

# Annual Report 2023 Executive Summary



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## European Chemicals Agency

P.O. Box 400, FI-00121 Helsinki, Finland

## 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 high-quality 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.

EUROPEAN CHEMICALS AGENCY  
P.O. BOX 400, FI-00121 HELSINKI, FINLAND  
ECHA.EUROPA.EU