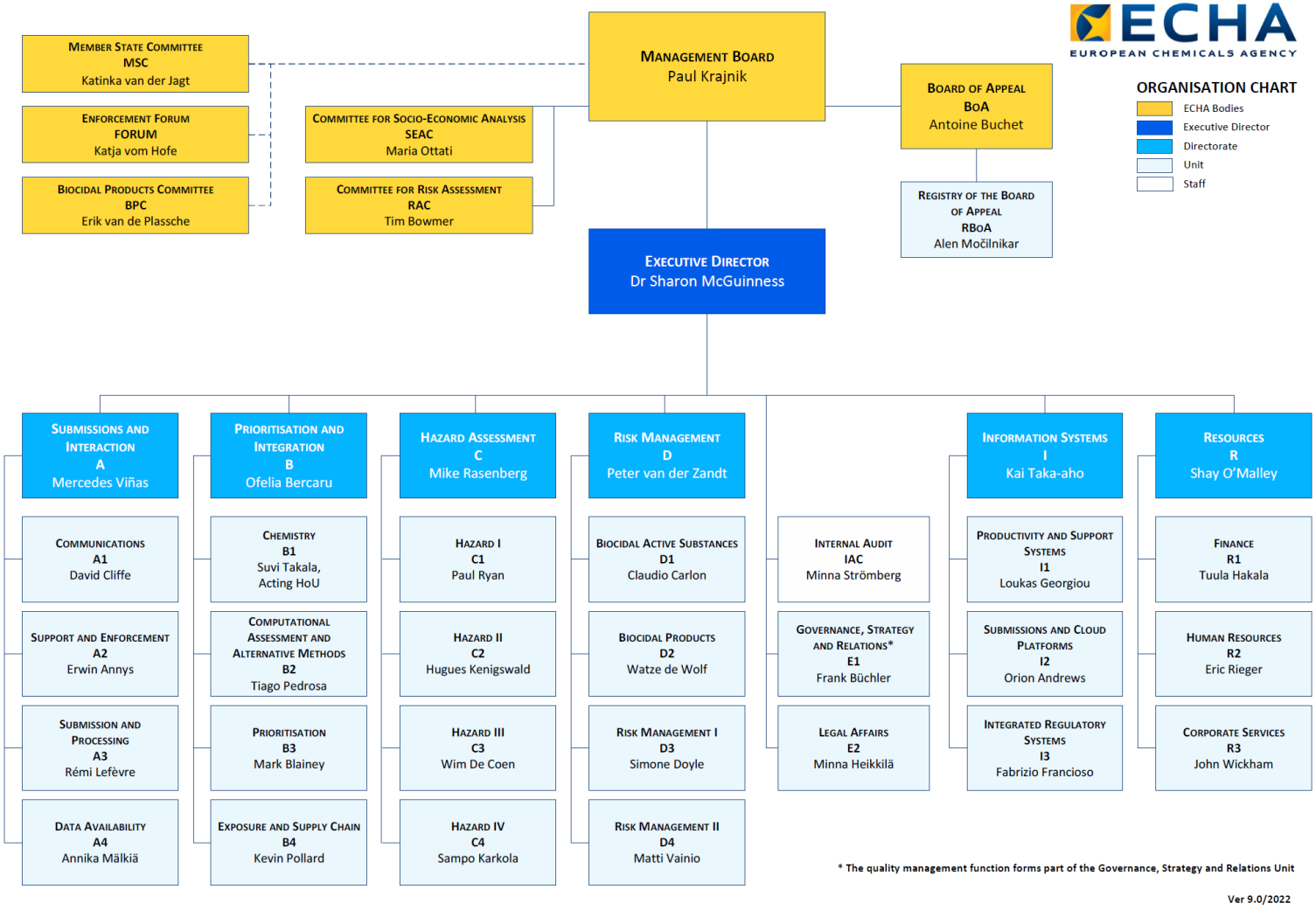
Title	Description	FS	Commitments Appropriations	Commitments Established	Com%	Payments Appropriations	Payments Executed	Pay%	Carried over commitment appropriations	Carried over payment appropriations
A-1	STAFF	C5	29 128	28 728	99%	29 128	28 728	99%	0	0
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	C5	231 092	231 092	100%	231 092	225 583	98%	0	5 509
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	C5	59 721	58 353	98%	59 721	35 710	60%	0	22 644
		C5	**319 941**	**318 173**	**99%**	**319 941**	**290 020**	**91%**	**0**	**28 153**

BL	Description	FS	Commitments Appropriations	Commitments Established	Com%	Payments Appropriations	Payments Executed	Pay%	Carried over commitment appropriations	Carried over payment appropriations
B6-000	IPA programme	R0	230 341	209 855	91%	230 341	201 507	87%	20 487	28 834
B6-010	EUON	R0	1 757 801	987 500	56%	1 763 982	705 606	40%	770 300	1 058 376
B6-011	EUCLEF	R0	3 339 455	1 345 498	40%	3 333 273	854 339	26%	1 993 957	2 478 934
B6-020	Occupational exposure limits	R0	1 323 717	746 497	56%	1 323 717	642 325	49%	577 220	681 392
B6-021	Further development of IUCLID (w/ third parties)	R0	2 428 511	2 317 795	95%	2 428 511	1 473 547	61%	110 716	954 963
		R0	**9 079 825**	**5 607 145**	**62%**	**9 079 825**	**3 877 325**	**43%**	**3 472 680**	**5 202 500**

Budget 2022: Implementation of the appropriations carried forward from previous year (C8) Per Title (EUR)

Title	Description	Carried Forward from 2021	Paid	Cancelled	% Cancelled
A-1	STAFF	271 123	264 334	6 789	3%
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	1 803 973	1 695 756	108 217	6%
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	6 617 928	6 531 816	86 112	1%
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	2 146 677	2 143 280	3 397	0%
B0-5	OPERATIONAL EXPENDITURE - ENVIRONMENTAL DIRECTIVES AND INTERNATIONAL CONVENTIONS	2 358 674	2 357 127	1 547	0%
		13 198 374	**12 992 312**	**206 062**	**2%**

Appendix III – Organisational chart



Appendix IV - Establishment plan and additional information on human resources management

Category and grade	Establishment plan in voted EU Budget 2022				Posts filled 31 December 2022*			
	TA				TA			
	REACH/ CLP	Biocides	ENV	TOTAL	REACH/ CLP	Biocides	ENV	TOTAL
AD 15				0				0
AD 14	6			6	2			2
AD 13	13	1		14	5			5
AD 12	12	2		14	7	2		9
AD 11	30	1		31	21	1		22
AD 10	41	5		46	40	3		43
AD 9	60	10	1	71	49	7	1	57
AD 8	52	9		61	60	6		66
AD 7	53	9	1	63	45	10	1	56
AD 6	27	5	3	35	50	8		58
AD 5	16	1		17	25	6	3	34
Total AD	310	43	5	358	304	43	5	352
AST 11				0				0
AST 10				0				0
AST 9	5			5				0
AST 8	8			8	4	0	0	4
AST 7	10	1	2	13	11	0	0	11
AST 6	18	1		19	16	0	0	16
AST 5	20	3	1	24	19	2	1	22
AST 4	17	3	2	22	12	3	2	17
AST 3	11	1	1	13	9	3	1	13
AST 2	5			5	20	1	2	23
AST 1	0		0	0	0	0	0	0
Total AST	94	9	6	109	91	9	6	106
AST/SC 6				0				0
AST/SC 5				0				0
AST/SC 4				0				0
AST/SC 3				0				0
AST/SC 2				0				0
AST/SC 1				0				0
TOTAL AD+AST	**404**	**52**	**11**	**467**	**395**	**52**	**11**	**458**

	CA estimated need of FTEs 2022					CA posts filled 31 December 2022[94]				
	REACH/ CLP	Biocides	ENV	Other tasks	TOTAL	REACH/ CLP	Biocides	ENV	Other tasks	TOTAL
CA FG IV	24	7	11	13	55	19	5	7	10	41
CA FG III	52	6	2	1	61	48	4	5	3	60
CA FG II	18	2			20	21	4	1	1	27
CA FG I					0					0
TOTAL	**94**	**15**	**13**	**14**	**136**	**88**	**13**	**13**	**14**	**128**

[94] Under recruitment (included in figures): REACH: 8 TAs

Percentage of posts filled on 31 December 2022

Percentage of posts filled on 31 December 2022			
	REACH/ CLP	Biocides	ENV
TA posts	97.77%	100.00%	100.00%
CA posts	93.62%	86.67%	100.00%

Geographical and gender balance (as per 31 December 2022)[95]

	Nationality		TA			CA			OVERALL	%
			Male	Female	Total	Male	Female	Total	Sum	
1	AT	Austrian	2	3	5	0	1	1	6	1.0%
2	BE	Belgian	12	10	22	2	1	3	25	4.3%
3	BG	Bulgarian	1	9	10	3	4	7	17	2.9%
4	CY	Cypriot	0	0	0	1	0	1	1	0.2%
5	CZ	Czech	0	2	2	1	0	1	3	0.5%
6	DE	German	18	11	29	2	0	2	31	5.4%
7	DK	Danish	1	1	2	0	0	0	2	0.3%
8	EE	Estonian	0	6	6	1	0	1	7	1.2%
9	ES	Spanish	16	13	29	5	5	10	39	6.7%
10	FI	Finnish	55	87	142	12	29	41	183	31.7%
11	FR	French	20	15	35	2	7	9	44	7.6%
12	GR	Greek	14	6	20	6	5	11	31	5.4%
13	HR	Croatian	0	0	0	0	1	1	1	0.2%
14	HU	Hungarian	2	7	9	0	3	3	12	2.1%
15	IE	Irish	11	4	15	0	2	2	17	2.9%
16	IS	Iceland	0	0	0	0	0	0	0	0.0%
17	IT	Italian	24	18	42	4	4	8	50	8.7%
18	LI	Liechtenstein	1	0	1	0	0	0	1	0.2%
19	LT	Lithuanian	1	5	6	0	0	0	6	1.0%
20	LU	Luxembourger	0	0	0	0	0	0	0	0.0%
21	LV	Latvian	1	5	6	1	2	3	9	1.6%
22	MT	Maltese	0	3	3	0	0	0	3	0.5%
23	NL	Dutch	12	5	17	1	1	2	19	3.3%
24	NO	Norwegian	0	0	0	0	0	0	0	0.0%
25	PL	Polish	7	9	16	1	3	4	20	3.5%
26	PT	Portuguese	5	6	11	0	3	3	14	2.4%
27	RO	Romanian	1	4	5	3	7	10	15	2.6%
28	SE	Swedish	3	3	6	1	0	1	7	1.2%
29	SI	Slovenian	3	3	6	1	0	1	7	1.2%
30	SK	Slovakian	1	2	3	0	2	2	5	0.9%
31	UK	British	2	0	2	1	0	1	3	0.5%
32	Other	Other	0	0	0	0	0	0	0	0.0%
		TOTAL	**213**	**237**	**450**	**48**	**80**	**128**	**578**	**100.0%**

[95] Data in the table includes statutory staff in place on the indicated date. Posts under recruitment are not included.

Middle and senior management – gender and nationality overview[96]

NATIONALITY		MALE	FEMALE	TOTAL	%
BE	Belgian	2	0	2	6.1%
DE	German	2	0	2	6.1%
ES	Spanish	1	1	2	6.1%
FI	Finnish	4	4	8	24.2%
FR	French	3	0	3	9.1%
GR	Greek	1	0	1	3.0%
IE	Irish	4	2	6	18.2%
IT	Italian	2	0	2	6.1%
NL	Dutch	3	0	3	9.1%
PT	Portuguese	1	0	1	3.0%
RO	Romanian	0	1	1	3.0%
SE	Swedish	1	0	1	3.0%
SI	Slovenian	1	0	1	3.0%
Total	**OVERALL**	**25**	**8**	**33**	**100%**

Results of the screening / benchmarking exercise

Key functions	Type of contract (official, TA or CA)	Function group, grade of recruitment (or bottom of grade bracket if published with such bracket)	Indication whether the function is dedicated to administrative support or operations subject to definitions used in screening methodology
Core functions			
Executive Director	TA – 5+5 years	AD 14	Management-Operations
Deputy Executive Director	TA – 5+5 years + indefinite	AD 14	Management-Operations
Director (Head of Directorate) (Level 2)	TA – 5+5 years + indefinite	AD 12	Management-Operations
Head of Unit (Level 3)	TA – 5+5 years + indefinite	AD 9	Operations/Administration
Administrator	TA – 5+5 years + indefinite	AD 5 and higher depending on profile	Operations/Administration
Administration			
Head of Administration (Head of Directorate) (Level 2)	TA – 5+5 years + indefinite	AD 12	Management-Administration
Head of Human Resources (Level 3)	TA – 5+5 years + indefinite	AD 9	Administration
Head of Finance (Level 3)	TA – 5+5 years + indefinite	AD 9	Administration

[96] Data in the table includes statutory staff in place on the indicated date. Posts under recruitment are not included.

Key functions	Type of contract (official, TA or CA)	Function group, grade of recruitment (or bottom of grade bracket if published with such bracket)	Indication whether the function is dedicated to administrative support or operations subject to definitions used in screening methodology
Head of Communications (Level 3)	TA – 5+5 years + indefinite	AD 9	Administration
Head of IT (Level 3)	TA – 5+5 years + indefinite	AD 9	Administration
Assistant	TA - 5+5 years + indefinite	AST 1 and higher depending on profile, up to AST 4	Operations/Administration
Special functions			
ECHA Committee or Board of Appeal Chair	TA - 5+5 years + indefinite	AD 10	Operations
Data Protection Officer	TA - 5+5 years + indefinite	AD 6	Administration
Accounting Officer	TA - 5+5 years + indefinite	AD 8	Administration
Internal Auditor	TA - 5+5 years + indefinite	AD 10	Administration

Benchmarking against previous results

ECHA undertook the benchmarking (job screening) exercise in 2022, in accordance with the Commission's requirements. The 2022 results indicate a decrease of 0.5% in the percentage of administrative support and coordination staff, an increase of 0.6% in the percentage of the operational staff and a decrease of 0.1% in the percentage of neutral staff in comparison to 2021.

Job Type (sub) category	2021	2022
Administrative support and Coordination	15.0	14.5
Administrative Support	12.1	11.7
Coordination	2.9	2.8
Operational	80.8	81.4
Top level Operational Coordination	2.6	2.6
Programme management and Implementation	55.6	57
Evaluation & Impact assessment	3.4	3.4
General operational	19.2	18.6
Neutral	4.2	4.1
Finance/ Control	4.0	4.0
Linguistics	0.2	0.1

Appendix V – Human and financial resources by activity

WP activity	Actual consumption of the human resources	Executed budget 2022
1.1 Dossier preparation	29	8 731 753
1.2 Registration and dossier submission	35	8 813 265
1.3 Identification and prioritisation	52	9 014 092
1.4 Evaluation	101	17 696 003
1.5 Authorisation	31	6 236 268
1.6 Restrictions	30	5 970 951
1.7 Classification and labelling	28	5 900 697
1.8 Safe and sustainable use of chemicals	8	1 752 719
1.9 Data management and dissemination	20	8 016 673
2. Biocides	55	10 285 620
3.1 Prior Informed Consent	8	1 435 202
3.2 Persistent organic pollutants	1	176 819
3.3 Waste Framework Directive	6	1 246 735
3.4 Drinking Water Directive	6	998 977
3.5 8th Environment Action Programme	1	280 052
4.1 EU Observatory for Nanomaterials	3	987 500
4.2 EU Chemicals Legislation Finder	1	1 345 498
4.3 Support to Occupational health legislation	6	746 497
4.4 Instrument for Pre-Accession assistance (IPA)	1	209 855
4.5 Support to other legislation	1	
4.6 IUCLID for EFSA	4	2 317 795
4.7 Partnership for the Assessment of Risk from Chemicals[97]	2	
Governance and enablers	159	26 631 164
Overall TOTAL	**588**	**118 794 135**

[97] Financed with REACH/CLP resources

Appendix VI – Contribution, grant and service-level agreements

	General information					Financial and HR impacts		
	Actual or expected date of signature	**Total amount**	**Duration**	**Counterpart**	**Short description**		**2021**	**2022**
Grant agreements								
1. IPA	21.12.2022	724 471	42 months	Commission DG NEAR	See Section 'Instrument for Pre-Accession Assistance (IPA)'	Amount	341 811	209 855
						Number of CA	1	1
						Number of SNEs	-	-
Total Grant agreements						Amount	341 811	209 855
						Number of CA	1	1
						Number of SNEs	-	-
Contribution agreements								
1. EUCLEF	10.12.2021	5 829 200	5 years (2021-2025)	Commission DG GROW	See Section 'EU Chemicals Legislation Finder'	Amount	1 329 403	1 345 498
						Number of CA	0	0
						Number of SNEs	-	-
2. EUON	09.12.2021	3 066 000	5 years (2021-2025)	Commission DG GROW	See Section 'EU Observatory for Nanomaterials'	Amount	1 021 616	987 500
						Number of CA	3	3
						Number of SNEs	-	-
Total Contribution agreements						Amount	2 351 019	2 332 998
						Number of CA	3	3
						Number of SNEs	-	-
Service-level agreements								
1. IUCLID for EFSA	26.03.2021	Annual fee of 784 712 plus project cost	N/A	EFSA	See Section 'IUCLID for EFSA'	Amount	2 244 577	2 317 795
						Number of CA	4	4
						Number of SNEs	-	-
2. OEL	23.02.2022	195 000 per opinion	18-24 months per case	Commission DG EMPL	See Section 'Support to occupational health legislation'	Amount	574 375	746 497
						Number of CA	4	4
						Number of SNEs	-	-
Total service-level agreements						Amount	2 818 952	3 064 292
						Number of CA	8	8
						Number of SNEs	-	-
TOTAL (grant agreements, contribution agreements and service-level agreements)						**Amount**	**5 511 782**	**5 607 145**
						Number of CA	**12**	**12**
						Number of SNEs	**-**	**-**

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