

# Annual Report 2023

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#### Annual Report 2023

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# List of acronyms

Acronym	Description
AD	Administrator
APCRA	Accelerating the Pace of Chemical Risk Assessment
ARN	Assessment of regulatory needs
ASO	Accredited Stakeholder Organisation
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
ССН	Compliance check
CCS	Chemicals Strategy for Sustainability of the Commission
CEFIC	Conseil Européen des Fédérations de l'Industrie Chimique
CEOS	Conditions of Employment of Other Servants of the European Union
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
CMR	Carcinogenic, mutagenic or toxic to reproduction
CoIAC	Conflict of Interest Advisory Committee
СОМ	European Commission
CoRAP	Community rolling action plan
CSA	Chemical safety assessment
CSR	Chemical safety report
CSS	Chemicals Strategy for Sustainability of the Commission
DEC	Discharge procedure

Acronym	Description
Acronym	
	2021/2157(DEC)
DG DIGIT	Directorate General for Informatics
DG EMPL	Directorate General for Employment, Social Affairs and Inclusion
DG GROW	Directorate General for Internal Market, Industry, Entrepreneurship and SMEs
DG NEAR	Directorate General for Neighbourhood and Enlargement Negotiations
DG RTD	Directorate General for Research and Innovation
DNA	Designated national authorities
DNEL	Derived no-effect level
DPP	Digital Product Passports
DU	Downstream user
DWD	Drinking Water Directive
EAP	Environmental Action Programme
EC	European Commission
ECA	European Court of Auditors
ECETOC TRA	European Centre for Ecotoxicology and Toxicology of Chemicals Targeted Risk Assessment
ECHA	European Chemicals Agency
eChemPortal	OECD Global Portal to Information on Chemical Substances
ED	Endocrine disruptor
EEA	European Economic Area
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EMA	European Medicines Agency
EMAS	EU Eco-Management and Audit Scheme
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EMS	Environmental management system
US EPA	United States Environmental Protection Agency
ERR	Exposure-risk relationship

Acronym	Description	Acronym	Description
ES	Exposure scenario	MS	Member State
EU	European Union	MSC	Member State Committee
EUCLEF	European Chemicals Legislation Finder	MSCA	Member State competent authority
EUON	European Union Observatory for	NAM	New approach methodologies
	Nanomaterials	NGO	Non-governmental organization
EUSES	European Union System for Evaluation of Substances	NEA	National enforcement authority
Forum	Forum for Exchange of Information on Enforcement	NeRSAP	Network of REACH SEA and Analysis of Alternatives practitioners
FRA	Final regulatory action	NONS	Notification of New Substances
FTE	Full-time equivalent	Odyssey	ECHA's tool to support evaluation
FWC	Framework contract		tasks
GIME	Groupe Interinstitutionnel de Management Environnemental	OECD	Organisation for Economic Co- operation and Development
	(Interinstitutional Group for Environmental Management)	OEL	Occupational exposure limit
GPP	Green Public Procurement	OSH	Occupational safety and health
HelpNet	Network of national BPR, CLP and	PACT	Public activities coordination tool
	REACH helpdesks	PAH	Polycyclic aromatic hydrocarbons
HR	Human resources	PARC	Partnership for the Assessment of Risks of Chemicals
IAC	Internal Audit Capability of ECHA	DDT	Persistent, bioaccumulative and
IAS	Internal Audit Service of the Commission	РВТ	toxic
ICT	Information communications	PCN	Poison Centre Notifications
	technology Industrial Emissions Directive	PFAS	Per- and polyfluoroalkyl substances
IED	2010/75/EU	PFCA	Perfluorocarboxylic acids
IMS	Integrated Management System	PFOS	Perfluorooctanesulfonic acid
IPA	Instrument for Pre-Accession Assistance	PIC	Rotterdam Convention on the prior informed consent procedure
IR	Information requirements		(and the respective Regulation)
IRS	Integrated Regulatory Strategy	PMT	Persistent, mobile and toxic Persistent organic pollutants
ISO	International Organisation for Standardisation	POP	Persistent Organic Pollutants
тт	Information technology	POPRC	Review Committee
IT IUCLID	International Uniform Chemical Information Database	POPs	Persistent organic pollutants (and the respective Regulation)
JEAP	Joint Evaluation Action Plan	PPORD	Product and Process Oriented Research and Development
JRC	Joint Research Centre		Plant protection products
KPI	Key Performance Indicators	PPP	Polyvinyl chloride
MB	Management Board	PVC	Quantitative Structure-Activity
МССР	Medium-chain chlorinated paraffins	QSAR	Relationship
MFF	Multiannual Financial Framework	R4BP	Register for Biocidal Products Committee for Risk Assessment
MISA	Metals and Inorganics Sectoral	RAC	
	Approach	REACH	Registration, evaluation, authorisation and restriction of

Acronym	Description
	chemicals (and the respective Regulation)
REACH-IT	Central IT system providing support for REACH
REF	REACH-EN-FORCE (Forum- coordinated REACH enforcement project)
DG RTD	Directorate-General for Research and Innovation
SCBTH	Serious Cross-Borders Threats to Health
SCIP	Database for information on Substances of Concern In articles as such or in complex objects (Products)
SEAC	Committee Socio-economic Analysis Committee
SLA	Service Level Agreement
SME	Small and medium-sized enterprises
SNE	Seconded national expert
SON	Security Officers Network
SPC	Summary of product characteristics
SVHC	Substance of very high concern
ТА	Temporary agent
ТР	Testing proposal

Acronym	Description
UNEP	United Nations Environment Programme
UNGHS	United Nations Globally Harmonised System of classification and labelling of chemicals
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
1S1A	One substance one assessment

# Management Board analysis and assessment

The Management Board welcomes the Annual Report 2023, combining the reports prepared according to the requirements of the REACH Regulation (General Report)<sup>1</sup> and those of the ECHA Financial Regulation (Consolidated Annual Activity Report)<sup>2</sup>.

We consider that this report provides a comprehensive account of the activities carried out by ECHA during 2023, the performance of the Agency against the expected inputs, outputs, outcomes, and the impacts defined in the Programming Document 2023-2026<sup>3</sup>. 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, achievements, financial information, results of audits, retrospective 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 2023 were high, as shown in Part I of the Annual Report.

In assessing<sup>4</sup> the Consolidated Annual Activity Report of the Authorising Officer for 2023, we:

- Emphasize the importance of the ECHA Strategy adopted in December 2023, in providing direction and priorities for ECHA in implementing its evolving mandate.
- Commend the secretariat and all ECHA bodies for being prepared for and having started to implement new or expanded legal mandates.
- Welcome that ECHA made progress with the Integrated Regulatory Strategy, including identification of (groups of) substances that are candidates for regulatory risk management measures, addressed the key actions from the Joint Evaluation Action Plan and started the review of its outcomes.
- Acknowledge the significant support provided to the European Commission in the implementation of the Chemicals Strategy for Sustainability (CSS).
- Express concern regarding the membership of the ECHA scientific Committees, which poses a risk of not meeting legal deadlines and targets in operational areas that are dependent on the Committees outputs.
- Acknowledge and support the efforts of all contributors in facilitating the preparation of the RAC/SEAC opinion on the Annex XV report for the UPFAS restriction, given its unique complexity and size.
- Acknowledge that the number of opinions that the Biocidal Products Committee (BPC) was in a position to deliver in 2023 was well below estimated numbers due to significantly less submissions by the Member States of evaluation dossiers both for active substances and Union authorisations.

<sup>&</sup>lt;sup>1</sup> Article 78(a) of the REACH Regulation.

<sup>&</sup>lt;sup>2</sup> Article 48 of ECHA's Financial Regulation.

<sup>&</sup>lt;sup>3</sup> https://echa.europa.eu/documents/10162/17623970/final mb 41 2022 echa pd 2023-2026 en.pdf

<sup>&</sup>lt;sup>4</sup> Assessment pursuant to Article 48(1) of the Agency's Financial Regulation.

- Acknowledge the efforts in promoting alternatives to animal testing, and in clarifying the
  opportunities and challenges in moving away from animal testing for the regulatory
  assessment of chemicals.
- Welcome the increased clarity in the way the secretariat reports to the Management Board.
- Note that ECHA defined 179 specific outputs for 2023 and accomplished 154 out of these during the year. In addition, 23 actions are in progress and 2 not done.

Based on the periodical reporting and the Annual Report 2023 prepared by the secretariat, the Board makes the following observations:

#### Management

• The 10 recommendations the Management Board provided for 2023 as part of the assessment of the 2022 Annual Report have been implemented or are in progress.

#### Budgetary and financial management

• We welcome the outstanding performance of ECHA in implementing its budget with 99% of commitment rate and 1% of cancelled payment appropriation rate, while keeping the strict segregation between its funding sources and operating in an environment of fluctuating and challenging to predict fee income.

#### Human resources management

• We commend ECHA for having maintained a high rate of filling its establishment plan posts and the strong focus on staff wellbeing, diversity and inclusion.

#### Audit and retrospective evaluation results and follow-up on recommendations

- We 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 retrospective evaluations.
- The European Court of Auditors adopted a positive opinion regarding the 2022 annual accounts, with no reservation or observation. We welcome that there are no pending observations or recommendations.
- The European Parliament, as the Discharge Authority, granted discharge to the Executive Director with respect to ECHA's 2021 budget, including the decision on the closure of the 2021 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 (IAS) of the Commission conducted an audit on 'Budget preparation, monitoring and reporting'. The audit did not result in any critical or very important recommendations. The audit identified two improvement areas, classified as important, on resource allocation and the exceptions register.

#### Internal control framework and Integrated Management System

- The internal control framework remains effective and functioning as intended. Areas identified for improvement are not considered major or critical and relate to areas such as performance management and stakeholder engagement.
- We welcome that the Integrated Management System Strategy and Framework was revised in 2023, to align it with the new ECHA Strategy 2024-2028.

• ECHA's ISO 9001:2015 and 14001:2015 quality certificates were renewed with no nonconformities found in the re-certification audit, and EMAS (Eco-Management and Audit Scheme) registration maintained.

#### Organisational risk management

- We welcome the development of the new organisational Risk Management Policy, which includes a dedicated role for a Chief Risk Officer. We found the regular updates on the risk register, including the continued specific reporting on the IT-security related risks, pertinent.
- We note that 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 Executive Director reporting, as well as the updates to the Agency Risk Register.
- We welcome that no high impact IT/cyber security incidents took place in 2023 and that ECHA is ready to implement the new EU regulation on cybersecurity for Union Institutions, Bodies, Offices and Agencies.

#### 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 2024

Based on our assessment, the Management Board requests particular emphasis in 2024 on the following actions, without prejudice to the implementation of the Single Programming Document 2024-2026:

- 1. Actively continue engaging with Member State partners and stakeholders.
- 2. Take appropriate actions to maintain the ECHA Committees' ability to deliver transparent, independent and high-quality outputs, including attention on ensuring the necessary level of competence, expertise and working structures.
- 3. Follow up on the results of the Integrated Regulatory Strategy (IRS), including promoting and facilitating the uptake of regulatory measures by Member States and further refining the performance indicators and targets for grouping.
- 4. Maintain efforts to bring to the Management Board timely and sufficient information on the implementation of current and potential new tasks, including impacts, synergies, efficiency gains, challenges and risks, including the sustainability of ECHA's Committees.
- 5. Support the preparation of the RAC/SEAC opinion on the UPFAS dossier to ensure the delivery of a transparent, independent and high-quality opinion in an appropriate timeframe.
- 6. Support the implementation of the new hazard classes in the CLP regulation.
- 7. Improve and facilitate cooperation with other Agencies and Commission Directorates General to promote issues of common interest.
- 8. Maintain efforts in providing fit-for-purpose support to Member State Competent Authorities for biocidal products, with a view to achieving progress with the Review Programme for existing active substances.
- 9. Review the costing of ECHA activities and assess whether the services delivered to duty

holders are fully charged.

10. Maintain strong focus on staff wellbeing, diversity and inclusion.

#### Acknowledgments

The members of the Management Board express their appreciation to ECHA staff, members of ECHA bodies and the Agency's partners, in particular Member States, for their commitment and achievements in 2023.

#### Conclusion

In assessing the Annual Report 2023, the Management Board concludes that the overall performance of ECHA is in line with the objectives included in the Agency's Programming Document 2023-2026.

Based on the above observations, the Management Board requests that the Annual Report 2023 be forwarded to the Member States, the Court of Auditors, the Commission, the European Parliament, the European Economic and Social Committee and the Council.

# Foreword



Dr Sharon McGuinness

**Executive Director** 

I am pleased to present the Agency's annual report for 2023. This is the final report under ECHA's Strategic Plan 2019-2023, and it shows that we have delivered the actions and performance metrics set out in our Work Programme for 2023.

We continued to deliver our legal mandate across the wide range of chemical legislation under our remit. With respect to the REACH and CLP Regulations, our two scientific committees (Risk Assessment Committee and Socio-Economic Analysis Committee) delivered six opinions on restriction dossiers, 58 opinions on uses of substances in authorisation applications and 42 opinions on proposals for harmonised classification and labelling. The Biocidal Products Committee (BPC) adopted 13 opinions for active substance approvals and renewals as well as 10 opinions on Union authorisations.

We continued the prioritisation of efforts on promoting alternatives to animal testing and held a collaborative workshop with all stakeholders to discuss how collectively we can work to promote and move to using alternatives to animal testing.

Support and input to the Commission on the Chemicals Strategy for Sustainability (CSS) was high on our agenda for 2023. We actively supported the decision-making process for the revised CLP Regulation and have already commenced work in preparation for its implementation. We also worked closely with the Commission to assist them in their considerations for the revision of the REACH Regulation and the Basic Regulation. While the anticipated publication of the REACH revision did not materialise as expected in 2023, we remain ready to support the Commission's proposal for a future revision. We also continue to support the Commission in relation to their work on the various legislative packages under One Substance, One Assessment as well as the Basic Regulation. This year also saw us commence work on implementation of the new regulatory tasks given to the Agency under the Drinking Water Directive, the Batteries Regulation, and the Serious Cross-Border Threats to Health Regulation.

While we have delivered on our mandate and Work Programme obligations, we also recognise that some issues continue to challenge. For instance, a recurring challenge was the low number of draft assessment reports for biocidal active substances and this year also a lower number of Union authorisation applications for biocidal products evaluated and submitted by Member States.

Another area of challenge is the ability to fully resource and sustain membership in our scientific committees. This poses a risk of not meeting legal deadlines and targets in operational areas that are dependent on input by Committee members. We recognise that Member States are finding it increasingly difficult to find experts with the right competencies and who can commit to the everincreasing workload. Together with the Commission and the Management Board, we have looked at ways to encourage and increase membership and participation. One first step was to review the current payments for member's rapporteur work together with the Management Board. Over the course of 2023, we emphasised the importance of a Basic Regulation for ECHA to enable us, and our committees deliver on existing and future tasks, and we hope that such a regulation will be forthcoming in the near term.

As this was my first full year as Executive Director, I spent time getting to meet ECHA's staff, partners and stakeholders. These included colleagues in the Commission, the EU Agencies, Member States, industry stakeholder groups and civil society organisations. As an Agency, we rely on close engagement and collaboration with these groups in our delivery of our legal mandate. I look forward to continuing my visits to the remaining Member States in 2024 as their current and future collaboration with ECHA is key for successful delivery of existing and future tasks.

While 2023 was the final year of our Strategic Plan 2019-2023, it was also the year that our Management Board adopted our new Strategy Statement 2024-2028. I would like to thank the members of the Management Board and all ECHA's staff for their support and active participation in the development of this new strategy. I look forward to working with them and our stakeholders in the coming period to implement our vision of chemical safety through science, collaboration, and knowledge.

Finally, I would like to express my thanks to the Management Board for their support and collaboration as I settled into my first year. A particular note of thanks and appreciation also to ECHA's management team and all the staff for their dedication and commitment in delivering our 2023 Work Programme.

# Executive summary

With 2023 the last year of our strategic plan 2019-2023, we concluded the delivery of our strategic objectives and performed the planned activities specified in our Work Programme. This year also saw us commence work on implementation of the new regulatory tasks assigned to the Agency under the Drinking Water Directive, the Batteries Regulation and the Serious Cross-Border Threats to Health Regulation. We also continued to deliver our legal mandate across the wide range of chemical legislation under our remit.

Two key deliverables under our strategic plan were the Integrated Regulatory Strategy (IRS) and the Joint Evaluation Action Plan (JEAP) and these are relevant to both the REACH and CLP regulations. Identification and prioritisation of substances and groups of substances for risk management actions is central to our Integrated Regulatory Strategy. In 2023, we made further strides in understanding the data on substances in our database with some 92% of substances registered above 100 tonnes now assessed.

Another important aspect of the IRS is to identify substances or groups of substances for which generation of data under dossier or substance evaluation may be needed. These substances are considered under the JEAP, which sets targets for checking the compliance of registration dossiers. In 2023, we performed 301 compliance checks under dossier evaluation. With the conclusion of our strategic plan in 2023, reviews of both the IRS and JEAP took place, the outcomes of which will be used to determine the next steps for implementation of our new strategic goals and priorities.

In substance evaluation, the Community rolling action plan (CoRAP) update for 2023-2025 was agreed by the Member State Committee (MSC) and published with 24 substances for evaluation by 12 Member States. Conclusions were also reached for 26 substances while 6 substance evaluation decisions were issued requesting data to address concerns regarding endocrine disruption, PBT/vPvB, and mutagenicity.

Risk management actions under REACH and CLP in 2023 included the delivery of six opinions on restrictions dossiers as well as 42 opinions on proposals for harmonised classification and labelling. These opinions were delivered by the Committee for Risk Assessment (RAC) and the Committee for Socio-Economic Analysis (SEAC).

One of the restriction opinions covered the use of PFAS in firefighting foams. Early in 2023, we also received the restriction dossier on per- and polyfluoroalkyl substances (PFAS) by the five Member States (Germany, the Netherlands, Sweden, Denmark and Norway), and by year end had concluded the initial public consultation and screening of the more than 5600 comments received. We will continue to progress this dossier through the RAC and SEAC in the course of 2024. We also received a mandate from the European Commission to prepare a restriction dossier by 2024 for chromium (VI) substances, which are covered in the growing number of authorisation applications currently being received. ECHA also completed several investigative and screening reports, including reports on Polyvinyl chloride (PVC) and additives and on substances that are carcinogenic, mutagenic or toxic to reproduction (CMRs) in childcare articles.

Other risk management actions taken in 2023 were the addition of a further 11 substances to the Candidate List for Authorisation, bringing the total number of substances of very high concern entries to 235. We also submitted eight substances under the 11<sup>th</sup> Recommendation for inclusion of substances to the Authorisation List to the European Commission. We saw an increase in the number of authorisation applications mainly for the use of chromium (VI) substances. The total numbers of applications and review reports received was 100 and our scientific committees RAC and SEAC delivered opinions on applications for authorisation of 58 uses of substances.

In 2023, we processed 13 749 registration dossiers and completed 416 SME company size verifications. Our Helpdesk answered 9200 questions, while the combined total of queries answered by Member State and European Economic Area country helpdesks was approximately 45000. While we continued to receive many questions on registration, we also saw queries on PFAS, authorisation of chromates and were seeing queries on the new legislative tasks that the Agency has been assigned. In furtherance of public availability of data, we devoted significant time to the development of our new data dissemination platform, ECHA Chem, which is scheduled to be launched in 2024. This work is the start of efforts in transforming the way we provide and make data available.

The Biocidal Products Committee (BPC) adopted 13 opinions for active substance approval and renewal, while for Union authorisations, 10 opinions were adopted in 2023. We continue to observe that estimates from Member States on submission of active substance dossiers are not met and nor are estimates of applications for Union authorisation. This is a worrying trend and requires renewed efforts by Member States to meet their ongoing regulatory obligations. We were pleased to have delivered the pollinators guidance and make progress in the move to use IUCLID for biocides dossiers.

We continued the prioritisation of efforts on promoting alternatives to animal testing in the year. We held a collaborative workshop with all stakeholders to discuss how collectively we can work to promote and move to using alternatives to animal testing. We published our fifth report on the use of alternatives to testing on animals for the REACH Regulation and highlighted the opportunities and challenges in moving away from animal testing for the regulatory assessment of chemicals.

We processed 10857 notifications under the Prior Informed Consent Regulation (PIC) with many of these related to the inclusion of benzene as the first substance in substance entry. In 2023, we published the three-years report on the operation of the PIC Regulation (Article 22 report) and provided the recommendations made in the report to the Commission's evaluation of the PIC Regulation. A key recommendation was the need to review the extent of which information is made publicly available in any future legislation as access to document (ATD) requests are increasing in relation to PIC.

In addition to the above regulatory areas, we continued to deliver on specific tasks in relation to environmental legislation or service level agreements with the Commission. For instance, we prepared a draft scientific dossier (Annex D proposal) for three substances in support of the Commission implementation of the Stockholm Convention. We continued to provide support under the Industrial Emissions Directive (IED) and followed closely the decision making for the revision of this legislation as it will formalise ECHA's role in this support work. We also delivered five opinions from the RAC on Occupational Exposure Limits (OELs) in fulfilment of our support to the Commission's Directorate General for Employment, Social Affairs and Inclusion (DG EMPL). We concluded a new contribution agreement for the period 2023-2026 with the Commission to continue providing support and training to pre-accessing countries.

Support and input to the Commission on the Chemicals Strategy for Sustainability (CSS) remained a high priority for us in 2023. We supported the Commission before and during the decision making on the revised CLP Regulation and have already commenced work in preparation for its implementation. We worked together with the European Environment Agency (EEA) under the 8<sup>th</sup> Environmental Action Programme (EAP), in establishing a new framework of indicators aimed at monitoring the drivers and impacts of chemical pollution and assessing the effectiveness of the chemical legislation. This framework will be published in 2024.

As noted already, we commenced work on the implementation of the new legislative tasks related to Drinking Water, Batteries and Serious Cross-Border Threats to Health. We supported the Commission in developing the implementing and delegated acts necessary for the operation of the Drinking Water Directive (DWD). As tasks under the DWD will eventually come under the RAC work area, we have already established a Working Group under RAC to commence

preparations for this new task by the committee. Our implementation planning for the tasks under the Batteries Regulation got underway with the publication of the legislation in August 2023. First tasks are expected to be delivered in 2025.

Significant levels of support and advice were provided to the Commission services to assist them in their considerations for the revision of the REACH Regulation and the ECHA Basic Regulation. While the anticipated publication of the REACH revision did not materialise as expected in 2023, we are ready to continue to support the Commission on a future revision.

The Commission's one substance, one assessment (1S1A) approach under the CSS was also an area where ECHA provided significant levels of input and advice. We were pleased to see that the legislative package to support 1S1A was published by year end. This package covered not only reattribution of tasks to ECHA but also a data regulation establishing a common EU data platform. We look forward to working with the Commission and decision makers in 2024 to progress this legislation.

As an agency that relies on science to develop our opinions and decisions, we worked closely with the research community to ensure that regulatory science needs are communicated and understood. In this regard, we continued to engage with 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. A key achievement for ECHA in 2023 was the publication of a report, *Key Areas of Regulatory Challenge*, which clearly set out areas where the research community could direct future research efforts.

Engagement and collaboration with stakeholders are fundamental to how we work. We continued to collaborate closely with EU agencies, particularly those with an environmental and health focus. Our close collaboration with 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, remained a focus in 2023. We have, as mentioned, worked closely 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 and chemicals legislation.

We received increased requests in 2023 to join our Accredited Stakeholder Organisation (ASO) list. We expect increased stakeholder requests to the ASO list to continue especially with our wider our legal mandate, which will bring in many new stakeholders who may not have previously worked with us. We developed a new stakeholder engagement approach, which together with our new communications strategy for 2024-2028 will enable us to continue to build strong engagement and communication channels and networks.

One of the key stakeholder groups for ECHA is our Member State colleagues, whom we work closely with daily in many different fora, for example, through our Management Board, our scientific committees, our Forum on Enforcement, Member State Communications Network, HelpNet and expert working groups. In 2023, we renewed our engagements directly with the Member States through visits to Member States so that we heard first-hand the views and requests of national authorities. Member States' full and active participation in all our committees is essential for delivery of opinions and decisions. Throughout the year, we kept a focus on facilitating sufficient nominations to the RAC and SEAC as well as ensuring that we can keep the members already involved. In these efforts, our Management Board and Commission colleagues engaged closely with us.

We are pleased to report that our legal, governance and management obligations for 2023 were all met. Our financial and HR key performance indicators were met and exceeded in many instances. We had no significant findings in any financial or other audits completed. We maintained our International Organisation for Standardisation (ISO) 9001:2015; 14001:2015 and EU Eco-Management and Audit Scheme (EMAS) certifications. We also successfully

organised meeting services for 640 events and official meetings, hosted 5000 visitors in person and 32,800 online. We continued to work to reduce CO2 emissions and in 2023 remained in line with our targets.

Our Management Board led the successful development of our new Strategy Statement for 2024-2028. This Statement was developed in close collaboration with our staff as well as Member States, Commission and stakeholders and we look forward to implementing it over the coming years.

While the year saw many deliverables and achievements, we also wish to note a number of areas that continue to challenge.

A major challenge again this year was 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 in the Review Programme by the end of 2024 as required by the Biocidal Products Regulation. While ECHA has and will continue to make efforts to support the Member States to make further progress, the reality is that Member States are not prioritising this work and many lack the capacity or resources to deliver in the near future.

Our scientific committees are a key component in delivering transparent, independent and highquality opinions, and decisions. These committees rely heavily on the participation, commitment, and expertise of members from the Member States. Keeping current members in the RAC and SEAC active and engaged was an ongoing effort in 2023. One aspect to ensure committee sustainability was to review the current payments for member's rapporteur work together with the Management Board. We hope these measures will encourage uptake across the members in the future. Notwithstanding these efforts, the number of members in the RAC and SEAC is falling as Member States find it harder to find nominees with the relevant experience and competence. This poses a risk of not meeting legal deadlines and targets in operational areas that are dependent on input by Committee members. In 2023, we worked closely with the Commission on how we can ensure a sustainable future for the committees, especially considering new tasks that have already been assigned or could be assigned because of published legislative proposals. The future ECHA Basic Regulation is an important means to achieve long term sustainability and competence for our scientific committees and ECHA has and will continue to emphasise that this Regulation is needed as soon as possible.

Another challenge is posed by the high number of authorisation applications significantly exceeding our capacity to deliver opinions. ECHA is closely monitoring the incoming applications and planning and phasing the opinion making. The European Commission has requested ECHA to prepare a restriction on chromium VI substances that may in time lead to a more efficient and timely management of the risks of these substances, while maintaining a level playing field for the operations in the industrial sectors involved.

In 2023, we commenced implementation of new legislation and new tasks. These efforts will continue over the coming years and will increase as proposals coming through the co-decision process will be finalised. Balancing implementation of new requirements while continuing to deliver a full regulatory programme will be a key area of focus in the coming period. ECHA's staff are fully committed to implementing these new tasks and we will be looking to work in close collaboration with our EU institutional partners, the Member States and other stakeholders to support us in delivering what is required.

With the publication of the 'one substance one assessment' legislative package at the end of 2023, we now can see the extent of the work required by all agencies to align their opinions and decisions across different scientific committees. We also welcome the introduction of new hazard classifications in the CLP Regulation, which will help further alignment. However, the achievement of full alignment may continue to be a challenge in the absence of changes in other legislation.

As our Strategic Plan 2019-2023 is concluded, we are reviewing some of the initiatives that supported its delivery, for example, the IRS and JEAP. These reviews have commenced in 2023. We need to determine how best to use the data in our databases to ensure that the appropriate risk management action is taken by the relevant parties, be that harmonised classification, authorisation or restriction. However, we also need to consider how we integrate additional risk management actions coming from new legislation into our thinking. Furthermore, while ECHA can analyse and provide information to the Commission and Member States, we do not have the legal basis to take action directly ourselves. Therefore, we need to have closer cooperation and engagement with the Commission and Member States to align on identification and prioritisation on appropriate risk management actions. The new Strategy Statement 2024-2028 identifies this as a priority, and we look forward to collaborating with all parties in this regard.

Further details on achievements and metrics are available in the following sections.

# Part I. Achievements of the year

### Dossier preparation

#### Highlights

In 2023, we continued to provide companies with the tools and support they need to successfully register and update their registration information. We successfully managed the inquiry process and took decisions on the data sharing requests. We updated the International Uniform Chemical Information Database (IUCLID) to incorporate new regulatory requirements at EU or international level. We contributed to development of the Organisation for Economic Cooperation and Development (OECD) test guideline programmes in key areas by actively participating in the expert group meetings and consultations.

We continued development of the Chemical Safety Assessment and Reporting tool (Chesar) to support both REACH and Biocides. The platform will fully integrate the European Union System for Evaluation of Substances (EUSES) models for environmental assessment, as well as the European Centre for Ecotoxicology and Toxicology of Chemicals' Targeted Risk Assessment (ECETOC TRA) models for workers and consumers. It 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. Integration of models for risk assessment in the platform brought a few technical challenges which lead to delays and prevented from launching in 2023 as originally planned.

The ECHA helpdesk answered 9200 questions in 2023. Intensive cooperation with the national helpdesks continued and they replied to 45000 questions, with a growing number of questions outside the original regulations in scope REACH, CLP and BPR. Most questions were on dossier preparation, the per- and polyfluoroalkyl substances (PFAS) restriction and chromates authorisation. The network of national helpdesks (HelpNet) held 26 meetings including dedicated workshops on REACH and CLP, approving four new or revised FAQs.

Two campaigns to address companies that were not in compliance with the update obligations for their registration dossiers were concluded during the year: one on compliance with harmonised classifications and one on compliance with authorisation obligations for substances in Annex XIV.

#### Main outputs

O1 Companies are supported in inquiries and in sharing their data across the EU, helping to reduce registration costs and to avoid unnecessary testing.

Inquiries and disputes on data sharing are handled.

O2 Harmonised IT tools and advice ensure consistency of risk management and safety information, thus promoting exchange across and between industry and regulatory authorities.

ECHA continues to lead the development of IUCLID and its promotion as the international harmonised format for chemical data.

Yes

✓Yes

IUCLID is progressively maintained to incorporate regulatory requirements, such as changes resulting from the amendment of REACH Annexes, other technical and scientific progress under REACH and CLP, or requirements from our OECD international partners.

ECHA contributes to the development of the OECD harmonised test guidelines relevant for the EU information requirements.

The unified CHESAR-EUSES platform is released, facilitating improved exposure assessments for both REACH and BPR.

Questions are timely and effectively answered; a number of topics are discussed and agreed among all national helpdesks for harmonised advice.

In support of the Commission implementing regulation on registration updates, a second campaign in collaboration with the national enforcement authorities is organised on cases of potential breach of the update obligation.

Indicators		Estimate	Actual
01	Effective working time for processing inquiries	0.3 person day	0.3 person day
	Inquiries received and concluded	4 200	4 835

### Dossier submission and processing

#### Highlights

In 2023, ECHA processed 13 749 registration dossiers with 5 883 invoices generated. Completeness check was performed on all dossiers, with around 30 % of these checks completed with the manual verification, a similar number compared to 2022. The completeness check rules were updated to address the revised REACH Annex VI-XI information requirements under the Commission-ECHA Joint Action Plan. ECHA put in place support actions and no major deviations were found in terms of incomplete submissions.

Over 400 companies submitted as SMEs went through the company size verification process to ensure that they were rightly benefitting from reduced fees. We provided advice to the Commission to support a review of this process into an ex-ante approach. The time between submission and SME verification continued to reduce this year.

The invalidation of registrations continued tackling non-existing companies, or companies subject to restrictive measures due to the war in Ukraine.

ECHA's submission systems' vision for the future was developed and the work towards a single Industry portal was kicked off including the setup of a user group for discussions with companies and information sessions for authorities.



✓ Yes



On-going

✓ Yes

/ Yes

#### Main outputs

O1 Access to market for duty holders continues to be fast and predictable and data comes in a way that supports subsequent regulatory work.

The flow of registration dossiers (initial and updates) is processed; completeness checks are performed, including manual verifications, invoices are issued, and confidentiality requests are assessed. Clear and timely feedback is provided to companies on how to successfully complete their submissions.

ECHA verifies the size of companies that registered in 2018 and previous deadlines and continues the initiation and verification of the size of SME companies which registered after the last registration deadline; the time gap of ca. 4.5 years between submission and beginning of the verification continues to be reduced.

Tools and processes for invalidation of registrations are further developed for different circumstances, such as the implementation of EU sanctions.

PPORD notifications are processed and indications for innovation and new kind of substances are monitored.

As part of the development of a registration obligation for certain polymers, ECHA supports the Commission in the development of a registration process, including a notification step, and the following regulatory activities, and starts preparations for the necessary changes in relevant IT tools.

# O2 Submission activities are built in a streamlined way to facilitate their long-term functioning.

Develop a vision paper for the future of ECHA's submission systems and  $\checkmark_{\rm Yes}$  commence implementation.

Indicators		Estimate	Actual
01	Number of PPORD notifications received	340	235
	Number of C&L notifications received	33 000	43 933
	Number of Registration dossiers received (incl. updates)	16 000	13 749
	Number of SME companies verified for their status	400	416
	Effective working time for processing a registration dossier (first submission)	0.50 – 0.60 person days	0.45 person days
	Registrations stopped for manual verification at technical completeness check	5 900	4 721
	Number of registrations failing first technical completeness check	1 600	1 035

✓<sub>Yes</sub>

✓<sub>Yes</sub>

✓Yes

✓Yes

/<sub>Yes</sub>

# Identification and prioritisation

#### Highlights

In 2023, we continued screening structurally similar substances individually or in groups. We screened 61 groups rather than the initially estimated 70 groups. However, the actual number of substances screened is higher than initially planned. Overall, we screened around 1380 substances and identified that 320 may eventually be or are already considered for risk management actions; around 280 require data generation to confirm the suspected hazard; and about 540 substances do not need further regulatory risk management as they are considered low hazard, have low exposure potential or there are already sufficient risk management measures in place.

By the end of 2023, we assessed 92 % of substances registered above 100 tonnes; less than 400 high-tonnage substances remained to be assessed.

We continued to publish the reports on the assessment of regulatory needs (ARN) for groups of substances, providing transparency to our work and supporting the work of our stakeholders.

We liaised with our industry stakeholders to provide further clarity on the content and scope of the ARN reports, including holding a well-attended webinar. To improve clarity, we updated the template and format of the reports based on the feedback received.

An internal review of our integrated regulatory strategy was initiated which will feed into a workshop with our stakeholders in spring 2024.

#### Main outputs

Indi	icators E	stimate Ac	tual
	Update information through Chemical Universe engine to show with assessing groups of substances.	the progress	Yes
	Prepare the publication of the assessments of regulatory needs substances.	for groups of	Yes
	Publish the annual report on the implementation of the Integrat Strategy.	ed Regulatory	Yes
	Support the annual update of the restriction roadmap based on of the group assessments results.	the outcomes	Yes
	Complete the assessment for 70 new groups of chemicals to needs of the main regulatory processes (evaluation, authorisations and harmonised classification).		Yes
01	ECHA, Member States and Commission services can perform ris and evaluation activities related to hazardous chemicals more e based on grouping of chemicals and their assessments an expertise and tools.	effectively and efficie	ntly,

O1 Number of substances registered above 100 t/y in the 250 156 unassigned region of the chemical universe for which a conclusion on potential regulatory follow up was drawn

Number of groups of substances for which the assessment of regulatory needs is carried out

70

61

### Evaluation

#### Highlights

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.

In 2023, ECHA carried out 301 full compliance checks and 104 testing proposal examinations, covering 367 unique substances. With these outputs we addressed the key actions from the Joint Evaluation Action Plan (JEAP). ECHA has started a review of the outcomes of the JEAP, and the review will continue together with the Commission and stakeholders at the beginning of 2024 (originally planned for 2023).

Collaboration with the Member State competent authorities was effective and showed good alignment as only 9% of the draft decisions were discussed by the Member State Committee (following proposals for amendment). Follow-up actions were conducted to verify that any updated information provided in response to evaluation decisions addressed what was requested.

An analysis revealed that around 19 % of completed dossier evaluation cases were 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.

We also put greater focus on those decisions where there is a backlog in follow up and testing proposal evaluations. The increased focus on clearing this backlog will continue in the coming years.

In substance evaluation, the Community rolling action plan (CoRAP) update for 2023-2025 was published in March. The list was updated with 24 substances for evaluation by 12 Member States. A conclusion was reached for 26 substances. Some of the regulatory follow-up actions at EU level included harmonised classification and labelling (20), identification as a substance of very high concern (10) and restriction (12). In 2023, 6 substance evaluation decisions were issued requesting data to address concerns regarding endocrine disruption, PBT/vPvB, and mutagenicity.

#### Main outputs

#### O1 Dossier evaluation is efficient, transparent and scientifically and legally robust.

Deliver the outputs in line with the objectives from the Joint Evaluation Action Plan, including 300 compliance checks concluded as draft decision or no action.

Organise - jointly with the Commission - a mid-term review of the achievements of the Joint Evaluation Action Plan (including screening, grouping and evaluation of chemicals), considering the impact of changes arising from the REACH and CLP reviews.



**On-going** 

02

Examine testing proposals within the legal deadlines striving for zero proposals that are not handled in time. On-going The information submitted in response to ECHA evaluation decisions is examined without delay and conclusions communicated to the Commission **On-going** and Member State competent authorities. The national enforcement authorities are informed in case of non-compliance ✓ <sub>Yes</sub> with the decision and follow-up decisions are drafted where appropriate Report on the progress made in (both dossier and substance) evaluation as Yes part of the annual report on the Integrated Regulatory Strategy and publish annually the updated recommendations to registrants stemming from evaluation. Contribute to the Caracal sub-groups and other fora in support of the Yes Commission in their policy activities, in accordance with the REACH Evaluation Joint Action Plan. Support the Commission in CSS relevant activities. It includes the review of Yes the Evaluation title in REACH and the annexes on information requirements. Request targeted study audits in case a concern about compliance with Yes principles of good laboratory practice is identified by ECHA or a Member State. Publish the report on the scientific and technical review of the received Yes extended one-generation reproductive toxicity studies in collaboration with the Member State Competent Authorities. Provide regulatory advice to registrants and other interested parties on Yes information requirements and on dossier and substance evaluation processes. For Substance Evaluation Member States are supported to conclude as fast as possible, in a scientifically and legally robust manner, enabling the initiation of appropriate regulatory risk management measures. Propose updates of the CoRAP to the MSC with substances for which Yes substance evaluation is the most appropriate tool to generate further hazard information.

Support Member States in achieving substance evaluation conclusions as fast as possible. Encourage that appropriate regulatory risk management measures and initiatives are taken up by Member states.

Keep reducing the number of substance evaluation cases currently opened.

Indi	icators	Estimate	Actual
01	Compliance checks concluded: draft decisions or no action	300	301

Yes

Yes

	Final decisions on dossier evaluation (testing proposals and compliance checks)	300	367
	Number of substances for which a conclusion was reached in the follow-up to dossier evaluation	200	202
02	Substance evaluation final decisions issued	10	6
	Number of substances for which a conclusion was reached in substance evaluation	25	26

### Authorisation

#### Highlights

In 2023 eleven substances were added to the Candidate List, bringing the total to 235 entries. These substances were found to have either very persistent and very bio accumulative properties, or were shown to be persistent, mobile and toxic, or displayed negative effects on reproduction. Other reasons for inclusion were the carcinogenic properties or endocrine disrupting potential of these substances.

In 2023, we submitted to the European Commission the 11th recommendation for inclusion of substances to the Authorisation List. It recommended to add eight substances, including lead. The inclusion of lead generated many comments from the stakeholders, related to the best timing, its combination with other ongoing or planned regulatory activities as well as the expected workload for industry and authorities at the next stage. This recommendation brought lead metal to the same regulatory stage as other lead compounds with similar uses already recommended for inclusion to the Authorisation List.

The number of applications for authorisation increased, mainly for the use of hexavalent chromium substances. In total we received just over one hundred applications and review reports for authorisation. The scientific committees, RAC and SEAC, delivered opinions on applications for authorisation of 58 uses of substances. To manage the gap between applications received and opinions delivered, we monitored closely the incoming applications and planned and phased the opinion making process. The European Commission requested ECHA to prepare a restriction dossier for chromium (VI) substances, to be delivered in 2024. In view of the widespread use of these substances, this may lead to a more efficient and timely management of the risks of these substances, while maintaining a level playing field for the operations in the industrial sectors involved.

We contributed to the Authorisation Taskforce that was set up in 2023 by the European Commission to discuss the operation and streamlining of the authorisation process under REACH, also in view of the judgement of the European Court of Justice on the 'Chemservice' case.

#### Main outputs

O1 Substances of very high concern are properly controlled and progressively replaced by suitable alternatives.

Identification of substances of very high concern and inclusion in the Candidate List

Prioritise the chemicals on the Candidate List and propose to the MSC the ones to be included in the 11th Annex XIV recommendation to the Commission for inclusion in the Authorisation List.

Provide web-based training to stakeholders on analysis of alternatives and informed substitution of substances subject to regulatory risk management.

# O2 Opinions of the Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) on applications for authorisations are timely and fit-for purpose.

Develop and implement - jointly with the Commission - an agreed approach to deal with the anticipated significant increase in the number of authorisation applications.

Hold workshops and network meetings to develop methodologies and to enhance the capacity of Member States and companies to carry out analysis of alternatives and socio-economic analysis with view of finding viable alternatives.

Indi	cators	Estimate	Actual
01	Number of new entries in the Candidate List	15	11
	Recommendation for inclusion of substances in the authorisation list	1	1
	Applications and review reports for authorisation received (number of uses)	100-140	102
	Number of downstream user notifications of authorised uses of SVHCs	3 000	2 742
02	Number of RAC and SEAC opinions adopted on applications for authorisation (number of uses)	60	58
	Effective working time of ECHA staff per opinion	38-46 person days	39 person days

### Restrictions

#### Highlights

We continued to deliver high impact restrictions dossiers and investigation reports. In 2023, we produced three restriction investigation reports and five screening reports (art.69.2) including reports on Polyvinyl chloride (PVC) and additives as well as on substances that are carcinogenic, mutagenic or toxic to reproduction (CMRs) in childcare articles. Our scientific committees (RAC and SEAC) delivered six opinions on restrictions dossiers for regulatory decision making, including opinions on medium-chained chlorinated paraffins (MCCPs) and on per- and polyfluoroalkyl substances (PFAS) in fire-fighting foams. Furthermore, we received the restriction



✓<sub>Yes</sub>



✓<sub>Yes</sub>

dossier on universal PFAS from five dossier submitter countries and handled the publication, consultation and screened the 5,642 comments received in a record two months' time to facilitate the further process. There were no Commission mandates received requiring delivery of Annex XV reports in 2023.

Furthermore, we continued to contribute to the development of scientific methodologies for regulatory assessments on the valuation of various health and environmental endpoints for socio-economic analysis together with OECD countries.

The implementation plan for the new tasks allocated to the Agency by the EU Batteries Regulation was developed this year and initial steps were taken to prepare for the first phase of the study on relevant substances and the recruitment of staff.

#### Main outputs

O1 Support the Commission in the implementation of the Restrictions Roadmap by developing timely fit-for-purpose restrictions dossiers.

Annex XV reports proposing restrictions developed for 2-3 substances from the restriction roadmap at the request of the Commission per year (e.g., flame retardants, ortho-phthalates).  $\times$  No

The investigative reports requested by the Commission related to risks of PVC and substances in PVC, CMR substances in childcare articles, and PAHs in rubber granules used on children's playgrounds prepared according to the deadlines agreed with the Commission.

Screening reports for 2-3 substances under Article 69(2) prepared per year.

# O2 Opinions of the Committees for Risk Assessment (RAC) and Socio-Economic Analysis

(SEAC) on restrictions are timely and fit for purpose.

Deliver restriction opinions, including for the use of lead in outdoor shooting and fishing, BPA+ in articles, chloroalkanes (C14-C17) and PFASs in firefighting foams.

Develop methodologies related to socio-economic analysis to create a fit-forpurpose toolbox, including i.a., the valuation of various health and environmental endpoints in OECD. The Commission's Better Regulation guidelines are taken into account.

O3 Opinions of the Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) on restrictions are timely and fit for purpose.

Batteries restrictions implementation plan

Indicators			Estimate	Actual		
01	Restriction reports dev		or	investigation/screening	5	8

✓ Yes

Yes

Yes

✓Yes

02	Number of RAC and SEAC opinions on restriction proposals	6	5
	Effective working time of ECHA staff per opinion (ECHA dossier)	220 – 330 person days	227 person days
	Effective working time of ECHA staff per opinion (Member State dossier)	200 – 300 person days	193 person days

# Classification and labelling

for the purpose of CLH proposals.

#### Highlights

We supported the Commission in the review of the CLP Regulation. After its adoption, we started the update of the tools and CLP guidance. Proposals for harmonised classification of 45 substances were brought to the Risk Assessment Committee. We started to support the Member States to develop the dossier for proposed Harmonised Classification for two groups of substances originated from the chemical universe screening.

As part of our new public chemicals database (see activity Data management and dissemination), we worked on a redesign of the Classification and labelling inventory that is expected to be launched in autumn 2024. Our preparatory work in 2023 took into account the proposed changes in the CLP regulation.

We received 4,748,401 Poison Centre Notifications (more than in 2022). The compliance deadline of 1 January 2024 for mixtures with industrial uses was met without major problems for submitters with the appropriate support in place.

We supported the European Commission in the context of the United Nations Globally Harmonised System of classification and labelling of chemicals (UN GHS) and in the implementation of the United Nations Environment Programme (UNEP) project to pilot the implementation of GHS in four African countries.

#### Main outputs

#### O1 Opinions of the Committee for Risk Assessment (RAC) are timely and fit-for purpose

Process incoming CLH dossiers, including industrial chemicals from the outcome of identification and prioritisation (based on the grouping approach) while continuing to process a high number of PPP and Biocides dossiers resulting from the joint Commission, EFSA and ECHA efforts to encourage timely submission of dossiers.

✓Yes

Undertake pilot projects with the relevant RAC subgroup for a number of identified groups of substances to improve the usability of grouping information  $\checkmark_{\text{Yes}}$ 

O2 Up-to-date information on the classifications for chemicals is publicly available in a userfriendly format, also for those substances for which no harmonisation at EU level has taken place yet As part of the creation of ECHA's new public data availability system, design and develop the new C&L Inventory, taking into account the changes in the revised CLP regulation.



Closely monitor the progress of the legislative process and, according to the expected entry in force, deliver an internal roadmap for the implementation of the planned legislative changes to the CLP Regulation including ECHA's role in the CLH process.

Start implementation of guidance updates, teams and systems for the entry in force of the revised CLP processes.

Provide scientific and technical support to the Commission in the context of the further development of the United Nations Globally Harmonised System of classification and labelling of chemicals (UNGHS), including:

- related to new hazard classes and criteria to fully address environmental toxicity, persistency, mobility and bioaccumulation; and to introduce endocrine disruptors, persistent, mobile, toxic, very persistent and very mobile substances as categories of substances of very high concern.
- for the implementation of revisions 8, 9 and 10 of UNGHS. This implementation should start in spring 2023 at the very latest.
- to the work of selected GHS working groups, notably the working group on the use of non-animal testing methods for classification.

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 and to the UNEP-GHS project in African countries.

# O4 Structured, high quality and consistent information for the EU poison centre scheme is timely available across Europe

Maintain the notification portal and system-to-system submission channel and keep it aligned with IUCLID.

Conclude the development of the searchable central database, to be used by the national appointed bodies and Poison Centres, based on the Commission's mandate and the feedback from national authorities on the use of the database.

Continue the promotion of the PCN activities, in preparation for the next compliance date of 1 January 2024 for mixtures with industrial uses.



Yes

Yes

Yes





Yes

**On-going** 

29

Indi	cators	Estimate	Actual
01	Proposals for harmonised classification and labelling	60	45
	Number of RAC opinions on proposals for harmonised classification and labelling	50	42
	Effective working time for processing RAC opinions	Approx. 40-55 person days	37.4 person days
03	Decisions made on requests to use an alternative chemical name (Art 24 CLP)	40	26
04	Poison centre notifications received and made available to Appointed Bodies and Poison Centres	2 million	4.4 million
	Poison centre notifications viewed by national authorities in the PCN central database	10 000	23 804

# Safe and sustainable use of chemicals

#### Highlights

Our work on safe and sustainable use of chemicals focused on providing technical and scientific support and guidance to companies. We also continued developing tools to support chemical safety assessment at company level (e.g., CHESAR) and ensured basic maintenance of industry-developed use maps.

We also continued to support the European Commission in testing its framework for safe and sustainable by design, by providing a priority list of substances of very high concern which could be considered as candidates for testing the framework.

#### Main outputs

O1 Registrants perform an effective chemical safety assessment, demonstrating (i) safe use to the authorities via the registration and (ii) delivering safe use advice for inclusion in the safety data sheets

Provide maintenance and ensure dissemination of tools developed to support industry work.

✓<sub>Yes</sub>

Support the Commission in developing case studies and testing the framework and criteria for Safe and Sustainable by design.



Indicators

Estimate Actual

30

O1 N/A

### Data management and dissemination

#### Highlights

During 2023, ECHA data services supported the Commission work on preparing several legislative packages including REACH and CLP review or the Directive 2004/37/EC on the protection of workers from the risks related to exposure to CMR substances at work. We also supported the Member States with data relevant for preparing their restrictions proposals. Tools that allow users to search, convert and manage their chemicals data in IUCLID format were further developed and we supported our key stakeholders such as EFSA and Member States in their use.

Data management has a central role in improving the consistency and integration of the EU regulatory system on chemicals. In 2023, we initiated a review of our data management approach and established a Data Governance Office responsible for managing our regulatory data. This work will further support regulatory data consistency, coherence and transparency.

During 2023, the first version of ECHA's new public chemicals database, ECHA CHEM, was developed, leaving it ready for launch in January 2024. The development of this new public database involved extensive engagement with our stakeholders to ensure it would meet the user needs. The new database has IUCLID as a central building block and is designed on a modular platform to ensure a stable and high-performing system that will enable efficient onboarding of new datasets in the future, as well as a starting point for a future EU common data platform on chemicals.

The OECD eChem portal was maintained and developed with new datasets coming from REACH Registrations.

#### Main outputs

O1 The regulatory processes performed by ECHA, Member States and Commission are efficiently supported and monitored.

Deliver a plan to consolidate data management and guarantee regulatory data consistency, coherence, transparency and reporting.



Yes

Yes

Yes

Deliver the necessary features to optimise the Interact Portal with due  $\checkmark_{\rm Yes}$  consideration of process and users' requirements.

Data analysis services upon request from EU institutions or Member States.

Tools to search, extract and analyse data in registration dossiers made variable to other authorities and industry.

Develop tools and methodologies to convert legacy toxicity data to IUCLID harmonised templates in collaboration with other Authorities and industry.

O2 Data submitted to ECHA under different regulations is publicly available in user friendly ways and progress of ECHA's regulatory activities is transparent.

Deliver the first prototype of ECHA's new public data availability system based on IUCLID, including hazard and classification and labelling data, and supporting the preparedness for the EU Common Data Platform. Deliver a plan to develop the new solution for dissemination of regulatory data and proceed with its integration into ECHA's new data availability system.

Further develop IUCLID as a key building block, considering the future EU common data platform on chemicals and bearing in mind the OECD intentions for a Global Chemicals Knowledge Base.

OECD Global Portal to Information on Chemical Substances (eChemPortal) is maintained and synchronised with ECHA's dissemination website.

Indi	cators	Estimate	Actual
01	Description and number of data requests	Internal: 50 External: 20	Internal:77 External:13
02	Number of user page views for published information on chemicals	48 million	50 million

# Promotion of alternatives to animal testing

#### Highlights

In 2023, we intensified our activities to promote alternatives to animal testing. We invested in many international activities, particularly APCRA (Accelerating the Pace of Chemical Risk Assessment), PARC (Partnership for the Assessment of Risks from Chemicals) and OECD (Organisation for Economic Co-operation and Development) to enhance regulatory knowledge on how we can protect health and the environment and reduce our reliance on animal testing. We also increased the access to toxicity data, aiming to support research and development within the wider regulatory and scientific community.

We published the fifth report on the use of alternatives to testing on animals for the REACH Regulation. The report shed light on opportunities and challenges associated with moving away from animal testing in the regulatory assessment of chemicals.

We strengthened our interactions with stakeholders and worked closely with the European Commission and international partners to support the development and uptake of alternatives that are suitable for regulatory purposes.

We organised a workshop to further explore new approach methodologies and work towards an animal testing-free regulatory system for industrial chemicals. The event brought together regulators, policy makers, scientists and stakeholders (industry, animal welfare NGOs, environmental NGOs) to discuss the state of the art and research needs for phasing out animal testing. The workshop supported the efforts at EU level to work towards development of a EU roadmap for fully replacing animal testing in the risk assessment of industrial chemicals.

✓Yes

Yes

Yes

#### Main outputs

O1 Industry generates hazard data using non-animal testing methods and new approaches, wherever appropriate, to fulfil the REACH information requirements.

Invest in further development of the QSAR toolbox to integrate new information (for example, metabolites, biocides or data from pharmaceuticals) and models.  $\checkmark_{\rm Yes}$ 

Expand data available for download (REACH studies results and pharmaceutical industry data contribution) that can be used for NAMs development and/or avoiding unnecessary animal testing.

Further implement predictive models to support substance grouping,  $\checkmark_{Yes}$  prioritisation and scientific decision making.

# O2 ECHA plays a proactive role towards the public and policy makers to provide clear, timely and sufficient information on alternatives to animal testing in a regulatory context, within ECHA's role and mandate.

Organise an external workshop on new approach methodologies (NAMs) to contribute to EU efforts towards building an EU roadmap for replacement of animal testing.

Publish the fifth report on the use of alternatives to testing on animals for the REACH Regulation (117.3).

Contribute to OECD activities related to further development of alternatives and integration of regulatory relevant alternatives in the OECD test guidelines.

Further develop high throughput NAMs in cooperation with ECHA's international partners.

Collaborate at international level towards the identification and acceptance of alternatives in regulatory frameworks (e.g., with US and Canada within the APCRA initiative (Accelerating the Pace of Chemical Risk Assessment).

#### Indicators

Estimate Actual

01 N/A

### **Biocides**

#### Highlights

The number of opinions that the Biocidal Products Committee (BPC) was in a position to deliver in 2023 was well below the estimated numbers due to significantly less submissions by the Member States of evaluation dossiers both for active substances and Union authorisations (UA). While we observed a decrease in numbers of UA applications this year, we also noted that these cover product families and therefore dossiers tend to be larger and more complex. In response to technical scientific questions from the Commission, the BPC developed opinions on alternatives to active substances and the comparative assessment of anticoagulant substances

Yes

Yes

Yes

Yes

Yes

used to control infestations of rodents, as well as on technical aspects of disagreements arising in the mutual recognition of biocidal products authorisations. On request of the Commission, we also reviewed the work of the BPC with respect to analysis of available alternatives and socioeconomic aspects related to potential non-approval of certain active substances.

We continued providing support to Member States under the Active Substance Action Plan. This included the organisation of two information sessions with Member States to discuss and share their best practices on active substance approval and renewal. Furthermore, we provided regulatory and scientific advice and allowed Member States to increase competence in areas such as genotoxicity and endocrine disruptors.

We also continued to provide the secretariat of the Coordination Group, assisting Member States in the resolution of disagreements arising during mutual recognition of biocidal products authorisations and in reaching agreements on horizontal topics which may help preventing certain future disagreements. This allowed for a reduction in the number of Art. 38 requests compared to what was initially foreseen. In the regular and ad-hoc meetings (19 in total), an increasing number of disagreements were discussed together with the endorsement of key specific procedures.

Regarding Union authorisations, we established a working procedure for processing applications for minor changes, which allows the swift evaluation of the first such cases. Additionally, several critical working procedures were improved and streamlined, including the procedure for processing application for major changes and for the linguistic review of the SPC translations.

Within the scope of one-substance-one-assessment, ECHA continued to collaborate with EFSA on common guidance documents, such as on the impact of water treatment processes on residues of active substances in drinking water. Furthermore, we introduced alignment mechanisms, such as identifying common substances early in advance and connecting and supporting the evaluating Member States across regulations. We also established an engagement procedure on inviting experts to meetings of working groups and of the BPC. The experience gained helped in defining collaboration practices with other EU agencies, in particular EFSA. In close collaboration with EFSA, we finalised the guidance for the assessment of risk to bees from the use of biocides as our contribution to maintain biodiversity.

We have established an IT vision for biocides that sets the direction towards further integration of the tools, ensuring structured data and increased data availability as well as efficiency gains for all stakeholders. The first implementation steps in the transfer of biocides information to IUCLID format, based on a roadmap agreed with Member States, were a major advancement in this regard.

#### Main outputs

O1 Provide timely fit-for-purpose opinions, including means for improved consideration of cross-regulations consistency, on active substance and Union authorisation applications.

Prepare ECHA's opinions on the approval of active substances and on Union  $\checkmark_{\rm Yes}$  authorisation of biocidal products.

✓Yes

Prepare ECHA's opinions on Union authorisation of same biocidal products and on administrative and minor changes to Union authorisations.

Cooperate with EFSA and within ECHA to interlink guidance documents and put in place means to improve synergies and alignment, with focus on the evaluation of common substances.

Update of the list of frequently used sentences in the SPCs translated in all the EU official languages.



/<sub>Yes</sub>

Perform assessments of applications for technical equivalence, inclusion in the Article 95 BPR list and classification for changes.



#### 02 Provide support to Member States and Commission to facilitate biocides processes and accelerate the Review Programme. Providing regulatory, procedural and technical support to the MSCAs in the ✓<sub>Yes</sub> evaluation and BPC opinion forming on the approval of active substances, with specific effort to progress with the Review Programme, and on Union authorisation of biocidal products. Contribute to the MSCAs capacity building by providing training and scientific-Yes technical advice. Support the MSCAs in their work on potential endocrine-disrupting substances. Yes /<sub>Yes</sub> Prepare the BPC opinions requested by the Commission pursuant to Article 38 of the BPR on scientific and technical questions. Yes Providing technical and scientific support to the Commission under Article 15(2) and 75(1)(q) of the BPR on general and case specific issues relevant for the implementation of the BPR. Provide training to stakeholders on analysis of alternatives and informed Yes substitution of substances. Develop and maintain guidance and provide support to the development of an Yes easily accessible, structured overview of ECHA guidance documents and relevant policy documents. Engage with stakeholders in different fora such as the BPC and its Working Yes Groups, organisation of biocides stakeholders' day, etc. Dossiers submitted by industry to ECHA are timely processed and feedback / Yes given as appropriate. 03 Continuing the integration of the biocides IT tools with the ECHA IT systems Integrate, where feasible, specialised Biocides IT tools with ECHA IT systems. Yes Yes Continue developing the Register for Biocidal Products (R4BP 3). Yes Continue developing the IT support tools (ECHA Act and Interact). Finalise the introduction of the biocides' environmental exposure scenarios in the CHESAR platform (see REACH activity Dossier preparation). **On-going** Move the SPC Editor into a IUCLID based solution. **On-going**

Promote and initiate the enhancement of structured data availability in IUCLID for Annex II and III BPR information requirements.

Propose and support a campaign on the IUCLID dossier filling for active substances and Union authorisation cases.

Indi	cators	Estimate	Actual
01	Number of opinions on active substances [approval & renewal]	28	13
	Number of opinions on Union authorisation of biocidal products	31	10
	Number of opinions on Union authorisations sub- processes: same biocidal products, administrative and minor changes	52	21
	Number of technical equivalence application assessments	30	32
02	Satisfaction of authority actors	Establishment of baseline	84 %
	Number of opinions on Article 15, Article 38 and Article 75(1)(g) requests	20	7
03	User satisfaction of ECHA IT tools (e.g., R4BP, SPC editor, Interact)	Establishing baseline with BPR user group	90%

### Prior informed consent

#### Highlights

The reception and processing of PIC notifications experienced an increase in volumes compared with previous years. A total of 10 857 notifications were processed in 2023 which represents 97% of the annual forecast (11 200) and is +8% compared to the number of notifications processed in 2022 (10 072)). This increase was mainly due to the addition of benzene, being the first 'substance in substance' entry in the list of substances subject to PIC notification obligations. ECHA continued to devote significant efforts to support all involved parties with these obligations.

In terms of reporting, the usual annual report on exports and imports subject to Rotterdam convention was published. In addition, we published the three-years report on the operation of the PIC Regulation ('article 22 report'). Its conclusions input to the Commission's ongoing evaluation of the PIC Regulation, as some changes in legal provisions could facilitate the implementation, in particular the extent of the information that is made publicly available. This was important as the increasing number of Access to documents requests showed public interest

✓<sub>Yes</sub>

✓Yes
in this information. In this context, we hosted an information session to exchange experiences among Member States with the access to documents under PIC.

We continued to support the Commission in the implementation of the Rotterdam Convention including participation in the 11th Conference of the Parties.

#### Main outputs

O1 Companies and Authorities in the EU and third countries can effectively manage the international trade of chemicals listed under the Rotterdam Convention and the PIC regulation.

Process effectively the received number of notifications allowing companies to export these chemicals in accordance with the EU's international commitments; execute related tasks such as stakeholder support.

✓<sub>Yes</sub>

Yes

Prepare the tri-annual report on the operation of the PIC Regulation (2020-2022).

# O2 The Commission and other Authorities receive fit-for-purpose support in the context of PIC implementation and UN Rotterdam Convention.

Produce and publish the annual report on PIC exports and imports.

✓<sub>Yes</sub>

/ Yes

Support the Commission with the EU contribution to the Rotterdam convention implementation.

Indi	cators	Estimate	Actual
01	Export notifications processed	11 200	10 857
	Share of notifications validated/accepted by ECHA	90 %	96 %
	Support provided to PIC duty holders (importers and exporters)	250	245
02	Scientific and technical support provided to the Commission, EU and non-EU DNAs	3 600	3 570

# Persistent organic pollutants

#### Highlights

At the European Commission's request and linked to ECHA's scientific support to the Commission in identifying new POP substances, we prepared in 2023 a draft scientific dossier (Annex D proposal) for Octamethylcyclotetrasiloxane (D4), Decamethylcyclopentasiloxane (D5) and Dodecamethylcyclohexasiloxane (D6).

We provided technical and scientific support to the Commission for discussions at the 19th meeting of the POPs Review Committee (POPRC-19). At this meeting in October 2023, the risk

profile for chlorpyrifos, an organophosphate pesticide, was adopted as was the risk management evaluations for Medium-chain chlorinated paraffins (MCCPs) and long-chain perfluorocarboxylic acids and related compounds (LC-PFCAs). Both substances were recommended for listing under Annex A (elimination) of the Stockholm Convention, with specific exemptions. Nevertheless, the POPRC agreed that further information on the scope of the chemical identity of MCCPs for the purpose of its listing under the Convention is required, which would be subject to further discussion at POPRC-20.

In addition, ECHA reviewed and commented on the POPRC document on long-range environmental transport which had been finalised in October 2023. This document is equivalent to a guidance on how to assess the long-range environmental properties of substances.

The Union Overview report detailing the implementation of the POPs Regulation in the EU was updated in May and December 2023. The report provides information on various aspects of POPs, such as manufacturing, market placement, stockpiling, enforcement actions and releases of POPs into the environment.

Finally, ECHA supported the European Commission in the following activities linked to the POPs: revising the document for the notification of articles use for submission to the Stockholm Convention, gathering UV-328 information to support the specific exemptions in the EU POPs Regulation (investigation report under Article 69(2)) and contributing to the amendment of the PFOS entry of the POPs Regulation.

#### Main outputs

O1 Prepare and support processing of the technical dossiers that the European Commission uses when proposing to list a substance as a POP in the Stockholm Convention, review the technical dossiers submitted by other parties and support the implementation of POP Regulation.

Draft scientific dossiers for a new EU proposal to list a potential POP substance under the Stockholm Convention on Persistent Organic Pollutants and provide further support to the Commission for the listing process.

✓Yes

/<sub>Yes</sub>

Maintain and develop where possible within the resource constraints the reporting system for the implementation of the POP Regulation and update the Union Overview report based on the Member States reports regularly.

Indicators		Estimate	Actual
01	Number of scientific dossiers drafted for the identification of new substances as Persistent Organic Pollutants	1	1
	Support provided to various stakeholders	50	55
	Scientific and technical support provided to the Commission, EU and non-EU Cas	10	14

## Waste Framework Directive

#### Highlights

The reception of notifications of SVHCs present in articles on the EU market continued in 2023

including corresponding support to duty holders. The total number of notifications received in 2023 is 10 653 336. The resulting Database for information on Substances of Concern In articles (SCIP database), making this information public, was maintained.

#### Main outputs

O1 Maintain a database on the presence of Candidate List substances in articles.

Maintain the notification portal and disseminate the SCIP database information.  $\checkmark_{
m Yes}$ 

Provide support to duty holders to allow EU suppliers of articles to submit the  $\checkmark_{\rm Yes}$  required information to ECHA.

Indicators			Estimate	Actual			
01	Successful updates)	SCIP	notifications	received	(incl.	8-12 million	10.6 million

# **Drinking Water Directive**

#### Highlights

With the revision of the Drinking Water Directive, ECHA assumed new responsibilities related to setting up and maintaining European positive lists of substances that are authorised to be used for the manufacturing of materials coming into contact with drinking water.

We provided support to the European Commission for drafting and smooth adoption of the implementing and delegated acts related to the adoption of the EU positive list, information requirements for materials in contact with drinking water and the process for submission and inclusion of substances on the EU positive list. The acts were successfully agreed through Comitology by the end of 2023.

We also worked to develop guidance and tools necessary to support applicants and set up a RAC working group to ensure overall readiness for entry into operation in 2025.

#### Main outputs

O1 Ensure the readiness for the implementation of Article 11 of DWD (2025) (including development of the delegated acts, delivery of the tools and processes for submission, accordance check and opinion forming, including setting up of a working group attached to RAC).

Provide technical and scientific support to the Commission in drafting and  $\checkmark_{\rm Yes}$  adopting the Implementing and Delegated acts.

✓Yes

Clarify the likely number of applications to be expected in period 2025-2028 through engagement with stakeholders.

Setup internal operational procedures and working instructions for handling the applications to be submitted from 2025 onwards.



Set up a Working Group associated to RAC and start developing procedures for opinion forming.

Finalise the DWD IT solution, including the adaptation of IUCLID to the specific needs of the DWD process.

Develop guidance documents for the applicants.

#### Indicators

Estimate

Actual

**On-going** 

**On-going** 

On-going

01 N/A

## Support to the 8<sup>th</sup> Environmental Action Programme of the FU

#### **Highlights**

In 2023, we worked further with EEA towards creating the first version of the framework and prepared to publish the relevant indicator dashboard. We also worked to develop a common report with joint messages on the EU progress towards the policy objectives of the CSS. The report accompanies the CSS indicator dashboard and is expected to be published in early 2024.

#### Main outputs

01 Ensure a sound, accessible and transparent evidence base to support the monitoring, measuring and reporting on chemicals

Implement indicators based on ECHA's data in ECHA's data platforms, Yes according to the plan agreed with the Commission and EEA.

Develop the public version of the indicator framework jointly with EEA and the /<sub>Yes</sub> Commission.

Together with EEA develop a joint synthesis report, offering policy-relevant messaging on the trends observed in the chemicals indicators

#### Indicators

Estimate Actual

Yes

01 N/A

# EU Observatory for Nanomaterials

#### **Highlights**

During 2023, EUON continued to produce and publish new and updated content regarding the markets and safety of nanomaterials. In the beginning of the year, the NanoData knowledgebase was refreshed with updated information about nanomaterials on the EU market. The EUON also commissioned new studies on topics of general interest and published regular 'Nanopinions' on

current matters related to nanomaterials.

#### Main outputs

O1 Provide better access to information on nanomaterials on the EU market, their uses and safety aspects, and related research activities.

Continue to fulfil specific data gaps in the public knowledge about  $\checkmark_{\rm Yes}$  nanomaterials via the commissioning of external studies.

Continue to promote the EUON via different channels to increase its outreach  $\checkmark_{\rm Yes}$  to a wide variety of audiences.

Indicators		Estimate	Actual
01	All traffic to EUON websites	125 000	186 084

# EU Chemicals Legislation Finder

#### Highlights

EUCLEF continued to provide up-to-date information on EU chemicals legislation throughout the year. A new framework contract for the data provision feeding EUCLEF was put in place ensuring its continuation.

#### Main outputs

O1 Improve transparency for the public and the business environment for EU companies and SMEs in particular, with regard to access to information on legislation applicable to a given substance.

Continue to operate EUCLEF and maintain updated the pieces of legislation in  $\checkmark_{\rm Yes}$  the scope of the service.

Continue to promote EUCLEF via different channels to increase the utility of the service for its target audiences.

Run the corresponding helpdesk.

Indi	Indicators		Actual
01	Number of data updates on EUCLEF pieces of legislation	4-6	5
	All traffic to EUCLEF pages	350 000	395 000

## Support to occupational health legislation

#### Highlights

In 2023 ECHA continued supporting the Directorate General for Employment, Social Affairs and

Yes

Yes

Inclusion (DG EMPL), through Service Level Agreements, in providing five opinions from the RAC on Occupational Exposure Limits (OELs). These OELs were 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. All RAC opinions were made in advance to the contractual deadlines set and covered the following substances: 1,2-dichloropropane, 1,2,3-trichloropropane, 2-chloro-1,3-butadiene (chloroprene), 2,3-epoxypropyl methacrylate (glycidyl methacrylate) and Nitrosamines.

ECHA's website was updated in 2023 to host a repository of substances, for which the recommendations and opinions relating to the toxicological evaluations of substances affecting the health of workers were adopted by the Scientific Committee on Occupational Exposure Limits (SCOEL) - Recommendations of the SCOEL - ECHA (europa.eu).

Five new requests for setting occupational exposure limits were received under the 2023 contribution agreement with the Commission: 1,3-butadiene, Boron and its compounds, Bisphenol A, Silicon carbide fibres, Pyrocatechol. RAC opinions for these substances will be adopted by 23 February 2025.

#### Main outputs

O1 Opinions of the Risk Assessment Committee (RAC) on OELs to the Commission are timely and fit-for purpose.

6 RAC opinions per year

$\mathbf{v}$	Yes

Indicators		Estimate	Actual
01	Number of OEL requests received under SLA	5	5
	Number of RAC opinions on OELs completed	6	5
	Number of scoping documents	0	0

# Instrument for Pre-Accession Assistance (IPA)

#### Highlights

We continued supporting the pre-accessing countries to the EU under a new contribution agreement with the Commission for 2023-2026. The focus of this support remained on training on the EU chemicals legislation and related IT tools. Quarterly bilateral meetings were held with beneficiaries to make sure topics and mechanisms to provide information and support are in line with their priorities.

#### Main outputs

O1 Enhance the readiness of EU (pre)candidate countries to assume their role in their path towards EU membership in the area of EU legislation for chemical management.

Implement support actions as agreed in the IPA grant agreement for 2023-25  $$\checkmark_{\sf Yes}$$ 

#### Indicators

Estimate Actual

01 N/A

# Support to other legislation

#### Highlights

In 2023, we provided input to the review of some Best Available Techniques Reference documents (BREF) under the Industrial Emissions Directive and prepared for the formal onboarding of tasks under the upcoming revision of the Industrial Emissions Directive foreseen to be adopted in spring 2024. We contributed to the workshop organised by the European Integrated Pollution Prevention and Control Bureau (EIPPCB), whose aim was to clarify with stakeholders the main priorities and approaches for further development of the Chemical Management System.

We worked with the Commission to determine the appropriate structure for ECHA to deliver on the new tasks received under the Serious Cross-Borders Threats to Health (SCBTH) Regulation. We also participated in the discussions with the other Agencies involved in the SCBTH regulation to share experiences and align approaches.

#### Main outputs

O1 Promote and support the use of the REACH/CLP data and expertise under other EU regulatory schemes

Sustaining active input to the review of the Best Available Techniques Reference documents (BREF) under the Industrial Emissions Directive.

At Commission's request, prepare for the onboarding of additional tasks under the upcoming revision of the Industrial Emissions Directive in relation to risk assessment methodology in the Chemical Management System framework.

O2 Establish a readiness structure within ECHA for delivering rapid risk assessments in case of cross-border threats to health

Agree on a process for delivering the risk assessments with the Commission.



#### Indicators

Estimate

Actual

01 N/A

## **IUCLID** for EFSA

#### Highlights

In 2023, we continued to provide support for the integration of IUCLID into the EFSA IT infrastructure by facilitating the publication of IUCLID data and assessing the implementation of



**On-going** 

Yes

data analysis tools. Data Uploader was successfully used by EFSA to upload OpenFoodTox to IUCLID format. Assessment on the use of Text analytics and Data extractor will be completed in 2024.

#### Main outputs

O1 Maintain cooperation between EFSA and ECHA and effective operation of the IUCLID platform.
 Assess applicability of IUCLID to other food regulated products (e.g., Food Contact Materials and synergies with Drinking Water Directive).
 Submission portal is enhanced to automate the handling of large PPP ✓Yes submissions.
 Assess the implementation of data analysis tools.
 Continue support to EFSA to perform its regulatory work. Estimate resources and compensation mechanisms. Execution of the Service Level Agreement for implementation of agreed scope and regular service accordingly.

#### Indicators

Estimate

01 N/A

# Partnership for the Assessment of Risk from Chemicals (PARC)

#### Highlights

As a co-leader of Task 2.1 'Priority setting' under PARC, ECHA's experts reviewed 34 projects, mainly related to hazard, exposure and risk assessment methodologies.

We also developed with the partners of Task 2.1 the process for a Rapid Response Mechanism (RRM) to submit project requests for specific information (e.g., urgent needs on hazardous chemicals). Furthermore, we actively participated in PARC projects addressing data gaps, for example, on bisphenol alternatives and development of innovative methods on different hazard endpoints (e.g., developmental neurotoxicity)

To better communicate ECHA's research needs to the scientific community, we started to map key areas of regulatory challenge. The identified key areas of regulatory challenge were formulated as an 'evolving research and development agenda' aiming to support and inspire researchers. The report was published during a joint webinar together with the European Environmental Agency and the European Food Safety Authority in June. These research needs will be updated and refined as the scientific areas evolve and key regulatory challenges develop. ECHA presented its research needs in various scientific fora (e.g., Joint Policy Session organised by DG RTD, at Eurotox 2023) and via relevant communication channels (e.g., ECHA Safer Chemicals podcast).

Actual

#### Main outputs

01 Ensure, together with EFSA and EEA, that the research activities will support current regulatory challenges and new areas identified in the Commission's Chemicals Strategy for Sustainability.

Steer the development and implementation of a prioritisation strategy (including surveys, interviews and workshops on regulatory needs with EU and national regulatory bodies) based on the initial work done during the PARC proposal development phase.

Contribute to the development of a framework with clear decision criteria to enable transparent decision making for the prioritisation of activities within PARC.

Support the development of annual work plans by steering the process of review of the projects submitted, ensuring identified EU priorities and knowledge gaps in the area of chemical risk assessment are appropriately considered in the process.

Steer for the development and implement a rapid response mechanism to allow national and European policy makers to submit requests for specific information to the PARC Consortium outside of the formal timeframes.

#### Indicators

Estimate

N/A 01

## Support to Forum

#### **Highlights**

We continued supporting the Forum of enforcement authorities, with a focus on the preparation, execution and reporting for the Forum-coordinated REACH and BPR enforcement projects. Three projects were under preparation (imports, online sales and SPCs for biocides), two under execution (safety data sheets and PFCAs in cosmetics) and four under reporting (authorisation, restrictions in products, biocides and classification of mixtures).

We provided advice on enforceability aspects of seven restrictions proposals to enhance their regulatory process and future implementation including the restriction on the universal PFAS and on CMR on childcare articles.

210 REACH and 630 BPR inspectors were trained via the train the trainers approach that supports the harmonisation of EU enforcement of chemicals regulations.

We provided support to the Commission as input to the preparation of legislative proposals in the context of the CSS ambition towards zero tolerance for non-compliance.

Henrik Hedlund (SE) was appointed as the new Forum chair and Helmut de Vos (BE) as the new BPRS chair.

Yes

Yes

Yes

✓Yes

Actual

#### Main outputs

O1 An equal level playing field for economic operators is promoted in the EU through harmonised enforcement

Prepare, execute, report and follow up on five Forum-coordinated REACH and BPR enforcement projects on: REACH authorisation (REF-9), REACH and POP Restrictions (REF-10), REACH safety data sheets (REF-11), control of REACH for imports (REF-12), BPR approved substances in biocidal products (BEF-2) and select the subjects of next REACH and BPR coordinated projects (REF-13 and BEF-3).

Establish best practice in enforcement by maintaining the Forum and BPRS Manuals of Conclusions on practical enforcement issues and running four Forum pilot projects on exemption from registration for recovered substances, classification of mixtures and poison centre notifications.

Deliver timely advice on enforceability on all submitted proposals for restrictions and revise the process for delivering the Forum advice.

Develop and deliver four trainings for national trainers and inspectors.

Contribute and facilitate Forum's input on the Commission's ideas on enhanced enforcement of chemicals legislation on imports, on European Audit Capacity for enforcement and other enforcement topics under the CSS/REACH revision.

Indicators	Estimate	Actual
O1 Number of enforcement trainers trained by the Forum	200	840

## Board of Appeal

#### Highlights

In 2023, the Board of Appeal adopted 15 final decisions, all under REACH. In those decisions it addressed important aspects such as the interpretation of REACH information requirements and the possibility for ECHA to revoke registrations. 10 cases (two under BPR) remained pending at the end of the reporting period.

The General Court confirmed three decisions of the Board of Appeal which were adopted in previous years. Most notably, the Court confirmed the decisions in which the Board of Appeal examined the relationship between REACH and the Cosmetics Regulation.

#### Main outputs

O1 Increase the efficiency of the Board of Appeal procedures, while continuing to ensure their quality.

Process and decide on appeals brought against decisions of the Agency, according to procedural requirements.





Yes

On-going





Communicate to parties and the general public about appeal decisions.	✓Yes
Defend appeal decisions when challenged before the EU Courts, together with the Secretariat.	✓Yes
Contribute to ECHA's input for the review of the REACH Regulation.	<ul> <li>✓ Yes</li> </ul>
Prepare and adopt a code of conduct applicable to members of the Board of Appeal who are Agency staff members.	✓Yes

Indi	cators	Estimate	Actual
01	Appeals submitted REACH	12	10
	Appeals submitted BPR	2	2
	Appeals concluded REACH	12	14
	Appeals concluded BPR	2	1

## Management

#### Highlights

ECHA continued to meet its governance and management obligations during 2023. All deliverables regarding annual reports, planning and budget requirements were done within the required timelines. With our new Executive Director, several governance and management changes and initiatives were completed. Our new Strategy Statement for the period 2024-2028 was developed and finalised. The development process involved significant staff and Management Board engagement and consultation. We also developed a new risk management policy, risk register and procedure. To ensure even greater levels of transparency to the Management Board, the Executive Director introduced a new ED report that is presented at each meeting. Discussions continued with the Management Board on ensuring our planning and other documents are clear, concise, and accessible to our stakeholders and partners. Further efforts on transparency included a new quarterly report to the Management Board as well as a review and update of our Conflicts of Interest policy.

We supported Commission colleagues in their policy development work under the Chemicals Strategy for Sustainability including our joint efforts on alternatives to animal testing. This facilitated the establishment of structured contacts around specific files. Due to this focus, drafting a Memorandum of Understanding with Commission services was de-prioritised. Although the REACH revision and ECHA Basic Regulation were not published in 2023, we provided significant support to these. We aim to continue the dialogue with the Commission on the Basic Regulation in 2024 given it is a priority us. We also paid particular attention to increasing our engagement with the Member States and institutional partners. This involved meetings with the European Parliament and EU agencies as well as several Member States visits initiated by the Executive Director, which will continue in 2024.

Following a successful audit, ECHA maintained its ISO 9001:2015 certification. We also completed several successful audits and evaluations and ensured the necessary follow-up was completed on their main recommendations. Outside of the day-to-day legal activities, ECHA defended its own decisions at the European Court of Justice and the Board of Appeal. We also supported the Commission at the European Court of Justice in risk management and biocides

related cases. Altogether more than 50 cases were pending at different stages during the year, and the judgments received were predominantly very positive, confirming the position of ECHA. We expect the level of litigation to continue similar or higher in the next years.

Our key focus was in communicating and engaging with our stakeholders and partners and will continue under the new strategy. As our legal mandate is widened, we will also be increasing our stakeholder and partner contacts in the EU, Member States, industry, and civil society organisations. We have resumed the organisation of regular NGO dialogues. We received increased requests for our Accredited Stakeholder Organisation (ASO) list in 2023 and we expect this to continue into 2024 and beyond. To help us prepare for the increased levels of engagement envisaged in our new strategy and new tasks, we completed our new stakeholder engagement approach and drafted our new communications strategy for the period 2024-2028. Both will be finalised and rolled out in 2024.

ECHA's communications activities in 2023 focused on supporting the organisation in presenting its work clearly and transparently, across the range of its activities to its different internal and external stakeholder audiences. Key initiatives included the introduction of the Executive Director, the promotion of ECHA's work on new alternative methodologies and key areas of regulatory challenge, the proposed universal restriction on PFAS amongst many others.

We continued to broaden our use of digital communications channels focusing, in addition to the website, on the development of our social media channels which are reaching a growing community, podcasts, audiovisual products and supporting stakeholder interaction through information and training webinars.

#### Main outputs

O1 ECHA's (multi-)annual planning provides clear direction that is aligned with its mandate and developing EU policies, while facilitating the efficient integration of new tasks

Adopt a multi-annual work programme (Strategic Plan) and associated objectives for integration in the Programming Document

Develop and implement a project portfolio management mechanism to provide continued effective support to the implementation of the Commission's Chemicals Strategy for Sustainability.

Develop and implement a project portfolio management mechanism to facilitate the integration of new regulatory tasks and changes to ECHA's governance structures.

# O2 The management bodies are in the position to drive performance and ensure compliance of ECHA.

Adopt and publish the Programming Document, including (multi-)annual work programme and budget in line with the Commission guidelines.

Prepare and take the decisions statutorily required from the management bodies, including the Management Board, within the applicable deadlines.

Monitor performance through monthly and quarterly reporting to the Management Board and address issues through mitigating actions; and report the overall status and achievements through the annual report published by end of April each year. Yes

✓Yes







/ Yes

Timely reporting on measures taken in the light of the observations accompanying the annual discharge from the EU budget authority.

Prepare and implement the corporate audit and evaluation plan, in consultation with the Management Board, with regular status reports and appropriate follow-up actions.

Maintain the ISO 9001:2015 certification.

Review ECHA's Policy for the Prevention and Management of Conflicts of Interest.

Defend ECHA's interests in legal proceedings and ensure legal advice to its operations and on issues relating to financial interests, human resources, procurement, intellectual property and access to documents.

# O3 ECHA addresses the individual circumstances and needs of its institutional partners and is aligned with EU priorities.

The Executive Director has a regular exchange of views with the European Parliament's Committee for Environment, Public Health and Food Safety and maintains regular contacts with its liaison MEP and other MEPs.

Organise regular bilateral interactions with Member States authorities.

Propose a draft Memorandum of Understanding on mutual expectations with the Commission services.

# O4 Stakeholders and general audiences are aware of ECHA's activities and impact and easily obtain the information they need from the Agency.

Implementation of 2023 Communications Action Plan to support the Work Programme.

Organise the biennial ECHA Conference.

Maintain and further develop the ECHA websites as key communication channels to provide accurate, relevant and up to date information to stakeholders.

Adopt a revised, cooperative approach for stakeholder engagement to support the implementation of the new multi-annual work programme (Strategic Plan) and clarify ECHA's work to key audiences in view the Agency's evolving role under the Chemicals Strategy for Sustainability and implement related actions.



On-goind



On-going



Yes

Yes

Yes

Yes

Yes

$\checkmark$	Yes





Yes

Indicators		Estimate	Actual
02	Areas where audits and evaluations results (including prevention of conflicts of interest and fraud) have been considered in future strategic decisions.	5	5
04	Combined neutral and positive feedback monitored in media publications	>90 %	96 %
	Website unique visitors/traffic to the web content	4.2 million	5.8 million

## ICT

#### Highlights

During the year 2023 ECHA embarked on the transformative ECHA IT 3.0 Journey, which has a primary focus on IT resilience, scalability and delivery capabilities.

ECHA systems maintained an availability rate of 99%, surpassing the target of 98%, ensuring good level of service delivery internally and towards all stakeholders. By keeping the focus on IT security and business continuity, and implementing the agency's cybersecurity policy, the Agency avoided major cybersecurity incidents, and maintained the high standards of defences against evolving threats.

In 2023, we made progress in implementing a modular and reusable IT architecture, aligning with the Target Enterprise Architecture vision established in 2022. Our modular approach ensures flexibility and adaptability, laying the groundwork for improved tooling support for regulatory processes. Following the same architecture prescriptions, a new version of ECHA's dissemination platform was designed and implemented. This revamp enhanced accessibility and scalability, ensuring seamless access to critical information for all stakeholders.

Our ongoing refresh of administrative tooling ensured optimal performance, allowing us to keep pace with technological advancements and streamline workflows. The potential of artificial intelligence (AI) was also recognised, and a horizontal working group was established to identifying opportunities and setting guidelines for AI-related initiatives.

#### Main outputs

O1 Improve the resilience and scalability of the IT product and services portfolio in order to improve the efficiency and cost effectiveness in absorbing a growing mandate (CSS, 1S1A, new tasks etc).

The target enterprise architecture is adopted, and implementation is started to improve tooling for regulatory processes for internal and authority users.



O2 Further develop the capability of the IT function to deliver through more effective organisational processes, refined architecture and leverage of new technologies.

Implement the cybersecurity policy adopted in 2022.

The refresh of end-of-life administrative tooling is continued.	✓Yes
The implementation of the roadmap for the future of the ICT infrastructure towards the public cloud begins.	<b>On-going</b>

Services 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.

The preparation and establishment of replacement framework contracts for Management Information Systems, Enterprise Content Management and for Managed IT Workplace Services.

Indicators		Estimate	Actual
01	Average availability of key systems	>98 %	99 %
02	High impact security incidents	<3	0

# Financial Resources

#### Highlights

We effectively managed our financing in 2023 through close monitoring of uncertain fee income development. On the final budget size of EUR 123.3 million, the Agency reached a 99% commitment rate and 87% payment rate, exceeding the targets set. The European Court of Auditors gave a clean audit opinion on ECHA's annual accounts for 2022 and their first audit mission on the financial year 2023 concluded without any preliminary findings.

We continued supporting the Commission in its design of a sustainable and more predictable financing model and a simpler budget structure. Details on ECHA's budget information and management in 2023 can be found in Part II and Appendix II of this report.

#### Main outputs

O1 ECHA's budget is implemented in line with the objectives set in the Programming Document, with a high degree of implementation and in line with the Financial Regulation.

Prepare and implement ECHA's budget in line with the objectives set in the Programming Document and the rules and deadlines set in the Financial Regulation.

The refresh of end-of-life administrative tooling is continued.

Prepare and present the annual accounts to the Management Board and Institutions in line with the rules and deadlines set in the Financial Regulation.

Prepare and implement procurement and contracting activities in line with the objectives set in the Programming Document and the rules and deadlines set in the Financial Regulation.

Provide data and analysis to the Commission to support achieving a stable and predictable financing model for ECHA, with a more flexible budget







Yes

Yes

allocation.

Provide regular reports to the Commission partner services and the Management Board's Sub-group on Finance, Audit and Risk, on the evolution of fee income, actual budget implementation, including revenue and expenditure estimates for the future.

Maintain regular contacts with the Commission's partner DGs' financial services to discuss ways of handling any shortfall or surplus during the budget year.

Monitor and report annually on the evolution of the transfer of a proportion of fees to Member States, propose improvements thereto, as necessary, and prepare updates to the related transfer amounts per country when the Commission country coefficients are updated.

Implement further efficiency measures, including the automation of electronic signature to contracts, further digitalisation of the financial workflows, streamlining the procurement process by onboarding PPMT (that provides a single platform access to all eProcurement tools) and further promotion of electronic invoicing.

Indi	cators	Estimate	Actual
01	Level of budget implementation: commitment rate and cancelled payment appropriation rate (including carry-forward)	Min. 95 % and max. 5 % respectively	99 % and 1 %
	Processing of payments within legal deadlines	No less than 99 %	99 %

### Human Resources

#### Highlights

During 2023, we continued to build our organisational capability to support the delivery of ECHA's Work Programme. The annual staff turnover rate was within target, while vacancies were promptly filled leading to a high 96.8 % of establishment plan posts filled. Our biennial staff engagement survey showed high levels of commitment and engagement and confirmed ECHA's recognition as one of Finland's most inspiring workplaces.

2023 was the final year of the existing HR Strategy and actions on priority areas were all delivered. Technical competencies were successfully reviewed and updated with a view to preparing for new tasks. Learning and development priorities were actively addressed and delivered to build and maintain critical competence in key areas, including management and leadership capabilities. ECHA continued to provide its staff with career development opportunities through regular career enhancement calls, an internal mentorship programme and career coaching addressing individual needs. The attractiveness of ECHA as an employer was promoted with our strategic partners, at both international and at host country level. We also revamped the organisation's presence in social media to further enhance our attractiveness as an employer.

Finally, we consulted all our staff and the Staff Committee in the development of the new People and Organisational Strategy for the period 2024–2028. This key document will support the

Yes

✓<sub>Yes</sub>

Yes

✓<sub>Yes</sub>

organisation in achieving its purpose, vision and goals as contained in ECHA's new Strategy Statement 2024-2028.

#### Main outputs

O1 ECHA attracts, develops and retains competent and committed staff to implement its current and future mandate.

Develop a new human resources framework, in line with the new ECHA multiannual work programme (Strategic Plan), addressing core topics such as competence development, recruitment, inclusiveness, gender balance and career development.

Implement ECHA's Wellbeing Action Plan 2023-2024 with the support of ECHA's Corporate Services Unit and the Agency's Joint Committee for Health and Wellbeing.

Provide competence development activities to ensure continuous capacity building of staff, including exploring joint training initiatives with peer Agencies.

Ensure regular communication with ECHA's Staff Committee to maintain a healthy working culture and positive relations and dialogue.

Implement ECHA's Diversity and Inclusion Action Plan 2023-2024 to advance diversity (including gender balance) in the management team and at organisational level.

Indicators		Estimate	Actual
01	Turnover of Temporary Agents	<5 %	1.1 %
	Turnover of Contract Agents	<10 %	4.6 %
	Percentage of Establishment Plan posts filled	95 %	96.8 %

## **Corporate Services**

#### Highlights

During 2023, we continued to adapt to the hybrid working environment and an external consultant conducted an analysis on optimising the use of our office building and Conference centre. In 2023, ECHA maintained its International Organisation for Standardisation (ISO) 14001:2015 and EU Eco-Management and Audit Scheme (EMAS) certifications, as well as business continuity and security while closely monitoring the geopolitical situation with local authorities. Our new environmental work programme 2023-2025 was coordinated and monitored effectively (more information can be found in Part II and Appendix VII).

We successfully organised meeting services for 640 events and official meetings, with 32 800 participants joining online through Webex, and hosted approximately 5 000 visitors to our premises. We also continued to work towards our aim to reduce CO2 emissions from both staff travel and building operations. A feasibility study of ISO 20121:2012 standard on event

Yes

Yes

Yes

/ Yes

sustainability management systems was concluded and based on this study, we will aim to implement this standard during 2024.

We launched and concluded a significant number of procurement procedures in 2023, including several new 4-year service contracts (for example, cleaning, security and reception services contracts). We also provided the facilities, support in safety and access management for two European Agencies who organised an official event at ECHA. ECHA's Wellbeing Action Plan 2023-2024 was progressed, by the Agency's Joint Committee for Health and Wellbeing and numerous implementation measures were undertaken throughout the year.

#### Main outputs

O1 ECHA provides a safe and healthy physical work environment for staff and guests that facilitates optimal Agency-wide performance.

Conduct an analysis on optimising the use of ECHA's office building and  $\checkmark_{Yes}$  Conference Centre, including related service delivery options.

Implement ECHA's Wellbeing Action Plan 2023-2024 with the support of ECHA's Human Resources Unit and the Agency's Joint Committee for Health and Wellbeing.

Coordinate and monitor implementation of ECHA's Environmental Work Programme 2023-2025.

Conduct staff awareness-raising activities in carbon neutrality.

Indi	cators	Estimate	Actual
01	Examine the feasibility of obtaining a relevant certification to confirm, and improve, the sustainability of ECHA's event-related activities.	Completed	Completed

/ Yes

Yes

✓Yes

# Part II. Management

#### Management Board

The Management Board (MB) provides strategic direction and governance to ECHA to enable the Agency to deliver on its purpose and vision and meet the expectations of its stakeholders. In 2023, eight new Board members were appointed. A number of significant decisions were taken by the MB including the development of ECHA's strategy for 2024-2028, approving the new policy for managing corporate risks and revising ECHA's conflict of interest policy.

The MB led the strategy development process via its dedicated subgroup, in close collaboration with the Executive Director. The MB assessed the evolution of ECHA's external environment, took stock of the achievements of the previous strategy period and gathered input from ECHA staff and the Agency's key stakeholder groups. The final Strategy Statement 2024-2028 was adopted in December 2023.

In June 2023, the MB adopted ECHA's revised conflict of interest policy to strengthen the monitoring of compliance with post-employment duties by former staff members. The policy also provides guidelines for Member States to ensure the independence of their services provided to ECHA and clarifies the duties applicable to staff and to external contributors.

In September 2023, the MB adopted the Agency's new framework for identifying, assessing, and managing risks to reduce the likelihood of negative impacts on ECHA's objectives and ensure that risk management is integrated into the decision-making process. Regular reports on risks related to IT security were provided to the MB as well as risks arising from legal obligations not being met due to committee capacity constraints or the size and complexity of dossiers.

With a view to resources and work programming, the MB was regularly updated on pending and upcoming Commission initiatives with an impact on ECHA's mandate and/or resourcing, as well as on ECHA's technical input to the Commission's preparatory work.

The MB adopted all statutorily required documents in line with the applicable rules and regulations. In its capacity of Appointing Authority, the MB took the necessary decisions in all staff matters for the functions reporting directly to it (Executive Director, members of the Board of Appeal), including probationary period and annual performance appraisal, as well as renewal of mandates.

#### Major developments

In 2023, the MB led ECHA's strategy development process via its dedicated subgroup, in close collaboration with the new Executive Director. The Strategy Statement 2024-2028 was adopted in December 2023, and it provides the framework for ECHA to deliver on its existing wide legal mandate, build on its expertise and experience, collaborate with its stakeholders and partners, implement new tasks and support the ambition of the EU policy goals on chemicals.

During 2023, ECHA continued to support the implementation of the Chemicals Strategy for Sustainability (CSS) as requested by the Commission. For instance, we provided scientific and technical input to the Commission during the trilogues with the European Parliament and the Council on the CLP Regulation revision, until a provisional agreement was reached at the end of 2023. In addition, ECHA provided technical input to the Commission during the preparation of the legal proposals for the revision of the Groundwater, Water Framework and Environmental Quality Standards Directives, the revision of the End-of-Life Vehicles (ELV) and Restriction of Hazardous Substances in electrical and electronic equipment (RoHS) Directives, as well as the

revision of the Toys Safety, Persistent Organic Pollutants (POPs) and Medical Devices Regulations, among others. For all these the Commission put forward legal proposals, reattributing scientific and technical tasks to the Agency. In addition, the Commission published a legal proposal to establish a Common Data Platform, which includes a number of "data-related" new tasks for ECHA, such as the development of an EU Common Data Platform for Chemicals, a new repository of reference values, the extension of the Public Activities Coordination Tool (PACT), the hosting of the Information Platform for Chemical Monitoring (IPCHEM), a new database of study notification, a new Early Warning Framework and the establishment of an EU data generation mechanism. For two newly adopted legislations, the Batteries Regulation and the Regulation on Serious Cross-Border Threats to Health, ECHA commenced our implementation plans with a view to become operational in 2024.

ECHA supported the Commission in its conceptual work on the future ECHA Basic Regulation. In this context, ECHA delivered five retrospective evaluations on ECHA's financial model, Committees (RAC, SEAC and MSC) and the Board of Appeal. Main recommendations on ECHA's financial model referred to ex-ante verifications for SMEs and a potential reserve fund, which are expected to further enhance the flexibility and agility of ECHA's management system, if implemented. Among the main recommendations of the evaluation of the committees were increasing the number of coopted members, reconsidering the payment schemes for rapporteurs, considering alternative legislative structures for ECHA to get the needed expertise and assigning a more active regulatory role for ECHA for some processes. These recommendations are expected to increase the flexibility for ECHA in attracting and keeping the right expertise for rapporteurs, relieve the Committees' workload and ultimately speed up the opinion making process.

#### Budgetary and financial management

#### **Financial management**

ECHA effectively managed its financing in 2023, closely monitoring fee income development and reaching a 99 % commitment rate and 87 % payment rate, exceeding the targets set. The European Court of Auditors gave a clean audit opinion on ECHA's annual accounts for 2022 and their first audit mission on the financial year 2023 concluded without any preliminary findings.

Details on ECHA's budget information and management in 2023 can be found in Appendix II.

# Delegation and sub-delegation of the powers of budget implementation to agency's Staff

ECHA has a system of operational and financial delegations as part of its Integrated Management System, which allows to effectively manage delegations and sub-delegations, taking into account the risk level of the particular process.

#### Human Resources (HR) management

#### Human resources management

ECHA continued to implement its 2019-2023 Human Resources (HR) Strategy and had a high rate of filled establishment plan posts (96.8 %) with a low Temporary Agent turnover (1.1 %) rate. We maintained a strong focus on staff wellbeing through delivery on our respective action plan, in close cooperation with ECHA's Joint Committee on Health and Wellbeing. Finally, the Diversity and Inclusion Action Plan was further implemented, and our efforts were recognised through the award of a Certificate of Excellence from the Network of EU Agencies.

ECHA's biennial staff engagement survey was conducted by ECHA's independent service partner in the spring of 2023. The results are above benchmark levels and show high employee engagement level. The service provider characterised ECHA as an inspiring workplace where business is developed together with employees. The results of the staff survey, together with the rest data sources, are analysed in the internal controls assessment (see Section III).

#### Strategy for efficiency gains

In the recently released draft discharge report for the financial year 2022<sup>5</sup>, the European Parliament commends ECHA for its strategy for efficiency gains, stating that the Agency's strategy focuses on achieving added value through performance-based governance, alongside the development of new tools that enhance Planning and Reporting processes. These tools, designed to be more user-friendly, offer better reporting capabilities, and save time for the entire staff. In terms of efficiency gains, the discharge report also observes that the Agency also started an infrastructure capacity optimisation exercise to minimise any excess capacity in the IT infrastructure and the Agency was able to reduce the usage by roughly 25 %.

With regard to ECHA's efficiency efforts in the area of IT management, in 2023 the Agency continued the process of organising its IT portfolio in modules, which allows a composable architecture and further enables synergies between activities and legislations.

According to the 2023 staff survey, 42 % of respondents fully agree and 44 % tend to agree that their units operate efficiently, pointing to a perception of ECHA as an efficient organisation.

As part of its efficiency initiatives, in 2023 the Agency prioritised the adoption of the PEPPOL platform for invoice exchange. This initiative ensures secure and timely transactions, benefitting both public and private sector entities within and outside the EU. The use of this platform has streamlined the recording of debit notes in the Agency's accounting system, handling an average of 2000 commercial invoices annually. Furthermore, to expedite financial transactions, the Finance unit now possesses the authority to approve payments below EUR 8,000. Approximately 75 % of invoice-based payments and 100 % of cost-claims, such as meeting participant reimbursements, are processed within the Finance unit, freeing up time for middle and senior management to focus on strategic priorities.

Another significant change occurred with the implementation of the new hybrid working arrangement as of 1 September 2023. This approach replaced the previous structural teleworking request system, resulting in around 82 % decrease in teleworking requests during Q4 2023 compared to Q4 2022. The adoption of hybrid teleworking arrangement brought several tangible benefits. It has reduced the administrative burden for both staff and managers (two approval workflows per year instead of weekly or monthly) and reinforced flexibility and trust between staff and managers. This new approach is expected to lead to increased staff engagement and commitment.

# Assessment of audit and retrospective evaluation results during the reporting year

#### **Retrospective (ex-post) evaluations**

In 2023, ECHA performed the following retrospective evaluations following the criteria and methodology as stipulated in the Better Regulation Guidelines<sup>6</sup>:

• Retrospective evaluation of ECHA's Committees, and namely: the Committee for Risk Assessment (RAC), the Committee for Socio-economic Analysis (SEAC) and the Member

<sup>&</sup>lt;sup>5</sup> <u>https://www.europarl.europa.eu/doceo/document/CONT-PR-753516\_EN.pdf</u>

<sup>&</sup>lt;sup>6</sup> http://ec.europa.eu/smart-regulation/guidelines/tool\_42\_en.htm

State Committee (MSC)<sup>7</sup>. Upon request of the services of the European Commission, this ex-post evaluation analysed the degree of effectiveness, relevance, efficiency, proportionality, coherence, added value and sustainability of the Committees established by the REACH Regulation. The results will be used to support the Commission's work on improving the governance of ECHA, for which the Chemicals Strategy for Sustainability (CSS) foresees the establishment of a self-standing basic regulation. Some process results may be used by the Commission in a possible future REACH revision.

- Retrospective evaluation of ECHA's Board of Appeal<sup>8</sup>. The objective of this evaluation was to analyse the degree of effectiveness, efficiency, proportionality, coherence, added value, relevance, and sustainability of the Board of Appeal (BoA), with the results supporting the European Commission's work on the Basic Regulation for ECHA.
- Retrospective 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 was 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 were also captured in the analysis. The results of the retrospective evaluation can be used to support the Commission's announced proposal for an ECHA Basic Regulation.

#### Internal Audit Service (IAS)

The Internal Audit Service (IAS) of the Commission conducted an audit on 'Budget preparation, monitoring and reporting'. The audit did not result in any critical or very important recommendations. The audit identified two improvement areas, classified as important, on resource allocation and the exceptions register.

#### Internal Audit Capability (IAC)

The Internal Audit Capacity (IAC) conducted one assurance audit 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 Follow-up to Dossier Evaluation process. The audit resulted in one very important recommendation:

• Provide a holistic overview and monitor dossier evaluation process (compliance checks and testing proposals) from start to end by e.g., preparing analysis on annual trends on status of Final decisions (closed, in follow-up evaluation, in enforcement).

and three important recommendations:

- To support efficient and effective enforcement of the Failure to respond cases:
  - Inform National enforcement authorities of the priority cases according to the ECHA's strategy and Integrated Regulatory Strategy
  - Continue cooperation with the National enforcement authorities.
- Complete the existing calculations on resource needs to deal with the accumulated backlog and the scenarios for the future. Agree on the need to allocate resources to additional tasks such as restructuring and simplifying the Follow-up to Dossier Evaluation process, IT development.
- To reinforce assessment of the regulatory risk management measures as a Follow-up to Dossier evaluation outcome clarify if Follow-up to Dossier evaluation team needs

<sup>&</sup>lt;sup>7</sup> https://echa.europa.eu/documents/10162/17086/retrospective evaluation of committees report en.pdf/e491f353-1e6e-8616-8990-48db2fed0056?t=1695807929141

<sup>&</sup>lt;sup>8</sup> file://echa/data/users/u09175/Roaming%20Profile/Downloads/ex post evaluation board appeal en%20(6).pdf

additional support.

The Agency follows up these recommendations with corresponding actions.

For earlier audits, the Internal Audit Capability conducted two follow-up audits (one finalised in February 2024) to verify the implementation of the action plans, concluding that two very important and four important actions are still being implemented.

#### European Court of Auditors (ECA)

In their statement of assurance<sup>9</sup>, the European Court of Auditors (ECA) concluded that the accounts of the Agency for the financial year 2022 present fairly, in all material respects the financial position of the Agency at 31 December 2022, 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 2022 and there are no observations open from previous years either.

#### Follow up of recommendations and action plans for audits and evaluations

#### Follow up of recommendations and action plans for audits and evaluations

- The follow-up of the evaluations performed in previous years showed that most of the recommendations on the retrospective evaluations, such as those concerning the SCIP database (Substances of Concern In articles as such or in complex objects (Products) established under the Waste Framework Directive (WFD))10, 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 retrospective 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.

# Follow up of recommendations issued following investigations by the European Anti-Fraud Office (OLAF)

N/A

#### Follow up of observations from the Discharge authority

For the discharge 2022, the Secretariat of the European Parliament Committee on Budgetary Control asked all EU Decentralised Agencies for a follow-up report to the 2021 budgetary discharge to be submitted by 15 September 2023.

<sup>&</sup>lt;sup>9</sup> <u>https://www.eca.europa.eu/en/publications/SAR-AGENCIES-2022</u>

<sup>&</sup>lt;sup>10</sup> https://echa.europa.eu/documents/10162/6205986/scip\_evaluation\_report\_en.pdf/2c677149-e876-f2b1-0ba7-3daca0a419ef?t=1665556373094

The report<sup>11</sup> provides an overview of the relevant observations and recommendations from the European Parliament Resolution<sup>12</sup> of 10 May 2023 on discharge in respect of the implementation of the budget of ECHA for the financial year 2021, together with the measures ECHA has taken in light of these.

On 10 May 2023, 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 2021: performance, financial management and control (2022/2134(DEC)). This resolution is a horizontal report containing recommendations and observations that accompanied the individual 2021 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, will be 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 nine recommendations from the European Parliament, out of which six have been implemented.

#### Environment management

#### **Environmental and sustainability management**

To sustainably use resources and maintain sound environmental practices, ECHA has integrated environmental management into its systems. In 2023, the Agency was recertified under both the EU Eco-Management and Audit Scheme (EMAS) and International Organisation for Standardisation (ISO) 14001, which both confirm that ECHA evaluates, reports and improves its environmental performance. These certifications are central to realising our vision of becoming an Agency with net-zero greenhouse gas emissions by 2030, as stated in our climate neutrality pledge.

ECHA's Environmental Work Programme (EWP) 2023-2025 outlines our goals, actions, and objectives for reducing the consumption of natural resources, cutting down waste, and minimising our carbon footprint. Overall, ECHA's total CO2 consumption was within the annual target of the 2023-2025 environmental work programme. This was made possible with the collective effort of all ECHA staff, who limited their work travel by respecting the limits set for total CO2 through the mission quota system introduced in 2023.

Environmental Objectives 2023-25	Result in 2023
(Benchmark year: 2019)	
Building CO2 emissions reduction of 20%	61 %* decrease
Travel (meeting participants) CO2 emissions reduction of 75%	73 % decrease
Travel (staff missions) CO2 emissions reduction of 50%	70 % decrease

\*Adjusted to 2022 CO2 emission factors

Actions of the EWP implemented in 2023 included the strengthening sustainability criteria and monitoring for Green Public Procurement (GPP), the development and implementation of an

<sup>&</sup>lt;sup>11</sup> <u>ECHA 2021 Discharge report follow-up.docx (europa.eu)</u>

<sup>12</sup> TA (europa.eu)

Internal Audit methodology of the ECHA Environmental Management system (EMS) and the review of the scope of CO2 related to ECHA's activities. Finally, to promote and implement ECHA's environmental objectives, over 30 communications activities were undertaken during 2023 to promote international, EU, national and ECHA climate awareness actions such as Earth Day, EU Green week and the Baltic Sea Day. ECHA was also active in inter-institutional activities and participates in the *Groupe Interinstitutionnel de Management Environnemental* (GIME) and European Union Agency Network (EUAN) Greening Network to exchange best practice on environmental management among the EU institutions and Agencies.

#### Assessment by management

Based on the information in the Section II, no significant weaknesses or gaps that may threaten the achievement of ECHA's objectives were identified. An overall conclusion taking into account the findings from the internal control assessment is available in **Section IV**.

# Part III. Assessment of the effectiveness of the internal control systems

Effectiveness of internal control system

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

The purpose of the annual internal controls 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, (POL-0001) 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.

The assessment is based on a wide range of sources, such as internal and external audits, retrospective evaluations, risks, non-conformities, complaints, appeals, financial, operational, IT, environmental and HR reports. Following the recommendations from the IAS audit on 'Budget preparation, monitoring and reporting', ECHA also sampled and analysed the whole exceptions register. The detailed conclusions from the sampling and analysis of all those sources are available in the internal controls assessment for the year 2023.

Internal control surveys were conducted to capture the self-assessment of Directors, Heads of Units and Management board members with regard to the functioning of the ECHA's management system. Staff members' perception was also analysed as part of the annual staff survey 2023 and stakeholders' input was captured in the media report and various retrospective evaluations. Interviews were also conducted to deepen the analysis in the areas with low scores. The data on perception together with the other sources mentioned above were analysed and triangulated to derive conclusions.

For 2023, 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.

Performance management, and stakeholder engagement are the main areas of attention as a result of the internal controls assessment 2023 (details are available in the next section). Improvement work is either ongoing or planned for 2024.

In terms of costing the controls, the Agency follows the definition in the General Financial Regulation<sup>13</sup> 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

<sup>&</sup>lt;sup>13</sup> Financial Regulation applicable to the general budget of the Union<u>: https://op.europa.eu/en/publication-detail/-/publication/e9488da5-d66f-11e8-9424-01aa75ed71a1</u>

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 3.4 % which is lower than the previous year, when the percentage was 3.7%.

The summary from the internal controls assessment as per the principles and characteristics of each component is covered in the next section below.

#### **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. In 2023, ECHA appointed a Chief Risk Officer and ECHA's Management Board adopted a new organisational Risk Management Policy. ECHA also developed a new Risk Management Procedure, together with implementing a revised internal framework for addressing risk management in ECHA. Regular updates were given to the Management Board and specific reporting continued on the IT-security related risks.

#### Transparency, accountability and integrity

Throughout 2023, 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 2023, ECHA published a IUCLID dataset for 528 approved pharmaceuticals, including results from animal studies and human data. The availability of this new data supports the development of alternatives to animal testing. In addition, a pilot project led by the European Federation of Pharmaceutical Industries and Associations (EFPIA), and supported by ECHA, has made an updated set of archived data from unpublished chemical tests available on the IUCLID website. The database contains now altogether information about the hazard properties of 94 substances from 517 tests.

#### **Prevention of conflicts of interest**

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 among ECHA staff, affecting the output of the Agency were identified in 2023. However, one issue was identified within a process where an external service provider contributed to the Agency's outputs. The provider had failed to declare that one of its experts was at the same time and on the same topic also advising a private entity potentially affected by ECHA's work. Immediately after detecting this potential for a conflict of interest, ECHA took the necessary mitigating measures, including terminating the contract in question and re-evaluating all of the outputs produced by the external service provider in this file, to fully exclude any undue influencing. Improvements were also made to the procurement process to avoid any similar situations in the future.

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.

#### **Policy update**

ECHA's Management Board adopted in June 2023 changes to ECHA's procedures for prevention and management of potential conflicts of interest. Based on recommendations issued by the European Parliament as discharge authority, the European Ombudsman and the European Court of Auditors, ECHA introduced additional measures to strengthen the monitoring of compliance with post-employment duties by former ECHA staff members. It also converted the existing individual Memoranda of Understanding between ECHA and Member State Competent Authorities (for ensuring the independence of Member State services to be provided to ECHA) into the format of a single document with guidelines for Member States, in order to streamline the process. Finally, it separated the duties applicable to ECHA staff from those applicable to members of ECHA bodies into two self-standing procedures under an overarching policy document.

#### **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 2023, twenty-five (25) staff members left ECHA: six (6) of them went to work for another EU institution, body or Agency. Four (4) staff members moved to a national public administration or international organisation. Eight (8) staff members moved to the private sector or started

self-employment and, in seven (7) 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 seven (7) cases, ECHA has not (yet) been informed about a new occupational activity, as the departure was due to retirement, permanent invalidity or death of a staff member. None of these cases concerned 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<sup>14</sup>.

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

#### **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.

The Committee comprises three members: *Mr Per Ängquist*, appointed by the Management Board of ECHA (he has succeeded *Ms Judite Dipane* whose mandate in Management Board and CoIAC expired end of May), *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 31 May 2023, the CoIAC convened for its annual meeting where it took the opportunity of the change in its composition but also of the presence of the ECHA's new Executive Director to recapitulate and discuss the past ten years of advice given by the CoIAC.

The CoIAC further received a request for advice from the Executive Director concerning analysis of ECHA's CoI prevention policy and implementing rules with a view to the expanding role and mandates of the ECHA Committees and the actors involved around the Committee work. The CoIAC agreed to base its advice on an analysis of the new and amended policy to be adopted in June 2023, and it held a number of interviews with Chairs of ECHA's Committees as well as Working Groups. The final advice will be delivered in 2024.

#### Ex-post controls

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

A sample check on 12 annual declarations submitted by the members of the ECHA Board of Appeal revealed that all of them were in place, publicly available and sufficiently complete to allow for effective conflict of interest prevention and management. However, while there is a duty for an annual update, for 1 declaration more than 21 months had expired since the latest update. While the Board of Appeal confirmed that the annual renewal process was ongoing also for this alternate member, they were reminded of the importance of the prescribed 12-month time limits to allow accurate assessments of potential conflict of interest situations.

<sup>&</sup>lt;sup>14</sup> <u>https://echa.europa.eu/documents/10162/13559/post-</u> employment senior managers en.pdf/8567fc1f-1631-05fe-eceb-8817a0e110d1

#### **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<sup>15</sup> 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.

The ECHA Anti-Fraud Strategy<sup>16</sup> 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. In autumn 2023 a mandatory all-staff ethics training was organised, with a focus on dealing appropriately and effectively with lobbyists.

#### 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 2023, the focus areas of support concerned contractual arrangements for IT solutions procured by the Agency, as well as an in-depth assessment of the privacy risks associated with ECHA's project of migrating its data to the public cloud. Actions have also been taken in the context of two data protection related complaints and three 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 2023, separate training sessions on security for service providers in ECHA's premises as well as numerous unit/directorate fire-safety and evacuation walk throughs were organised. Based on a scheduled fire safety inspection the agency's Emergency Rescue Plan was updated and communicated to the Helsinki Rescue Authorities. ECHA's emergency procedures were audited as part of the ISO-audit and as part of the EMAS verification of ECHA's environmental statement.

Radiation safety training was organised for ECHA's Radiation Safety Officer by the STUK organisation. ECHA's business continuity organisation was reviewed and updated in 2023 to better reflect the needs of the organisation. The agency has maintained and updated its physical security and safety equipment, in accordance with legal requirements and with due consideration to best practice throughout the year and continuously monitors its geopolitical operating environment.

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https://echa.europa.eu/documents/10162/13559/code of good administrative behaviour en.pdf/a4aa9 4f7-f631-43d6-8c28-77a10a0d0720

<sup>&</sup>lt;sup>16</sup> https://echa.europa.eu/documents/10162/10709201/final mb 47 2022 annex1 anti-fraudstrategy 2023-2026 en.pdf/c42eb6f4-1d61-5be9-83a4-3f4af5ee6b4e

Co-operation and security briefings with Commission's Representation in Helsinki, the Helsinki police and other local authorities on security and safety matters continued during year 2023. Finally, the Agency received one request for support from the EU Agencies Security Network related to security management.

Regarding cybersecurity the new EU regulation on cybersecurity for Union Institutions, Bodies, Offices and Agencies was adopted in December 2023. Preparations for the new legal obligations were made and implementation will follow in 2024 and beyond. This includes cybersecurity risk-management, governance and control framework, maturity assessment, risk-management measures and cybersecurity plan.

Public cloud services were being put in place the cybersecurity and resilience and continuity arrangements were put in place. In addition, regarding data protection various impact assessments were performed.

Cybersecurity awareness campaign was continued with two more mandatory courses for ECHA staff as well as phishing simulation exercises and European Cybersecurity Month "Be Smarter than a Hacker" in October 2023.

Although the Cybersecurity service of the Union Institutions, Bodies, Offices and Agencies (CERT-EU) reported unprecedented rise of cybersecurity incidents in the second half of 2023, cybersecurity of ECHA infrastructure and data, including hybrid working practice, was maintained and no high impact security incidents were encountered in ECHA.

Component	Conclusion
Governance	
1.1 Mission and vision	ECHA's purpose, vision and values were reviewed in the context of the new ECHA strategy in 2023 building on input from staff, MB members and via them stakeholders.
1.2 Ethical and organisational values	The principle is present and functioning. ECHA is perceived as a transparent organisation. Values have been updated in 2023 in consultation with staff and MB and reflect ECHA's new tone at the top and strategy 2024 -2028. Awareness raising efforts on dealing with sensitive topics need to remain high.
1.3 Management responsibility	The Integrated management system is functioning, and management committed to its continual improvement and flexibility. The overall management perception of ECHA's ability to support effective decision-making at the right level is neutral towards positive for senior management. The overall perception of the efficiency of decision-making is positive among staff. The decreasing allocation of resources in the area of quality, internal control, internal audits and process improvements at ECHA is impacting the support to the work of the QAO network.
1.4 Human Resources	ECHA has competent and highly qualified staff, and there is Management commitment to enhance staff and competence development. There is a need for improvement in the areas of identifying competence gaps and assessing staff performance in an objective, equal and transparent way.
1.5 Stakeholders and partners engagement	ECHA is well committed to its stakeholders and their needs. In 2023 there was a new Communications' strategy and a stakeholder methodology developed and efforts were made towards identification, classification and prioritisation of stakeholders. However, it cannot yet be concluded that the actions taken have been effective in handling the deficiencies as identified in the IAC audit in 2022 since the strategy has not yet been implemented and there is work ongoing under the new stakeholders' approach. It will be beneficial to ensure stakeholder contacts are transparently

#### Conclusions of assessment internal control systems

	shared in the organisation and tailor made to the Agency's strategic and operational goals.
Strategy, planning a	nd risk management
2.1 Priorities planning and resource allocation	In 2023, Management Board adopted ECHA's new strategy and the SPD for 2024- 2026 where it defined ECHA's strategic and operational priorities and their implementation. ECHA demonstrates commitment to stakeholders, priorities and objectives, which is demonstrated in the new strategic statement. The resources allocation based on strategic goals, including in horizontal services, is an area for improvement.
2.2 Risk management	The corporate level risk exercise is well established. MB involvement and establishment of clear roles and responsibilities with the new risk policy in 2023 is a positive development. Process-level risk management is less structured, and controls are partly perceived as disproportionate or as removed without prior risk assessment. Different indications exist for the cost-benefit ratio of horizontal functions. No overall analysis is available.
Operations and opera	ational structure
3.1 Activity management	The activity and process management enables synergies. Efforts were made in 2023 to define the outcomes, expected performance, efficiency, and impact of activities, however, biggest part of this work will take place in 2024 in alignment with the implementation of ECHA's new strategy. There are control mechanisms in place to manage suppliers and contracts at ECHA. The Agency may benefit from an overall systematic analysis of how and if the risk of overdependence has materialised in the different activities of ECHA, together with a consideration of the costs, risks and benefits of the dependency versus the transition to new potential contractors. Awareness raising around management of contractual risks and strengthening ECHA's negotiating power may target contract managers and process owners in the operational units.
3.2 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. There is ongoing work with regard to improving the overall efficiency of the IT systems and the systematic involvement of stakeholders in the development of IT products and services. Measuring the efficiency and economy of ECHA's IT initiatives, i.e. around re-using existing IT platforms and tools will be beneficial.
3.3 Change management	ECHA overall responds to changes flexibly whilst ensuring continuity of operations. Changes to ECHA's financial model are expected to further enhance the flexibility and agility of the system. Specific consideration should be paid to the prerequisites (including the legislative ones) for maintaining a flexible and agile management system in the future in view of the changing stakeholders' requirements and the onboarding of new tasks.
Evaluation and improvement	
4.1 Performance management	The structures ensure overall reliability of reporting, accuracy, completeness, and timeliness of data. No critical gaps were found from the analysis of non-conformities, complaints and exceptions register. Attention is required in the area of data management with the need to build more consistent reports and avoid manual interventions. The adequacy of corporate metrics will need to be addressed, taking into account the balance between quantitative and qualitative indicators, such as stories, and the data needs of the different stakeholder groups.

4.2.4	ECHA has adequate tools in their disposal to oversee the effectiveness, adequacy,
4.2 Assessments,	and suitability of the Agency's Integrated Management System through assessments,
audits, and	audits, and evaluations. There is a need to improve the communication around the
evaluations	Management Review topics and to ensure that cost-risk-benefit analysis is performed
	when new initiatives are started.

#### Statement of the manager 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 12 March 2024

signed

#### Shay O'MALLEY

And

Frank BÜCHLER

signed

Director of Resources

Head of Unit Governance, Strategy and Relations

# Part IV. Management assurance

#### Review of the elements supporting assurance

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 and will feed into the Management Review 2024, 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 2024. 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.

#### Reservations

Not applicable

# Part V. Declaration of assurance

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<sup>17</sup> 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 22 March 2024

signed

#### **Dr Sharon McGuinness**

**Executive Director** 

<sup>&</sup>lt;sup>17</sup> 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.

# Appendices
# Appendix I - Key indicators

WP Activity	Indicator	Estimate 2023 (PD)	Actual	Progress
1.1 Dossier preparation	Inquiries received and concluded	4200	4835	115%
1.2 Dossier submission and processing	Number of SME companies verified for their status	400	416	104%
1.3 Identification and prioritisation	Number of substances registered above 100 t/y in the unassigned region of the chemical universe for which a conclusion on potential regulatory follow-up was drawn	250	156	62%
1.3 Identification and prioritisation	Number of groups of substances for which the assessment of regulatory needs is carried out	70	61	87%
1.4 Evaluation	Compliance checks concluded: draft decisions or no action	300	301	100%
1.4 Evaluation	Final decisions on dossier evaluation (testing proposals and compliance checks)	300	367	122%
1.4 Evaluation	Number of substances for which a conclusion was reached in the follow-up to dossier evaluation	200	202	101%
1.4 Evaluation	Substance evaluation final decisions issued	10	6	60%
1.4 Evaluation	Number of substances for which a conclusion was reached in substance evaluation	25	26	104%
1.5 Authorisation	Number of new entries in the Candidate List	15	8	53%
1.5 Authorisation	Number of RAC & SEAC opinions adopted on applications for authorisation (number of uses)	60	58	97%
1.6 Restrictions	Number of RAC & SEAC opinions on restriction proposals	6	5	83%
1.6 Restrictions	Restriction proposals or investigation/screening reports developed	5	8	160%
1.7 Classification and Labelling	Number of RAC opinions on proposals for harmonised classification and labelling	50	42	84%
1.7 Classification and Labelling	Decisions made on requests to use an alternative chemical name (CLP Article 24)	40	26	65%
1.7 Classification and Labelling	Poison centre notifications (millions) received and made available to Appointed Bodies and Poison Centres	2	4.4	220%
2. Biocides	Number of opinions on active substances [approval & renewal]	28	13	46%
2. Biocides	Number of opinions on Article 15, Article 38 and Article 75(1)(g) requests	20	7	35%
2. Biocides	Number of opinions on Union authorisation of biocidal products	31	10	32%
2. Biocides	Number of opinions on Union authorisations subprocesses (same biocidal products, administrative and minor changes)	52	21	40%
2. Biocides	Number of technical equivalence application assessments	30	32	107%
3.1 PIC – prior informed consent	Export notifications processed	11200	10857	97%
4.2 EU Chemicals Legislation Finder	Number of data updates on EUCLEF pieces of legislation	4	5	125%
4.3 Support to occupational health legis	la Number of RAC opinions on OELs completed	6	6	100%
5.2 Board of Appeal	Appeals concluded under REACH	12	14	117%
5.2 Board of Appeal	Appeals concluded under BPR	2	1	50%
5.4 ICT	Average availability of key Systems	>98%	99.96%	99.96%
5.5 Financial resources	Commitment rate	95%	99.20%	99.20%
5.6 Human resources	Percentage of Establishment Plan posts filled	95%	96.80%	96.80%

# Appendix II - Budget implementation reports and statistics on financial management

#### **Budget overview**

The initially budgeted total payment appropriations for the Agency's expenditure in 2023, as concluded by the Management Board in December 2022, amounted to EUR 117.7 million. In addition the budget 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 2023, amounted to EUR 118.0 million. The budget for the Other tasks was increased by EUR 4.5 million.

Revenue	Initial voted budget	Amending budgets	Final voted budget
Total revenue	117 724 442	249 258	117 973 700
Expenditure	Initial voted budget	Amending budgets	Final voted budget
Commitment appropriations	117 756 974	265 505	118 022 479
Payment appropriations	117 724 442	249 258	117 973 700

#### Revenue

The budget funding of ECHA in 2023 consisted of the following (amounts in EUR):

Description	Initial voted Budget 2023	Budget Amendment s 2023	Final voted Budget 2023	Entitlements established 2023	Revenue received 2023
Fees and charges from Registrations & Updates	23 413 785	2 744 690	26 158 475	26 680 580	26 680 580
Fees and charges from Authorisations	2 932 200	200 000	3 132 200	3 297 666	3 297 666
Fees SME Administration	814 500	(114 500)	700 000	817 549	817 549
Fees and charges from CLP	90 500	-	90 500	100 600	100 600
Fees and charges from Appeals	-	26 309	26 309	33 484	33 484
Total REACH Fees & Charges Income	27 250 985	2 856 499	30 107 484	30 929 879	30 929 879
Fees relating to Biocidal Active Substances	705 712	(452 579)	253 133	236 500	236 500
Fees for Union Authorisation of Biocidal products	1 430 884	(442 982)	987 902	922 200	922 200
Miscellaneous fees	2 494 878	(735 913)	1 758 965	1 631 700	1 631 700
Fees and charges from Appeals	-	-	-	2 500	2 500
Total BPR Fee & Charges Income	4 631 474	(1 631 474)	3 000 000	2 792 900	2 792 900
REACH EU Contribution	70 711 023	(3 900 000)	66 811 023	66 811 023	66 811 023
BPR EU Contribution	7 556 055	2 000 000	9 556 055	9 556 055	9 556 055
ENV EU Contribution	4 907 490	-	4 907 490	4 907 490	4 907 490
EFTA Contribution - REACH	2 003 016	-	2 003 016	2 003 016	2 003 016
EFTA Contribution - BPR	190 924	-	190 924	190 924	190 924.00
Confederation of Switzerland Contribution - BPR	333 222	49 233	382 455	382 455	382 455.00
EFTA Contribution - ENV	140 253	-	140 253	140 253	140 253
Total EU and other Contributions	85 841 983	(1 850 767)	83 991 216	83 991 216	83 991 216
Contribution Agreement EUON	-	609 000	609 000	614 000	614 000
Contribution Agreement EUCLEF	-	1 519 000	1 519 000	1 053 400	1 053 400
Contribution Agreement IPA	-	641 348	641 348	641 348	641 348
Contribution Agreement OELs	-	975 000	975 000	975 000	975 000
SLA with EFSA	784 712	777 380	1 562 092	1 562 092	1 562 092
Total Contribution Agreements and SLAs	784 712	4 521 728	5 306 440	4 845 840	4 845 840

### Annual Report 2023

Description	Initial voted Budget 2023	Budget Amendment s 2023	Final voted Budget 2023	Entitlements established 2023	Revenue received 2023
Bank Interest Income	-	875 000	875 000	930 573	930 573
Other income - miscellaneous	-	-	-	96 067	128 475
Total Administrative Operations Income	-	875 000	875 000	1 026 640	1 059 048
Total	118 509 154	4 770 986	123 280 140	123 586 475	123 618 883

#### **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 2023, in terms of cash received, amounted to EUR 30.90 million (EUR 33.36 million in 2022). In addition, EUR 0.03 million (EUR 0.03 million in 2022) was recorded in relation to REACH appeal fees<sup>18</sup> giving a total of fees and charges of EUR 30.93 million (EUR 33.40 million in 2022).

Broken down by fee category, ECHA collected a total of EUR 26.68 million from REACH Registrations and Updates fees (EUR 29.72 million in 2022). Furthermore, the Agency collected in 2023 EUR 3.30 million from Applications for Authorisation (EUR 2.78 million in 2022) and EUR 0.10 million from CLP fees (EUR 0.07 million in 2022). 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 2023 (EUR 0.52 million in 2022). On top of the additional registration fees, the Agency generated EUR 0.82 million in administrative charges (EUR 0.79 million in 2022) levied on companies who were deemed non-eligible for the granted SME fee rebates.

# B) REACH/CLP Contributions from the General Budget of the EU

During 2023, the Agency received an EU balancing contribution for REACH/CLP of EUR 66.81 million (EUR 64.22 million in 2022) and a European Free Trade Association (EFTA) contribution of EUR 2.00 million (EUR 1.61 million in 2022).

# **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 collected by ECHA are determined by the Biocidal Products Regulation, the Fees and Charges Regulation and by the decisions of the Management Board. The budgetary revenue from biocidal product fees and charges for 2023, in terms of cash received, amounted to EUR 2.79 million (EUR 6.76 million in 2022). The significant decrease in the collected BPR fee income relates primarily to the significantly reduced number of Union Authorisation applications, for single products and for product family, received in 2023 compared to 2022 (6 applications in 2023 vs. 42 applications in 2022).

<sup>&</sup>lt;sup>18</sup> 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.

#### B) BPR Contributions from the General Budget of the EU

During 2023, the Agency received an EU balancing contribution of EUR 9.56 million (EUR 7.10 million in 2022) and an EFTA contribution of EUR 0.19 million (EUR 0.20 million in 2022). In addition, the Agency received a contribution from the Confederation of Switzerland of EUR 0.38 million (EUR 0.31 million in 2022).

#### **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 8<sup>th</sup> Environmental Action Programme (8<sup>th</sup> EAP), ECHA is fully financed through an EU contribution for these activities. In 2023, the EU contribution amounted to EUR 1.22 million for PIC (EUR 1.16 million in 2022), EUR 0.29 million for POPs (EUR 0.20 million in 2022), EUR 1.34 million for SCIP (EUR 1.49 million in 2022), EUR 1.72 million for DWD (EUR 1.52 million in 2022), and EUR 0.33 million for 8<sup>th</sup> EAP (EUR 0.33 million in 2022), totalling EUR 4.91 million (EUR 4.73 million in 2022). Furthermore, in 2023, the Agency received an EFTA contribution of EUR 0.14 million (EUR 0.12 million in 2022) in total for the above tasks.

#### **Contribution Agreements 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 has signed a Service Level Agreement with the European Food Safety Authority (EFSA) for developing and implementing IUCLID software solutions for plant protection products. In 2023, ECHA received an amount of EUR 4.85 million in aggregate for implementing these tasks (EUR 4.54 million in 2022).

#### Other miscellaneous income from Administrative operations

The table below shows the other miscellaneous income received by the Agency in 2023 (amounts in EUR).

Description	Entitlements established 2023	Revenue received 2023
Bank Interest income	930 573	930 573
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
Other income - miscellaneous	96 067	128 475
Total Administrative Operations Income	1 026 640	1 059 048

#### Fee Invoicing (other information in accordance with Article 71 of FR)

In accordance with Article 71 of the Agency's Financial Regulation, the number of debit notes issued and their global amount shall be provided in the Agency's report on budgetary and

financial management. In addition, where fees and charges are entirely determined by legislation or decisions of the Management Board, the Authorising Officer may abstain from issuing recovery orders and directly draw up debit notes, after having established the amount receivable. Where the Agency uses a separate invoicing system, the Accounting Officer shall regularly, and at least on a monthly basis, enter the accumulated sum of fees and charges received into the accounts.

The Agency uses a separate invoicing and debtors' system for daily transactions related to fee income, namely the REACH IT (REACH/CLP fees and charges) and REACH-NG (Biocidal Products fees and charges) invoicing modules. The invoices raised and the payments received are recorded in the central accounting system on a monthly basis.

# A) REACH Fees and Charges

The total net invoiced by the Agency in 2023 amounted to EUR 31.01 million (EUR 33.02 million in 2022 and EUR 26.63 million in 2021). The table below depicts the breakdown of the net invoiced REACH fees during the years 2021-2023.

REACH	2	.023	2	022	2	021
Description	No of Invoices	EUR	No of Invoices	EUR	No of Invoices	EUR
Invoices issued	5 743	33 510 775	6 579	35 011 416	6 588	28 295 673
Credit Notes	131	(1 790 613)	494	(1 628 744)	215	(1 161 459)
Unpaid	136	(710 941)	111	(364 332)	118	(505 526)
Considered paid	14	(259)	17	(842)	29	(488)
Net Invoiced		31 008 962		33 017 498		26 628 200
Write offs	5	(87 682)	13	(238 488)	29	(458 573)

On 31 December 2023, the amount to be recovered for REACH fees and charges, before any year-end accounting adjustments, stood at EUR 2.05 million relating to 266 open invoices (on 31 December 2022, the amount to be recovered for REACH fees and charges, before any year end accounting adjustment, stood at EUR 1.95 million relating to 290 open invoices).

# B) Biocidal Products Fees and Charges

The total net invoiced by the Agency in 2023 amounted to EUR 2.88 million (EUR 6.80 million in 2022 and EUR 3.00 million in 2021). The table below depicts the breakdown of the net invoiced BPR fees during the year.

BPR	2	023	2	022	2	021
Description	No of Invoices EUR		No of Invoices	EUR	No of Invoices	EUR
Invoices issued	608	3 618 500	1 201	8 232 100	730	3 383 700
Credit Notes	51	(589 500)	103	(1 347 000)	39	(363 700)
Unpaid	14	(149 500)	37	(81 400)	14	(13 700)
Considered paid	-	-	3	(95)	2	(110)
Net Invoiced		2 879 500		6 803 605		3 006 190

On 31 December 2023, the amount to be recovered for Biocidal product fees and charges before any year end accounting adjustments, stood at EUR 0.18 million relating to 24 open invoices (on 31 December 2022, the amount to be recovered for BPR fees and charges, before any year end accounting adjustment, stood at EUR 0.10 million relating to 18 open invoices).

# Expenditure

ECHA's expenditure budget consists of commitment appropriations (CA) and payment appropriations (PA). The initial CAs totalled EUR 117.8 million and the initial PAs totalled EUR

117.7 million, while the figure concluded in the final budget is EUR 118.0 million for CAs and EUR 118.0 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 commitment appropriations for the current year (C1)

The initially adopted budget for the Agency in 2023 was EUR 117.7 million and the overall net increase during the year, including 22 transfers and three amending budgets, was EUR 0.3 million, to arrive at EUR 118.0 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.

The final executed amount totalled EUR 117.2 million corresponding to an execution rate of 99.3 % for the appropriations.

#### Carry over of appropriations to 2024

The commitment and payment appropriations carried over to 2024 totals EUR 14.4 million, corresponding to 12.0 % of the committed amount.

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

In Title 2, covering the Agency's infrastructure, the carry-over totalled EUR 2.6 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 Environmental Action Programme). The carry-over in operational titles totalled EUR 11.5 million and is mostly related to IT development 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 2022 (C8)

The amount carried over from 2022 totalled EUR 15.6 million and the finally executed amount was EUR 15.4 million, corresponding to 99 %. The cancelled 1 % relates mostly to IT projects in Title 2 and lower than anticipated costs for legal services related to debt collection of administrative charges.

#### Late interest payments

During the year 2023, ECHA did not pay late interest for commercial invoices.

#### **Procurement procedures**

During 2023 budget implementation, ECHA signed 337 **c**ontracts and purchase orders<sup>19</sup>. Out of the 337 signed contracts, 276 were specific contracts and orders under framework contracts (FWC) and 61 were contracts resulting from tendering procedures. Out of the 61 contracts resulting from procurement, ECHA concluded four new FWCs: for managed IT workplace services, for consultancy on IT User Experience, for New Approach Methodologies (NAMS), and for the EU Chemicals Legislation Finder (EUCLEF) and led the procurement to establish two interagency FWCs for standard management certification services and for interim services to be signed in early 2024. ECHA also signed three multiannual contracts: for security and reception services, for cleaning services, and for the Cloudia e-procurement platform. ECHA also joined seven inter-institutional FWCs: for event management and related communication services (DG RTD), for audits and controls (DG BUDG), for leadership and management skills (EPSO), for learning and development (DG HR), for attracting and sourcing of candidates (EMA), for HR consultancy services (DG HR) and for Microsoft high-level services (DIGIT), and two DPS of DIGIT for Software (SIDE III) and Telecommunication Services.

A total of 11 contracts were signed following negotiated procedures without prior publication based on the relevant rules of the Financial Regulation (Annex 1–11.1), eight of which refer to legal services; and three for technical reasons for subscriptions to a scientific database and professional journals, as well as for specialised software. Furthermore, there were two IT FWC ceiling increases that had been foreseen in the specifications of the original procurement procedure.

In 2023, 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. Preliminary market consultation in the form of questionnaires to be filled in by potential tenderers continues being an established practice in ECHA before launching procurement. Green Public Procurement (GPP) remains a priority and an integral part of the Agency's management system.

ECHA continued relying on and adopting suitable IT tools (e.g., Cloudia, PPMT) in its procurement and contract processes, and undertook the revision work of its overall and sectoral procurement strategy, which included participating in a 4-month specialised training delivered by the KEINO Academy of the central purchasing body (Hansel) in Finland. The annual list of contractors is published by ECHA by 30 June of each year for the previous year on ECHA's website <sup>20</sup>.

#### 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) of ECHA's Financial Regulation, the directors have further subdelegated 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 8 000 to staff in the Finance Unit.

<sup>&</sup>lt;sup>19</sup> This number also includes amendments with budgetary commitment.

<sup>&</sup>lt;sup>20</sup> <u>https://echa.europa.eu/view-article/-/journal\_content/title/annual-list-of-awarded-contracts</u>

# Statistics on Financial Management and Budget (Expenditure)

# Budget 2023: Breakdown and changes in commitment appropriations and implementation of the appropriations for the current year (C1) per Title<sup>21</sup> (EUR)

Title	Description	Budget 2023 (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	79 708 220	145 217	79 853 437	79 574 605	99.7%	79 853 437	79 278 523	99.3%	296 082	0.4%	278 832
A-2	BUILDING. EQUIPMENT AND MISCELL OPER EXPEND	17 067 482	-62 455	17 005 027	16 970 489	99.8%	17 005 027	14 363 906	84.5%	2 606 583	15.4%	34 538
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	16 645 769	-264 219	16 381 550	15 964 264	97.5%	16 332 771	7 308 895	44.7%	8 607 206	53.9%	417 286
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	1 898 690	440 346	2 339 036	2 245 984	96.0%	2 339 036	976 720	41.8%	1 269 264	56.5%	93 052
B0-5	OPERATIONAL EXPENDITURE - ENVIRONMENTAL DIRECTIVES AND INTERNATIONAL CONVENTIONS	2 436 813	6 616	2 443 429	2 420 319	99.1%	2 443 429	831 865	34.0%	1 588 454	65.6%	23 110
		117 756 974	265 505	118 022 479	117 175 661	99.3%	117 973 700	102 759 909	87.1%	14 367 589	12.3%	846 818

<sup>&</sup>lt;sup>21</sup> 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 2023: 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 2023 (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	68 878 569	-28 350	68 850 219	68 656 483	99.7%	68 850 219	68 405 623	99.4%	250 860	0.4%	193 736
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	14 473 218	-54 685	14 418 533	14 389 257	99.8%	14 418 533	12 178 875	84.5%	2 210 382	15.4%	29 276
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	16 645 769	-264 219	16 381 550	15 964 264	97.5%	16 332 771	7 308 895	44.7%	8 607 206	53.9%	417 286
		99 997 556	-347 254	99 650 302	99 010 004	99.4%	99 601 523	87 893 392	88.2%	11 068 448	11.2%	640 298

#### BIOCIDES

Title	Description	Budget 2023 (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	8 833 154	93 345	8 926 499	8 868 065	99.3%	8 926 499	8 837 326	99.0%	30 739	0.3%	58 434
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	1 979 831	-5 932	1 973 899	1 969 887	99.8%	1 973 899	1 667 524	84.5%	302 364	15.3%	4 012
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	1 898 690	440 346	2 339 036	2 245 984	96.0%	2 339 036	976 720	41.8%	1 269 264	56.5%	93 052
		12 711 675	527 759	13 239 434	13 083 937	98.8%	13 239 434	11 481 570	86.7%	1 602 367	12.2%	155 497

#### ENVIRONMENTAL DIRECTIVES AND INTERNATIONAL CONVENTIONS

Title	Description	Budget 2023 (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	1 996 497	80 222	2 076 719	2 050 056	98.7%	2 076 719	2 035 573	98.0%	14 483	0.7%	26 663
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	614 433	-1 838	612 595	611 344	99.8%	612 595	517 507	84.5%	93 837	15.3%	1 251

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	AND INTERNATIONAL CONVENTIONS	5 047 743	85 000	5 132 743	5 081 720	99.0%	5 132 743	3 384 946	65.9%	1 696 774	33.4%	51 023
B0-5	OPERATIONAL EXPENDITURE - ENVIRONMENTAL DIRECTIVES	2 436 813	6 616	2 443 429	2 420 319	99.1%	2 443 429	831 865	34.0%	1 588 454	65.6%	23 110

Budget line		Available commitment appropriations	Commitments made	%	Available payment appropriations	Payments made	%
B3-111	Substance evaluation and Rapporteurs (Multiannual)	910 363	909 694	99.93%	771 664	771 618	99.99%
B3-801	Cooperation with international organisations for IT programs	610 000	609 982	c.100%	699 920	699 894	c.100%
Total		1 520 363	1 519 676	c.100%	1 471 584	1 471 512	c.100%

Out of the total available commitment appropriations of EUR 2 672 838, the amount of EUR 1 152 475 is stemming from commitments made in earlier financial years. The available commitment appropriations for 2023 totalled EUR 1 520 363 out of which EUR 1 519 676 (c.100%) were committed.

# Budget 2023: 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	59 171	38 827	66%	59 171	38 827	66%	20 345	20 345
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	C4	6 176	0	0%	6 176	0	0%	6 176	6 176
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	C4	32 839	3 362	10%	32 839	1 939	6%	29 477	30 900
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	C4	606	453	75%	606	261	43%	153	345
B0-5	OPERATIONAL EXPENDITURE - ENV	C4	159	159	100%	159	92	58%	0	67
		C4	98 951	42 801	43%	98 951	41 119	42%	56 150	57 832
Title	Description	FS	Commitments Appropriations	Commitments Established	Com %	Payments Appropriations	Payments Executed	Pay%	Carried over commitment appropriations	Carried over payment appropriations

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A-1	STAFF	C5	28 728	28 728	100%	28 728	28 728	100%	0	0
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	C5	11 299	11 299	100%	11 299	11 299	100%	0	0
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	C5	33 043	21 384	65%	33 043	19 769	60%	0	1 615
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	C5	852	852	100%	852	852	100%	0	0
		C5	73 922	62 263	84%	73 922	60 648	82%	0	1 615
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	644 465	189 377	29%	644 465	171 977	27%	455 088	472 488
B6-010	EUON	R0	1 544 900	855 341	55%	1 544 900	648 055	42%	689 559	896 844
B6-011	EUCLEF	R0	3 338 602	1 532 088	46%	3 338 602	1 012 758	30%	1 806 514	2 325 845
B6-020	Occupational exposure limits	R0	1 591 105	1 030 206	65%	1 591 105	889 623	56%	560 899	701 483
B6-021	Further development of IUCLID (w/ third parties)	R0	2 517 055	2 114 362	84%	2 517 055	1 748 316	69%	402 693	768 739
		R0	9 636 128	5 721 375	59%	9 636 128	4 470 729	46%	3 914 753	5 165 399

# Budget 2023: Implementation of the appropriations carried forward from previous year (C8) Per Title (EUR)

Title	Description	Carried Forward from 2022	Paid	Cancelled	% Cancelled
A-1	STAFF	196 707	192 366	4 342	2%
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	1 761 736	1 723 707	38 029	2%
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	10 147 612	10 040 092	107 521	1%
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	1 929 864	1 922 169	7 696	0%
B0-5	OPERATIONAL EXPENDITURE - ENVIRONMENTAL DIRECTIVES AND INTERNATIONAL CONVENTIONS	1 519 288	1 513 877	5 411	0%
		15 555 208	15 392 209	162 999	1%

# Appendix III – Organisational chart



Ver 5.0/2023

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

# Last establishment plan adopted

	Establishmen	nt plan in vote	d EU Budg	jet 2023	Po	sts filled 31 I	December 20	023*
Category and		ТА				1	Α	
grade	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	4			4
AD 12	12	2		14	9	1		10
AD 11	30	1		31	18			18
AD 10	41	5		46	42	5		47
AD 9	60	10	1	71	41	7	1	49
AD 8	52	9		61	64	7		71
AD 7	53	9	1	63	44	7	1	52
AD 6	27	5	3	35	47	9		56
AD 5	16	1		17	27	6	3	36
Total AD	310	43	5	358	298	42	5	345
AST 11				0				0
AST 10				0				0
AST 9	3			3				0
AST 8	8			8	5			5
AST 7	10	1	2	13	12			12
AST 6	18	1		19	16	1		17
AST 5	26	3	2	31	22	2	1	25
AST 4	16	3	2	21	8	2	3	13
AST 3	10	1		11	11	3		14
AST 2	3			3	18	1	2	21
AST 1				0				0
Total AST	94	9	6	109	92	9	6	107
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	390	51	11	452

			СА		СА					
		estimated r	need of F1	Es 2023	рс	posts filled 31 December 2023 <sup>22</sup>				
	REACH/ CLP	Biocides	ENV	Other tasks	TOTAL	REACH/ CLP	Biocides	ENV	Other tasks	TOTAL
CA FG IV	27	7	8	13	55	20	5	6	10	41
CA FG III	53	6	2	1	62	59	6	4	4	73
CA FG II	17	2	0	0.5	19.5	16	2			18
CA FG I					0					0

<sup>22</sup> Under external recruitment (included in figures): REACH: 2 TAs and 2 CAs; BIOCIDES: 1CA

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TOTAL	97	15	10	14.5	136.5	95	13	10	14	132
	-			-			-	-		

Percentage of posts filled on 31 December 2023								
	REACH/ CLP	Biocides	ENV					
TA posts	96.53%	98.08%	100.00%					
CA posts	97.94%	86.67%	100.00%					

# Geographical and gender balance (as per 31 December 2023)<sup>23</sup>

				ТА			СА		OVERALL	
	N	lationality	Male	Female	Total	Male	Female	Total	Sum	%
1	AT	Austrian	2	4	6	0	0	0	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	3	3	1	0	1	4	0.8%
6	DE	German	16	9	25	1	0	1	26	4.5%
7	DK	Danish	1	1	2	0	0	0	2	0.4%
8	EE	Estonian	0	6	6	1	0	1	7	1.2%
9	ES	Spanish	16	12	28	6	5	11	39	6.7%
10	FI	Finnish	59	85	144	15	30	45	189	32.6%
11	FR	French	20	15	35	2	6	8	43	7.4%
12	GR	Greek	14	6	20	6	6	12	32	5.5%
13	HR	Croatian	0	0	0	0	1	1	1	0.2%
14	HU	Hungarian	2	6	8	0	4	4	12	2.1%
15	IE	Irish	10	7	17	0	1	1	18	3.1%
16	IS	Iceland	0	0	0	0	0	0	0	0.0%
17	IT	Italian	25	18	43	5	2	7	50	8.6%
18	LI	Liechtenstein	1	0	1	0	0	0	1	0.2%
19	LT	Lithuanian	1	6	7	0	0	0	7	1.2%
20	LU	Luxembourger	0	0	0	0	0	0	0	0.0%
21	LV	Latvian	1	5	6	1	1	2	8	1.4%
22	MT	Maltese	0	3	3	0	0	0	3	0.5%
23	NL	Dutch	9	5	14	2	1	3	17	2.9%
24	NO	Norwegian	0	1	1	0	0	0	1	0.2%
25	PL	Polish	8	9	17	1	3	4	21	3.6%
26	PT	Portuguese	5	7	12	0	2	2	14	2.4%
27	RO	Romanian	2	5	7	3	7	10	17	2.9%
28	SE	Swedish	3	1	4	1	0	1	5	0.9%
29	SI	Slovenian	3	3	6	1	1	2	8	1.4%
30	SK	Slovakian	1	2	3	0	2	2	5	0.9%
31	Other	Other	0	0	0	0	0	0	0	0.0%
		TOTAL	212	238	450	52	77	129	579	100.0%

<sup>&</sup>lt;sup>23</sup> Data in the table includes statutory staff in place on the indicated date. Posts under recruitment are not included.

	NATIONALITY	MALE	FEMALE	TOTAL	%
BE	Belgian	2	0	2	6.1%
DE	German	2	0	2	6.1%
ES	Spanish	2	1	3	9.1%
FI	Finnish	3	4	7	21.2%
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	2	0	2	6.1%
MT	Maltese	0	1	1	3.0%
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	24	9	33	100%

# Middle and senior management – gender and nationality overview<sup>24</sup>

# **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	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	Operations/Administration

<sup>&</sup>lt;sup>24</sup> Data in the table includes statutory staff in place on the indicated date. Posts under recruitment are not included.

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Key functions	Type of contract (official, TA or CA)	Function group, grade of recruitment (or bottom of grade bracket if published with such	Indication whether the function is dedicated to administrative support or operations subject to definitions used in screening methodology		
		profile			
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		
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	AD 10	Administration		

Key functions	Type of contract (official, TA or CA)	Function group, grade of recruitment (or bottom of grade bracket if published with such	Indication whether the function is dedicated to administrative support or operations subject to definitions used in screening methodology
	years + indefinite		

### Benchmarking against previous results

ECHA undertook the benchmarking (job screening) exercise in 2023, in accordance with the Commission's requirements. The 2023 results indicate an increase of 0.3% in the percentage of administrative support and coordination staff, an increase of 0.2% in the percentage of the operational staff and a decrease of 0.5% in the percentage of neutral staff in comparison to 2022.

Job Type (sub) category	2022	2023	
Administrative support and Coordination	14.5	14.8	
Administrative Support	11.7	12.1	
Coordination	2.8	2.8	
Operational	81.4	81.6	
Top level Operational Coordination	2.6	2.5	
Programme management and Implementation	57	56.1	
Evaluation & Impact assessment	3.4	3.2	
General operational	operational 18.6		
Neutral	4.1	3.6	
Finance/ Control	4.0	3.6	
Linguistics	0.1	0.0	

# Appendix V – Human and financial resources by activity

WP activity	Actual consumption of the human resources	Executed budget 2023		
1.1 Dossier preparation	29	7 595 644		
1.2 Dossier submission and processing	34	8 375 567		
1.3 Identification and prioritisation	55	12 739 439		
1.4 Evaluation	91	16 617 743		
1.5 Authorisation	26	5 549 010		
1.6 Restrictions	29	6 137 817		
1.7 Classification and labelling	33	6 399 609		
1.8 Safe and sustainable use of chemicals	1	202 710		
1.9 Data management and dissemination	23	6 800 546		
1.10 Promotion of alternatives to animal testing	6	2 454 907		
2. Biocides	56	10 213 821		
3.1 Prior Informed Consent	7	1 598 449		
3.2 Persistent organic pollutants	1	218 104		
3.3 Waste Framework Directive	4	968 043		
3.4 Drinking Water Directive	7	1 263 755		
3.5 8th Environmental Action Programme	1	313 731		
4.1 EU Observatory for Nanomaterials	3	855 341		
4.2 EU Chemicals Legislation Finder	1	1 532 088		
4.3 Support to Occupational health legislation	6	1 030 206		
4.4 Instrument for Pre-Accession assistance (IPA)	1	189 377		
4.5 Support to other legislation	1			
4.6 IUCLID for EFSA	4	2 114 362		
4.7 Partnership for the Assessment of Risk from Chemicals	2			
Governance and enablers	169	29 726 767		
Overall TOTAL	590	122 897 036		

# 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		2022	2023
Grant agree	ements							
1. IPA	20.12.2022	675 103	42 months	Commission DG NEAR		Amount Number of CA Number of	1	1.5
						SNEs Amount Number	-	-
						of CA Number	1	1.5 -
Contributio	n agreements					of SNEs		
contributio						Amount		
1. EUCLEF	10.12.2021	0.12.2021 5 829 200	5 years (2021-	Commission DG GROW		Number of CA	0	0
			2025)			Number of SNEs Amount	-	-
2. EUON	09.12.2021	3 066 000	5 years (2021-	Commission DG GROW		Number of CA	3	3
			2025)			Number of SNEs Amount	-	-
						Number of CA	3	3
						Number of SNEs	-	-
Service-leve	el agreement	S						
1. IUCLID for	26.03.2021	Annual fee of 784 712 plus	N/A	N/A EFSA		Amount Number of CA	4	4
EFSA		project cost					Number of SNEs Amount	-
	195 000 per opinion	18-24 months	Commission		Number of CA	4	4	
			per case			Number of SNEs	-	-
Total servic	e-level agree	ments				Amount Number of CA	8	8
						Number of SNEs	-	-
TOTAL (con	tribution agr	eements and S	LAs)			Amount Number of CA	12	12.5
						Number of SNEs	-	-

# Annex VII - Environment management

#### Context of the Agency and its environmental management strategy

ECHA implements the EU's chemicals legislation to protect health and the environment. Our work also contributes to a well-functioning internal market, innovation and the competitiveness of Europe's chemicals industry.

Through ECHA's work, better knowledge and regulation of harmful chemicals helps to protect workers, consumers and the environment, makes recycling easier, and encourages industry to develop safer alternatives.

ECHA has an environmental policy which commits ECHA to continually improve its environmental performance, and ECHA has pledged to be climate-neutral by 2030.

#### Overview of the Agency's environmental management system

ECHA has put in place a quality and environmental management system, aligned to its strategy, which commits to incorporating sustainability measures within the internal follow-up of actions and reporting.

To achieve climate neutrality, ECHA has set objectives, targets and actions which are described its environmental work programme which was renewed in 2023 to cover the period up to 2025.

In 2023, ECHA was recertified under ISO 14001:2015 standard (Environmental Management System) and ECHA's 2022 Environmental Statement was successfully registered under EMAS.

#### Environmental aspects, indicators and targets



#### Environmental Objectives - Target emissions (t CO<sub>2</sub>)



#### **Electricity Consumption**









# Actions to improve and communicate environmental performance

In support of the ISO 14001:2015 environmental re-certification and EMAS registration, which includes additional planning and reporting on ECHA's environmental performance, the Agency has established a dedicated team for Environmental Compliance and Sustainability whose role is to facilitate the implementation the actions identified in ECHA's Environmental Work Programme.

2023 was the first year of ECHA's updated multi-annual Environmental Work Programme (2023-2025) which maintained the previous objectives and introduced new actions and targets. In 2023 ECHA:

- reduced CO2 emissions from travel (staff missions)
- strengthened environmental and sustainability standards into ECHA procurement (including the canteen services).
- adapted the programming in building management systems and improving automation of technology.
- promoted over 30 staff information campaigns and environmental initiatives at local, national, EU and international levels of interest.
- reduced waste volume and the amount of landfill waste by leasing ICT equipment with sustainability requirements in the contract and recycling used equipment (mobile phones for Ukraine).
- reviewed the scope of ECHA's CO2 footprint to ensure a comprehensive overview and to avoid gaps and reputational damage which will be included in future environmental reports.
- took preparatory actions to implement a pilot project on carbon capture to begin CO2 offsetting under the forthcoming EU carbon certification Regulation.
- developed and implemented an Internal Audit Methodology for its Environmental Management System in cooperation with the European Environment Agency.

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