ECHA
EUROPEAN CHEMICALS AGENCY

Annual Report 2021

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Management Board analysis and assessment

The Programming Document 2021-2024[1] sets out the objectives for the work of the European Chemicals Agency (ECHA) in line with and implementing its Strategic Plan for this four-year period, accompanied by the resource planning until 2024, and the Work Programme 2021.

This report complies with the reporting requirements of the REACH Regulation (General Report)[2] as well as those of the ECHA Financial Regulation (Consolidated Annual Activity Report)[3].

Analysis of the Management Board

The Management Board welcomes the Annual Report 2021, which provides a comprehensive account of the activities carried out by ECHA during the year, the performance of the Agency against the expected inputs, outputs, outcomes and impact defined in the Work Programme 2021. It also represents a thorough overview of the evolution of its budget, staffing, management, and its internal management system strategy and framework.

To provide guidance, steer and recommendations, we analysed all parts of the report, including the activities carried out, the achievements, financial information, results of audits, ex-post evaluations and 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

In our view, the present report reflects the key deliverables of the Agency in 2021 and demonstrates that the objectives set for the three strategic priorities were met. We acknowledge that not all planned activities were delivered according to the initial ambition level, which is reasonable considering the complexity of ECHA's operations. We are satisfied by the progress achieved – under the exceptional circumstances of the COVID-19 pandemic, which saw mostly remote working conditions for staff, Member State representatives and stakeholders.

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

ECHA realised 194 out of the 214 actions and outputs set in the Work Programme 2021. The two not met actions and outputs relate to resource availability in the context of CSS support. The 18 ongoing or partially met items relate to the impacts of the Covid-19 pandemic, to late or less than foreseen input from partners and are planned to progress in 2022.

In assessing[4] the Consolidated Annual Activity Report of the Authorising Officer for 2021, we:

- Welcome the input provided by the Agency for the implementation of the Chemicals Strategy for Sustainability (CSS), which was appreciated by the Commission. This resource investment is considered appropriate to support a milestone policy initiative and is in line with ECHA's scientific-technical capacity.
- Appreciate the work by the Agency in progressing with the Integrated Regulatory Strategy and allocating substances, increasingly in groups, to either of the pools of data generation, risk management or no further action based on current knowledge. This allowed continuing the mapping of the substances registered and concluding on all lower tonnage substances that are structurally similar to the screened high tonnage ones, as well as accelerating the assessment of substances of concern and propose risk management where needed.

It is notable that the progress made in 2021 by implementing the work programme was only possible with the

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

remarkable commitment and dedication of all actors involved under continued remote working conditions.

The Board makes the following observations[5]:

Management

We welcome the implementation of the 15 recommendations by the Management Board provided for 2021 as part of the assessment of the 2020 Annual Report.

Budgetary and financial management

The Board appreciates the Secretariat for its efforts and success in managing the decreasing and fluctuating fee income for REACH/CLP, increasingly relying on the balancing EU subsidy, and making the necessary adjustments to the expenditure side, considering the uncertain planning parameters due to Covid-19.

We note that the Agency's initial budget for 2021 amounted to c. EUR 113.1 million and was reduced during the year by c. EUR 2.0 million to c. EUR 111.1 million, with a final implementation rate of 98 %, for the appropriations for the financial year.

The Board also notes the further improvement in implementation of the appropriations carried over from the previous year, with the cancellation of carry-overs amounting to EUR 268 825, representing 2 % of the total amount carried over.

Human resources management

The Board appreciates the efforts by the Secretariat and ECHA staff in implementing the work programme and responding to the increased need for technical-scientific input in the preparation of the CSS. This demonstrates the resilience of the Agency, amidst the continuation of the challenging circumstances caused by the COVID-19 pandemic.

The Board is satisfied that ECHA has been recognised as one of the most inspiring workplaces in Finland, and that the health and wellbeing of staff was addressed as a matter of priority throughout the year. We encourage the Agency to continue implementing the reviewed HR strategy, promoting a culture of high performance, continuous improvement and agility.

We also note that the Agency has again achieved a high occupancy rate of 97 % for temporary agents and contract agents, securing the availability of competent staff to fulfil its mandate.

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

The Board is satisfied with the level and frequency of information and assurance provided by the Internal Audit Capability (IAC) on audits and how the Secretariat followed up on the ex-post evaluation.

We take note of the positive opinion from the European Court of Auditors (ECA) regarding the 2020 annual accounts with no reservation or observation and with the closure of pending actions.

We are pleased with the decision of the European Parliament, as the Discharge Authority, to grant the discharge in respect to ECHA's 2019 budget, including the decision on the closure of the accounts related to 2019. We take note of the Secretariat's reply to the Discharge Authority's observations and encourage to implement the recommendations in due course.

The Board is satisfied with the assurance provided by the Internal Audit Service of the Commission on the independence of the internal audit activity.

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

Internal control framework and Integrated Management System

The Board notes that the internal control framework functions well as indicated by the internal controls assessment, and weaknesses identified are addressed promptly without compromising the internal control system's effectiveness.

We are also satisfied with the renewal of ISO 9001:2015 certificate.

Risk management

The Board notes that appropriate measures are in place to identify, monitor and manage risks threatening the achievement of ECHA's objectives. Notable and of concern are the risks related to the volatility of the fee income and to the availability of resources in Member States to contribute to ECHA's activities.

We appreciate the continuous dialogue between the Board and the Secretariat on risk related matters and that the Secretariat regularly signals significant risks and control issues, including as part of the quarterly reporting, as well as the updates to the risk register.

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 Agency's Executive Director.

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

Recommendations for the Secretariat for 2022

Based on our assessment, the following Management Board requests require particular emphasis in 2022, without prejudice to the implementation of the Programming Document 2022-2025:

1. Continue making progress towards achieving the objectives set in the ECHA Strategic Plan 2019-2023, following the guidance provided by the Management Board as outcome of the review of the strategy[6].

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

3. Focus ECHA's scientific technical input to the Commission in the implementation of the CSS on ECHA's core competences, experience and data, aiming for maximum impact within the availability of resources. Maintain the transparency towards the Management Board on progress made in relation to CSS tasks and in particular on possible new tasks for the Agency.

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

5. In the context of the post-pandemic new normal and within the applicable regulations, develop new, hybrid ways of working for staff and meeting arrangements for ECHA bodies. Consider ECHA's climate neutrality ambition and the continued ability of ECHA bodies to deliver and staff commitment and wellbeing.

6. Maintain the investments in IT and enhance cyber security as necessary in light of emerging threats. Inform the Management Board of the progress made, as well as the evolution of the main risks.

7. Work towards stabilising the positive trend in the acceleration of the Biocides Review Programme. The Management Board notes with satisfaction the planned work in this respect for the years to come and asks the Secretariat to provide regular updates on the progress made and any issues arising.

8. Provide support to the Management Board in the process of appointing the future Executive Director. Facilitate

6 MB/30/2021 final.

The Management Board considers that ECHA delivered on its work programme and provided valuable support to the Commission on the CSS. We thank ECHA staff for all their extraordinary efforts over the course of this exceptional and challenging year.

Paul KRAJNIK

Chair of the Management Board

the transition to a new senior management team, in particular the new Executive Director and rely on the Management Board's support as necessary, in order to ensure continuity of business.

Conclusion

In assessing the Annual Report 2021, the Management Board concludes that the overall performance of ECHA is in line with the objectives included in the Agency's Programming Document 2021-2024.

Acknowledgments

The members of the Management Board thank ECHA staff for all their extraordinary efforts over the course of this exceptional and challenging year. The Management Board considers that it constitutes an outstanding achievement that ECHA delivered on its work programme and provided valuable support to the Commission in the implementation of the CSS. The Management board remains equally grateful to the members of all ECHA bodies, as well as ECHA's partners, in particular Member States, for assisting ECHA in the delivery of its work programme.

Foreword

Bjorn HANSEN

Executive Director

In 2021, some of the uncertainties from previous years began to fade.

Brexit became reality and we revoked 3 000 void registrations held by UK companies. We gained clarity on our future financing and staffing, with the Commission agreeing to create a more stable financial basis for ECHA. And we also started mapping out possible tasks where ECHA could support the Commission with their Chemicals Strategy for Sustainability.

What remained, however, through 2021 was the strain caused by COVID-19. Although the pandemic has been draining, we achieved the majority of our Work Programme milestones. This is in large part due to the admirable drive and determination shown by our staff, and they rightfully deserve praise for that.

Throughout the year, we reorganised our work and staff, and transformed our management team. These changes helped to make the Agency more agile and allowed us to prioritise activities for identifying and managing risks of chemicals of concern. And there have been some noticeable successes worth highlighting.

We continued our shift away from assessing individual substances and published the first assessments of regulatory needs for groups of substances at the end of the year. ECHA and Member States have been assessing substances in groups in an effort to speed up regulatory action on chemicals of concern. The publication of these group assessments is a huge step that puts us on track to better understanding how the chemicals landscape will look in the EU in 2027, and what challenges the future versions of REACH and CLP will need to solve.

The information being gathered through the authorisation process should improve with changes made to the application and opinion formats. And we have continued to focus on restricting chemicals causing concern – with the proposed restriction of lead in ammunition for hunting, shooting and fishing in focus in 2021.

For biocides, we have started to see an increase in the rate at which active substances are reviewed, albeit still at a relatively modest level. We are hopeful that this pace will continue to accelerate.

In June, we published our five-year report on how REACH and CLP have been operating. This gave us the chance to harvest our learnings and provide our input to the Commission's policy development as they design REACH and CLP 2.0. While the report showed that REACH and CLP have been largely successful, a rose never comes without thorns.

There are tasks that we believe could have synergies with our existing work. But, so far, almost all new tasks we have received have one way or another not made the best use of our competences. At the same time, they are diverting a lot of time away from our core activities. Therefore, it is important that we are included in discussions early on to ensure our efforts can have a real impact.

We have invested significant resources in boosting our compliance check activities and to an extent we have been successful in identifying non-compliant registration and following up with companies that need to improve their data. Despite this, around 40 % remain incompliant. After requesting further information and checking if it is coming in, if still not submitted we send these cases to the Member States for enforcement. When Member States act, the missing information is, ultimately submitted to ECHA in around 92 % of cases. However, enforcement takes time and cases could be resolved more quickly if ECHA were given the legislative means to revoke registration numbers from companies that do not comply.

We have a robust and secure IT system in place. However, when it comes to developing new IT systems, we face challenges. The scale of our operations is so large to maintain that we are left with little capacity to develop. The only way to resolve this is to reduce the number of products we maintain. Otherwise, with current staffing levels, the pace of development work could decrease. The website issues we have experienced through the year are a symptom of this.

With all of this said, what is clear to me is that we are operating at our absolute maximum capacity with the human resources we have available. Any new tasks we receive need to be thought through, need to have synergies with existing activities and need to be resourced appropriately – not financially, but in a way that guarantees we would have enough staff to dedicate to such work.

My words here though are simply my reflection for you. The report itself covers all of the outputs from the Agency in much more detail. So, take a moment to look through and I hope you enjoy reading it.

Bjorn Hansen

Executive Director

Executive Summary

This Executive Summary provides the conditions and challenges faced by the Agency in 2021, together with the key achievements of the year. These are described for each of its three strategic priorities, as well as the corresponding governance and enablers, framing the work of ECHA with a view to its contribution to EU priorities.

In the second year of the pandemic, ECHA achieved its work programme objectives thanks to the agility of staff and investments in our solid infrastructure. It has been encouraging to see how well ECHA's committees and bodies have adapted to the remote setting and have been able to deliver under these conditions.

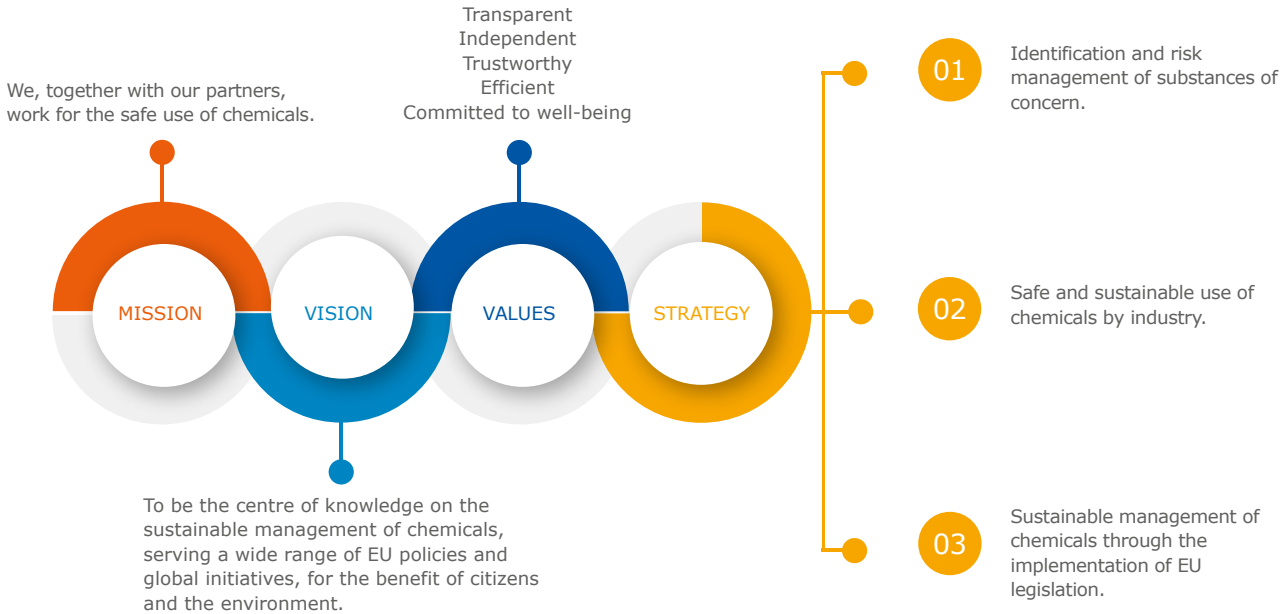
Under the umbrella of the EU Green Deal, the Commission's Chemicals Strategy for Sustainability (CSS) is expected to become a game changer for chemicals management in Europe in the next decades. To support the Commission, we established working methods and agreed where and how ECHA's expertise best serves them in the reviews of REACH and CLP. In 2021, with the implementation of its Work Programme, ECHA also contributed to the Commission's preparatory work and many other initiatives under the CSS and Green Deal. For instance, ECHA gave its views on the possible amendment of registration requirements und REACH and discussed with the Commission how CLH dossiers could be prioritised and developed in ECHA under a revised CLP Regulation.

ECHA gained further experience with on-boarding new tasks and identifying how competences and resources can be efficiently allocated across different activities. Our involvement can bring broader regulatory synergies while the impact on resources and other parts of the Agency have to be continuously calibrated. The Agency has to keep on delivering on its core mandate, that is to achieve high quality regulatory outputs, and to invest smartly into getting ready for changes resulting from policy developments.

As an important input to the Commission's review of the EU's chemicals legislation, we published our five-year report on the operations of REACH and CLP.[7] This retrospective reflection illustrates the impact that legislation has had on people's health, the environment, internal market, competitiveness, innovation and promoting alternatives to animal testing. The lessons we have learned will serve to provide more tailor-made input for the ongoing development of possible changes to the legislation and as compass for ourselves to continue working to protect health and the environment from harmful chemicals.

The Management Board of ECHA reviewed the strategic plan 2019-2023. While confirming its validity for the remaining time, it gave steer to the Agency in how the strategic priorities should be understood and translated into action. With this as a guide, ECHA is well prepared to move ahead.

The Agency in brief:



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

Strategic priority 1: Identification and risk management of substances of concern

This strategic priority represents an important part of ECHA's core mandate. The majority of ECHA's legally mandated operational work in managing chemicals under the REACH, CLP, BPR, PIC and POPs regulations aims to identify substances of concern and manage their risks.

The impact of this work is illustrated by the progress ECHA and Member States have made in identifying new substances of potential concern. We have become more effective and efficient in this by focusing on groups of substances – but inherently assessing groups of substances isa complex task.

We assess groups of substances and assign them to pools for further data generation, risk management and those that currently require no further action. The number of not yet assigned substances decreased from 18 341 to 17 126 in 2021, and as such we have better clarity on which risk management routes (if any) are planned and for which substances further data on properties and hazards is needed. This gives companies better predictability on the regulatory actions that authorities plan to take.

ECHA issued more than 440 decisions on dossier evaluation in 2021, of which 37 were adopted with the Member State Committee's involvement. The Agency also obtained hazard data for more than 200 substances on decisions taken earlier, although the 40 % non-compliance rate after these information requests is still high. These cases have been sent to the Member States for further enforcement actions.

On average, when Member States enforce ECHA dossier evaluation decisions, the missing information is ultimately submitted to ECHA in around 92 % of cases. Regardless, this is still late and after the legal deadlines.

Furthermore, ECHA published the first assessments of regulatory needs for groups of substances, evidence of the Agency's continued shift away from assessing individual substances, seeking synergies and increasing efficiencies. Group assessments make it easier for companies to predict what actions regulators are planning and help them to prepare strategies to replace harmful chemicals with safer alternatives, where relevant. The Agency assessed several important groups of substances which have received particular attention over the past years due to their extensive use in consumer products, such as bisphenols and phthalates.

Key achievements under strategic priority 1

- ECHA assessed the **regulatory needs of 1 900 substances** and shifted to dealing with them in groups rather than individually. 15 % of the 1 900 were substances registered above 100 tonnes per year. From this, we identified 300 that **require further risk management measures, 800 that need more data** to be generated and 800 **that currently do not require further action**. The regulatory needs of 1 300 substances registered above 100 tonnes per year still need to be assessed and have not yet been assigned. But we remain on target to conclude for all registered substances by 2027.
- To increase transparency on the regulatory actions being pursued and the progress made on groups of substances, ECHA published the **first assessments of regulatory needs** for 19 groups covering more than 450 substances at the end of 2021.
- The results of an EU-wide enforcement project of products sold online shows that **three out of four inspected products breach EU chemicals laws**.
- The **extension of the technical completeness** checks carried out for each new and updated registration now includes checking the content of **chemical safety reports**. This enables substances to be better prioritised for regulatory action by authorities, enhances the dissemination of use information and improves the starting point for appropriate supply chain communication.
- ECHA continued its efforts to **phase out animal testing** in Europe to the extent possible under the existing regulatory framework and support industry, authorities and institutions in making progress towards this goal. In this respect, ECHA updated its comprehensive guidance for companies on how to reliably combine different sources of non-animal data when assessing **skin sensitisation** of chemicals. The advice outlines how to use computer simulation tools such as the QSAR Toolbox to assess skin sensitisation and protect people from skin allergies without testing on animals.

- We conducted a total of **371 compliance checks** covering more than 2 100 registrations and addressing **341 unique substances**. This is a slight increase compared to 2020. For the vast majority of compliance checks, ECHA verified, as a minimum, the relevant higher-tier hazard endpoints for substances or groups of substances of potential concern. From this total, 300 were full compliance checks addressing all relevant endpoints for 288 unique substances of potential concern. 71 were targeted compliance checks. They resulted in 280 draft decisions being sent to companies, requesting more data to clarify long-term effects on human health or the environment.
- For the 363 **follow-ups** to dossier evaluation performed in 2021, around **40 %** of dossiers remained **incompliant**. These have been sent to the Member States for further enforcement.
- ECHA received **535 registrations covering 143 nanoforms** by the end of 2021. The exact number of nanomaterials on the EU market is unknown and there is reason to believe this figure ought to be higher. But there may be differences in tonnage that explain the discrepancy between the number of registered nanoforms, and the number of nanomaterials reported in the EU Observatory for Nanomaterials (EUON).
- In line with actions under the Commission and ECHA **REACH evaluation joint action plan**, we continued to support industry initiatives that help companies review their chemical safety data, for instance by defining a strategy for filling data gaps when assessing the environmental impact of petroleum substances.
- In preparation for identifying and proposing **new persistent organic pollutants**, ECHA provided the draft evaluation and the draft risk profile for two substances: **methoxychlor** is an organochlorine pesticide used as an insecticide, and **UV-238** is used as a UV stabiliser found in plastic shrink films and outdoor furniture.
- Under **authorisation**, ECHA's Committees for Risk Assessment (**RAC**) and Socio-Economic Analysis (**SEAC**) adopted 18 opinions for substances that have **endocrine-disrupting properties**, and another 31 opinions for substances with other properties. 12 substitution plans were also evaluated.
- Regarding **harmonised classification and labelling dossiers**, RAC processed **54 opinions**, and issued opinions on the evaluation of occupational exposure limits (**OELs**) for **asbestos**, and for **cadmium** and its inorganic compounds.
- Work on **glyphosate** re-commenced in coordination with **EFSA** where RAC will provide an opinion on the proposal for harmonised classification and labelling, and EFSA will develop its opinion on the authorisation of the use as a pesticide.
- Improvements to **applications for authorisation** were implemented, with an improved format of opinions on applications that provides clearer input to the Commission on scientific elements. The authorisation application format was also adapted, which should help to get better information into the process.
- Publication of a **meta-analysis** of the socio-economic impacts of **authorisation** based on data from 2010 and 2020 indicated that the authorisation system has inbuilt dynamics that inherently promote substitution.
- ECHA collaborated with the REACH **exposure expert group** (REEG), a community of Member State experts, on the levels of use and exposure information needed to swiftly move hazardous substances beyond screening into various risk management processes.
- Following agreement at the Member State Committee (**MSC**), **12 substances were added to the Candidate List** of substances of very high concern, mostly because they are toxic for reproduction, carcinogenic, respiratory sensitisers or endocrine disruptors.
- A restriction proposal was issued on **lead in ammunition** for hunting, outdoor sports shooting and fishing.
- Concerning **restriction proposals**, RAC and SEAC provided two opinions, on **PFHxA** (a subgroup of PFAS) and on the proposal to restrict formaldehyde, PAHs, dioxins, furans and PCBs in single-use **baby diapers**.
- Publication of a **study on costs and benefits of restrictions**[8] that estimated that restricting the manufacture and use of chemicals that pose a risk would result in **health benefits amounting to EUR 2.1 billion** each year.

8 https://echa.europa.eu/documents/10162/17228/costs_benefits_reach_restrictions_2020_en.pdf

- Investment in actions intended to accelerate the **review programme** under the Biocidal Products Regulation has started to pay off, with **18 competent authority reports** evaluating active substances received during the year, including Review Programme, new active substances, renewal of approval and backlog cases that re-start a peer-review phase – almost double the amount received in 2020.
- The Biocidal Products Committee (**BPC**) issued **18 opinions on active substance approvals** in 2021, compared to **15** last year. The number of BPC opinions on Union authorisation also increased to 15, compared to 9 in 2020.

Strategic priority 2: Safe and sustainable use of chemicals by industry

The Agency calibrated its engagement on this priority following the decision to prioritise our focus on legally required tasks under strategic priority 1. As a result, we targeted our efforts on supporting companies to carry out their chemical safety assessments and improving Chesar for this purpose.

Functioning communication up and down in the supply chain on hazards and risks, and, first and foremost, appropriate safety assessments are essential elements of risk management by economic operators. ECHA's support helps them to comply with their legislative obligations that are challenging to achieve through other means such as formal decision making or enforcement.

Due to the priority setting for strategic priority 1 in 2021, the impact remains limited to targeted support.

Key achievements under strategic priority 2

- **Two new versions of Chesar** published, upgrading the tool with new functionalities to better support companies in carrying out their chemical safety assessments.
- The obligation to notify **hazardous mixtures for professional and consumer use** started in 2021. Notifications must be made in a harmonised format defined under CLP, while labels must also include a unique formula identifier (**UFI**) – a unique code that allows **poison centres** to precisely identify the composition of the mixture and the product involved in a poisoning incident. ECHA processed a large number of notifications and made them available to the national authorities. This helps poison centres give quick and accurate advice when someone is accidentally poisoned.
- ECHA has collaborated with the **European Integrated Pollution Prevention and Control Bureau** (EIPPCB), providing REACH data and chemicals management advice to enhance the implementation of the Industrial Emissions Directive.

Strategic priority 3: Sustainable management of chemicals through the implementation of EU legislation

Implementing strategic priority 3 impacted ECHA in two ways. Firstly, the Agency has gained further experience in onboarding new tasks, supporting the legislator in preparing new or revised legislation, and how to run corresponding processes where ECHA has a role in such new tasks. ECHA staff has a very good understanding, based on concrete experience, of what it takes to integrate new regulatory work into the organisation's portfolio. Onboarding activities have brought synergies and economies of scale to the Agency in some cases while in other cases it became clear that the intended synergy effect could not materialise.

Secondly, the Agency engaged successfully in implementing new tasks. Here, the main challenge has been to provide the necessary resources during the pre-onboarding phase, when the ultimate scope of the work is not yet defined, and dedicated resources are not yet available. ECHA is able to deploy experienced staff to this conceptualisation work, with the downside that this staff is then missing from initial activities and process work, and then this work needs to be compensated.

With the Commission's Chemicals Strategy for Sustainability, the demands on ECHA have increased, with the Agency supporting the definition of possible new tasks and performing early analyses on process conceptualisation and resource predictions.

We continued trustful cooperation with other agencies on topics of common interest, such as 'one substance, one assessment', the development of IUCLID for the European Food Safety Authority's (EFSA) evaluation of active substances in plant protection products and exchanging information and data with the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in the context of developing an early warning system for new psychoactive substances.

With the launch of the SCIP database collecting notifications on substances of concern in products, ECHA is also providing another tool for economic operators, consumers and authorities to help them understand where harmful substances are used, increasing ambitions to replace them with safer alternatives.

Key achievements under strategic priority 3

- *Ad hoc* support to the Commission in the early phase of implementing the **Chemicals Strategy for Sustainability** and coordination of tasks involving ECHA's competences and experience.
- Launch of the **SCIP database** for substances of very high concern (SVHCs) contained in products. This is useful for consumers who want more information about the products they buy and will also help to improve the treatment of waste, particularly recycling processes. Around 6 800 companies across the EU successfully submitted more than 15 million notifications to the database.
- Further development and promotion of **IUCLID** as a widely accepted format for information on chemicals across the world. Collection and use of data in the same format in the EU and internationally facilitates the recording, storage, maintenance and exchange of digital scientific data on chemicals.
- Supporting Member States and the European Commission under the **Prior Informed Consent (PIC)** Regulation, which implements the UN Rotterdam Convention in the European Union.
- ECHA contributed to the risk management evaluation of methoxychlor, which has been proposed by the European Union for listing as a **persistent organic pollutant** under the Stockholm Convention. A consultation was launched for the risk management evaluation of methoxychlor, as well as for the risk profile of UV-328.
- ECHA coordinated the publication of studies **assessing the gaps and needs** of Montenegro and Serbia in readying themselves to implement EU chemicals legislation on their path towards membership. Following this, ECHA also procured a second study to assess existing situation in Albania, Kosovo, Turkey, North Macedonia and Bosnia Herzegovina to guide the organisation in our future work in support these countries in their harmonisation of **EU acquis for chemicals**.
- Contacts were established with the European Environmental Agency (EEA) and ECHA participated in the Zero Pollution focus group. This work is a step towards safety and sustainability and will contribute to establishing **indicators** under the **8th Environmental Action Programme** to 2030 and the CSS.
- ECHA began setting up EU-wide positive lists of chemicals that can be safely used in materials that come into contact with **drinking water** under the respective directive. The aim is to protect people from contaminated drinking water, improve their access to safe drinking water, and ensure that safety and hygiene standards are uniform throughout the EU.
- Provision of informal support to review sectoral **best available techniques reference documents (BREFs)**. For example, in the review of the BREF for the textile sector, ECHA gave input on how chemicals management systems could be structured and described.

Key achievements on governance and enablers

- The Management Board led the **mid-term review of the multiannual strategy** and confirmed that ECHA's strategic direction remains largely valid, while providing guidance to the secretariat for the remaining part of the implementation period. The Board also appointed the new Legally Qualified Member of the Board of Appeal.
- High quality outputs were delivered during the continued COVID-19 pandemic and support was provided to

stakeholders as we work in a **hybrid setting**, with 650 virtual meetings and around 45 000 participants.

- The initial budgeted expenditure of 2021 totalled EUR 113.1 million (including the separately funded 'Other tasks') and the final total expenditure figure concluded in the second amending budget in September 2021 was EUR 111.1 million. The decline of the fee income levels of the REACH/CLP part of the budget was managed well by finding savings in meeting and travel costs through virtual meetings. For fees under the Biocidal Products Regulation (BPR), the persistently high volatility and unpredictability continued. **The Agency met its budget implementation targets** reaching a 98 % commitment rate and an 86 % payment rate (estimates were 95 % and 80 %, respectively).
- A high number of **internal mobilities** in line with our HR strategy and organisational culture that provides an agile and flexible working environment.
- Continuous investment in a **healthy work environment** based on collaboration, agility and a well-developed management culture led to the Agency being recognised as one of the most inspiring workplaces in Finland. The turnover of temporary agents remained low at 2 % and 97 % of establishment plan posts were filled.
- ECHA applied for registration to the **EU Eco-Management and Audit Scheme (EMAS)** as a premium management instrument for organisations to evaluate, report and improve their environmental performance.
- The third **Enterprise Architecture Roadmap (2021-2023)** has resulted in an increased integration or modularisation of IT to support the increased integration of business processes.

Achievements of the year

Advancing knowledge and transparency on chemicals

Chemical safety reports now covered by completeness checks

The technical completeness checks, carried out for each new and updated registration, were extended to cover chemical safety reports. The new checks ensure that registrants have fulfilled their obligation to assess the safety of the uses of substances they place on the European market. A well-documented safety assessment is the starting point for appropriate supply chain communication. In 2021, 1 800 CSR documents were checked for completeness, with almost a third found to not contain the required elements.

A chemical safety report is required for all substances registered in quantities of 10 tonnes per year or more. The reports document industry's hazard, exposure and risk assessments, and are submitted as text documents within IUCLID registration dossiers. They are not automatically validated so ECHA staff manually verify that companies have included the key information required by law. Through this work, the Agency ensures that an exposure (and therefore a risk) assessment is made for each reported use.

To help companies facing difficulties due to COVID-19 and because of budget implications affecting our work, this extension was postponed until 2021. However, companies had been pre-warned that these changes were coming already in 2019. In 2021, we received 14 952 registrations (including updates) and manually checked 1 800 chemical safety reports.

With REACH no longer applying to the UK from 1 January 2021, the consequences of the UK's withdrawal and the impact on access to markets became clearer. ECHA revoked 2 964 registrations held by UK companies that had become void as they had failed to transfer them to EU entities by the end of 2020. This amounted to approximately 3 % of the total number of REACH registrations. To be transparent, the information contained in the UK registrations is still available on ECHA's website after their revocation, with their registration status updated.

In August, the Guidance on registration was updated to align with two European Commission implementing regulations – on registration and data sharing of phase-in substances[9] after the final registration deadline, and on updating registrations[10]. The new version clarifies how registration happens now that pre-registrations are no longer valid and gives advice to companies on when they need to update their registrations and how to calculate their tonnage bands.

Updates to REACH-IT also helped to further facilitate data sharing and increase transparency on ongoing compliance check activities concerning joint submissions. New sections were made available in the tool providing the contact details of submitters of (robust) study summaries as well as information on when summaries were submitted. A new section on the joint submission page also provides information on past and ongoing dossier evaluations that may concern joint submission members.

9 https://echa.europa.eu/-/rules-for-registration-of-phase-in-substances-clarified

10 https://echa.europa.eu/-/deadlines-for-updating-registration-dossiers-clarified

Addressing knowledge gaps for nanoform substances

ECHA received 535 registrations for 143 nanoform substances by the end of 2021. While the exact number of nanomaterials on the EU market is unknown, based on data from national registries and under the Cosmetics Regulation, there is reason to believe this figure ought to be higher. But there may be differences in tonnage that explain the discrepancy between the number of registered nanoforms, and the number of nanomaterials being reported in the EU Observatory for Nanomaterials (EUON)[11].

During 2021, dossier evaluation – which covers compliance checks and evaluating testing proposals – was initiated on registrations, specifically addressing the requirements for substances in nanoforms. The initial focus was on substance identity and justifications for sets of nanoforms. In addition, guidance on human health-related information requirements for substances in nanoforms was updated as planned.

The EUON gathers information about existing nanomaterials on the EU market and generates new data through market studies and surveys. Information on safety, innovation, research and use of nanomaterials benefits a range of stakeholders from policy makers, consumers and workers to industry representative and green NGOs. In March, we launched a call for further topics that could be addressed in upcoming studies to fill knowledge gaps on nanomaterials.

Throughout the year, views from different experts were published on the EUON website. A range of topics were covered including an overview of the work of our nanomaterials expert group, how nanotechnology can be used to treat Parkinson's disease and how protective measures may still be needed to prevent exposure at work.

In the late stages of the year, an EUON report was published investigating product lifecycles, waste recycling and the circular economy for nanomaterials. It found that data is lacking to be able to accurately estimate the amount of waste streams that contain nanomaterials. But despite this, scientists, waste operators and regulators can use existing public databases to estimate the flow of nanomaterials to waste management facilities and their fate in the environment.

The study showed that incineration and wastewater treatment are highly efficient at limiting environmental emissions of commonly used nanomaterials. And that substantial progress has also been made in characterising and measuring nanomaterials, which should help more accurate data on nanomaterial waste to be generated in the future.

FIGURE 1: EUON social media post

11 The development of the EUON is financed by a separate contribution agreement with the European Commission. At the end of 2021, this agreement was renewed for a further five years.

When scientists and regulators around the world use IUCLID to collect and share data, their work becomes more effective for safer chemicals and products.

Mercedes VINAS

Director of Submissions and Interaction

Managing chemicals data and making it accessible

Steps have been taken towards a consolidated and more integrated approach to assessing chemicals data throughout the EU. To facilitate that data is collected and used in the same format in the EU and internationally, ECHA significantly invested in developing and reinforcing IUCLID[12] as the most widely accepted format for information on chemicals across the world.

In October, the IUCLID format was updated to take into account the latest OECD Harmonised Templates – standard data formats for reporting information used to assess the risks of chemicals. The update also covered the latest evolutions to the CLP Regulation (including poison centre notifications) and the SCIP database for information on substances of concern in products.

With its customisability, documented in an OECD report updated in 2021[13], IUCLID is also increasingly meeting the needs of several other regulatory organisations. The European Food Safety Authority (EFSA) has required IUCLID to be used for active substance dossiers for pesticides since March 2021, thus ensuring compliance with the requirements of the Transparency Regulation[14].

ECHA has also been cooperating with the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), exchanging information and data to support EMCDDA in the development of an early warning system for new psychoactive substances.

These examples show that steps are being taken to boost cooperation and data sharing under a one substance, one assessment approach.

Internationally, it is used, for example, in Australia to support the Australian Industrial Chemicals Introduction Scheme (AICIS) and, since 2021, in New Zealand where the Environmental Protection Agency has transitioned to using IUCLID for its classification system.

Work also continued in 2021 to release and further develop IUCLID's data uploader and extractor – tools that help users transfer data from external sources to the IUCLID format, and extract data from a IUCLID database according to a set of user-defined rules. The text analytics search engine was also upgraded, allowing users to quickly search all IUCLID fields including the text content of attachments.

The EU Chemicals Legislation Finder (EUCLEF)[15] – a free of charge tool that gives users an overview of how their substances are regulated across the EU – was expanded and now covers all 56 pieces

12 Organisations can use IUCLID to record, store, maintain and exchange digital scientific data on chemicals.

13 Customisation opportunities of IUCLID for the management of chemicals data, 2nd edition, OECD.

14 https://ec.europa.eu/food/horizontal-topics/general-food-law/implementation-transparency-regulation_en ECHA's work for EFSA in developing IUCLID is financed via a service-level agreement.

15 EUCLEF is funded by the EU Programme for Competitiveness of Enterprises and Small and Medium-sized Enterprises (COSME). ECHA maintains and develops EUCLEF through a contribution agreement with the Commission. At the end of 2021, this agreement was renewed for a further five years.

of chemicals legislation it was intended to cover. Among others, added legislation covers pesticides, end-of-life vehicles, food contact materials, medical devices, and safety and health at work. The finder is free of charge and seamlessly integrated into our chemicals database. Users can use it to search for information on their substances, find the laws that apply to them and check what obligations they have.

ECHA's public chemicals database suffered from production issues during 2021, affecting among others the publication of information on registered substances and related Infocards. Further to this, while the scheduled update to the software behind our website and chemicals database was concluded in summer, it also led to some features and content being temporarily unavailable. Work continued throughout 2021 to resolve these issues, and to stabilise the platform and website. At the same time, we initiated work on a new data availability system meant to replace the current public database in the coming years.

Substance Infocards are now also generated by default for all substances – not just for registered substances under REACH or notified substances under CLP. This means that blocks of information such as properties of concern and nanoforms will always be visible for substances when this information is available.

INFOBOX

HARMONISING ADVICE FOR COMPANIES

With ECHA needing to balance resources and refocus on priority areas, specifically on identifying and managing the risks of chemicals of concern, some enquiries that have been handled by the Agency's Helpdesk in the past were transferred to the network of national helpdesks – HelpNet – for reply.

In practice, this meant that a part of the regulatory questions received on REACH and CLP, including enquiries on poison centre notifications, would be handled by the national helpdesks instead of directly by ECHA. From October, national helpdesks were also the first contact points for questions received from non-EU companies. Enquiries related to IT tools, the PIC Regulation and the SCIP database remain in the Agency's remit. The division of biocides enquiries between ECHA and the national helpdesks remains the same.

This new division of tasks enhances cooperation between ECHA and the national helpdesks, and will help to ensure that companies continue to receive high quality and consistent advice to comply with their obligations. The extended role of national helpdesks also means that more companies will be able to receive advice in their own language.

We have also provided support to help inspectorates in Member States when questions arise over whether certain objects should be treated as a substance, mixture or an article. In 2021, the Agency discussed with experts from six Member States within a HelpNet dedicated working group to catalogue several borderline cases. This work will continue into 2022.

Throughout 2021, the HelpNet replied to around 11 958 enquiries on REACH, 11 597 on CLP and 31 476 on biocides. The lingering impact of COVID-19 meant that meeting in person was still not possible, but virtual meetings were organised to exchange information and share best practice to maintain pre-pandemic engagement levels.

The ECHA Helpdesk responded to 5 283 regulatory and 6 378 IT enquiries throughout the year. For regulatory support, the hot topics were substances in articles and SCIP, restrictions, dossier-related questions, poison centre notifications and biocides. For IT support, topics of interest were the UK's withdrawal from the EU, IUCLID and ECHA's chemicals databases.

Faster and more accurate advice from poison centres

Since 1 January 2021, mixtures for professional and consumer use have had to be notified in a harmonised format defined under CLP. Mixture labels must also include a unique formula identifier (UFI) – a unique code that allows poison centres to precisely identify the composition of the mixture and the product involved in a poisoning incident. This helps poison centres to give quick and accurate advice when someone is accidentally poisoned.

In 2021, ECHA processed 1.7 million poison centre notifications, including updates. The majority of appointed bodies and poison centres in Member States now only accept poison centre notifications through the ECHA Submission portal – a secure and online way to centrally manage notifications for hazardous mixtures.

We updated the Guidance on Annex VIII to CLP in February to reflect amendments to the legal text and address issues that certain industry sectors had raised. To help reduce the number of necessary notifications and UFIs, solutions were made for companies using multiple suppliers for components of a particular mixture. Sector-specific solutions were also published for fuel, petroleum, and construction products – as these often have highly variable and unpredictable compositions. Similar support was also provided to help companies formulating bespoke paints meet customer demand.

Along with the October IUCLID update, a new version of the poison centre notification format was released allowing companies to make group submissions for their mixtures. Users could also include multicomponent product identifiers and provide new reasons for updating their submissions. There were also changes to standard formulas when compiling mixtures with unknown or varying compositions, and a web-based report of notification information was made available. The IUCLID Validation Assistant – which helps companies check for inconsistencies in their notifications and fix them before submission – was also updated to reflect the latest changes.

Along with the release, we gave advice and hands-on support through webinars explaining the changes to the ECHA Submission portal and step-by-step advice companies may need from preparing their notifications to placing their mixtures on the market.

Towards the end of the year, we launched a multilingual #UFImattersEU campaign through our social media channels. The aim was to reach parents of small children across Europe to raise their awareness about the UFI code and how it can help them get faster medical advice if their loved ones have an accident involving everyday chemical products. The campaign was run together with partners such as A.I.S.E.[16] and some national authorities and, to spread the word further, many institutional multipliers were contacted and mobilised before its launch.

FIGURE 2: UFI social media campaign

16 The International Association for Soaps, Detergents and Maintenance Products: https://aise.eu

Contributing to safer global trade in chemicals

Supporting Member States and the European Commission was a major part of ECHA's work under the Prior Informed Consent (PIC) Regulation in 2021.

In 2021, ECHA processed 10 699 export notifications – an approximate 11 % decrease compared to the previous year. The drop can be explained by the absence of additional new substances to PIC, as well as the higher acceptance rate (around 95 %) of notifications – and therefore less resubmissions and reprocessing – compared to 2020 (around 92 %).

While the UK's withdrawal from the EU halted the processing of notifications for exports from the UK (Great Britain) to the rest of the world (around 750 in 2020), this was largely balanced by the validation of approximately 660 notifications for exports from the EU to the UK (Great Britain) in 2021. Moreover, 443 export notifications from the UK (Great Britain) to the EU were received and processed.

ECHA provided its support to the European Commission on designing how to subject substances containing benzene to the export notification requirement. Benzene is used, for example, to make plastics, resins and synthetic fibres and is already listed under PIC so exporters must notify designated national authorities (DNAs) of their intention to export this substance and mixtures containing it. But, for the first time, benzene-containing substances (hence 'substance in substance') are also now being considered for listing under PIC.

Supporting the development of common implementation practices, we have been working on the definition of what an article is under PIC and made a suggestion to DNAs at a meeting in spring on how to practically apply this definition. Under PIC, the export of an article is subject to notification if it is a finished product containing chemicals listed in PIC where the use of those chemicals is banned in the EU. Further guidance on this is planned for 2022.

To promote and support the implementation of the Rotterdam Convention by non-EU countries, ECHA also participated in five Rotterdam Convention workshops, presenting how the Convention is implemented in Europe to regional groups in multiple languages (English, French, Spanish and Arabic). These workshops are particularly valuable to clarify the EU-specific provisions of the PIC Regulation to non-EU countries and to further enhance information exchange.

Two new releases of ePIC – the IT system supporting PIC's implementation – were published, enhancing, among other things, the messaging module for companies and authorities. We provided training to DNAs on the new features and a workshop on explicit consent management ahead of the expected peak in workload at the end of the year.

Enforcing e-commerce reveals significant breaches of EU law

In December, ECHA published the results of an EU-wide enforcement project[17] where national authorities checked almost 6 000 products sold online. With three out of four inspected products shown to be breaching EU chemicals laws, the results show a need to reassess how online sales are regulated.

The project examined whether products sold online followed rules set under REACH, CLP and the Biocidal Products Regulation (BPR). 78 % of checked products – including textiles, leather, childcare articles, toys and jewellery – contained harmful chemicals above legal limits set by REACH restrictions. More than 1 800 products contained restricted cancer-causing substances (CMRs), such as lead in solders used for welding and boric acid. This is a major concern – they should only be used by professionals, but 99 % were wrongly available for consumers to buy.

Inspectors also checked that safety data sheets were available online and in the relevant EU languages. These are documents with instructions workers can use to know how to safely handle chemicals. Here, the non-compliance rate was quite low at only 5 %, but information on chemical hazards was severely lacking. It should have been available in the advertisements but was missing in 75 % of cases. And even when it was available, it was often not clearly visible.

17 REF-8 project on enforcement of CLP, REACH and BPR duties related to substances, mixtures and articles sold online: https://echa.europa.eu/documents/10162/17088/project_report_ref-8_en.pdf

With volumes of online sales expected to increase and non-compliance rates four times higher than found during spot checks in stores or by customs, there is a pressing need to address how online sales are regulated in the EU.

Karin RUMAR

Chair of the REF-8 project working group

For biocides, 77 % of checked products were non-compliant with at least one requirement of the BPR – with repellents and attractants having the most issues. Advertisements were also a problem for biocides, with many of them featuring misleading statements that are forbidden, such as "low-risk", "non-toxic" or "animal friendly".

With e-commerce likely to grow in the future, the project results offer a sobering reflection on how online sales are currently regulated. The report recommends making online marketplaces liable for ensuring products sold through them are legally compliant. It also recommends companies to be more proactive and transparent about their sellers, and for consumers to avoid buying products when there is incomplete or no information about the seller and to be proactive in learning about the general legal requirements for consumer products[18].

As a further step towards harmonised enforcement, we updated the compendium of analytical methods[19]. The compendium is a living database of recommended laboratory methods that authorities can use to check if companies comply with REACH restrictions. The compendium provides a set of reliable and comparable methods to ensure harmonised results across Member States.

18 Information on consumer's rights can be found at: https://ec.europa.eu/info/live-work-travel-eu/consumer-rights-and-complaints_en

19 https://echa.europa.eu/documents/10162/13577/compendium_of_analytical_methods_en.pdf

FIGURE 3: EU-wide enforcement project for products sold online social media post

INFOBOX

INFOBOX: INTERNATIONAL OUTREACH AND CAPACITY BUILDING

On their path towards membership, the gaps and needs of Montenegro and Serbia in readying themselves to implement EU chemicals legislation were assessed and published in March 2021.[20]

The findings showed that both countries require targeted support to help them align with EU chemical standards. With only limited resources available, both countries face challenges to implement and enforce REACH, CLP, PIC and the BPR.[21]

To overcome these obstacles, the study recommends the respective governments to strengthen the administrative capacity of national authorities, ensure enough finances to implement and enforce the legislation, facilitate cooperation with academia and increase communication activities and IT capacity. We stand ready to continue supporting the countries through training and capacity building on risk assessment, IT security and tools, as well as enforcement.

In 2021, ECHA partnered with the European Commission, UNEP[22] and UNITAR[23] in their capacity building efforts to support the global implementation of the UN's Globally Harmonised System (GHS) for classifying and labelling chemicals, with a focus on extending its use in Africa. Implementing GHS would help African countries to start managing chemicals in a more strategic way and to know which chemicals are in commerce in their countries.

So far, only Mauritius, South Africa and Zambia have fully implemented GHS. Four countries – Ghana, Ivory Coast, Kenya and Nigeria – have been suggested as pilots for an initial project with the aim to build a framework that could later be applied to further countries.

20 Montenegro: https://echa.europa.eu/documents/10162/1459379/wp5_action_plan_montenegro_en.pdf ; Serbia: https://echa.europa.eu/documents/10162/1459379/wp5_action_plan_serbia_en.pdf

21 The instrument for pre-accession is financed by a grant agreement with DG NEAR.

22 United Nations Environment Programme.

23 United Nations Institute for Training and Research.

Making safe and sustainable use a reality

Faster action on groups of harmful chemicals

ECHA published the first assessments of regulatory needs for groups of substances at the end of the year, evidence of the Agency's continued shift away from assessing individual substances. Group assessments make it easier for companies to predict what actions regulators are planning and helps them to prepare strategies to replace harmful chemicals with safer alternatives, where relevant.

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Our assessment of the regulatory needs of groups of substances assures companies on the regulatory actions planned for their chemicals. This allows them to prepare to replace harmful chemicals in their portfolios with safer alternatives.

Ofelia BERCARU

Director of Prioritisation and Integration

ECHA's grouping approach can help authorities to use all available data to cover a bigger share of registered substances, including those where hazard and exposure information is lacking. It also helps to improve regulatory consistency and increases the predictability of authority actions when similar substances are addressed together.

During 2021, in our assessment of regulatory needs of substances, ECHA assessed more than 1 900 substances, mostly grouped based on their structural similarity. Out of these around 1 650 are registered under REACH, and nearly 700 are registered above 100 tonnes per year.

From these 1 900 substances, we have identified around 300 that require further risk management measures, and around 800 substances that currently do not require further action. For the remaining 800 substances, data needs to be generated and this has either been proposed or is ongoing (either on the substance itself or for a related substance).

The regulatory needs of close to 1 300 substances registered above 100 tonnes per year still need to be assessed, and these have not yet been assigned to any regulatory pool in the chemical universe. But we are still on target to conclude on the regulatory needs for all registered substances by 2027.

To increase transparency on the regulatory actions being pursued and the progress made on groups of substances, ECHA published the first assessments of regulatory needs[24] for 19 groups covering more than 450 substances at the end of 2021[25]. These included groups of phthalates and phthalate-like substances that were assessed due to their potential reprotoxic, endocrine disrupting, or persistent, bioaccumulative and toxic (PBT) properties. A potential restriction has been proposed for some to limit potential releases from articles. Some ortho-phthalates require harmonised classification and labelling, identification as substances of very high concern (SVHCs) or both. For other substances in these groups, there is currently not

24 The Regulatory Management Option Analysis list was modified and re-formed as the Assessment of Regulatory Needs (ARN) List. Screening work under ECHA's integrated regulatory strategy is now included in ARN and the public activities coordination tool (PACT) was also updated to reflect this change.

25 ECHA has so far assessed the regulatory needs of around 150 groups, covering more than 3 600 substances in total. For more than half of the assessed substances, there is currently no need for additional regulatory action. To confirm this, however, data generation is proposed as an immediate action for many of the substances.

ECHA's participation in the BREF process adds value, enhancing the coherence and synergies between the Industrial Emissions Directive and chemicals legislation. The methodology to prioritise chemicals for prevention or control of emissions is also welcome.

Aneta WILLEMS
Head of DG Environment's Industrial Emissions and Safety Unit

enough information to confirm a potential hazard, and a few do not require any new regulatory actions for now.

All the assessments will be gradually published on ECHA's website in the public activities coordination tool (PACT) when the assessments have reached a sufficiently mature state to avoid unnecessary questions or measures from stakeholder side.

The grouping approach can also be used in the context of other legislative frameworks. As an example, in 2021, the approach was applied to identify substances with potential plasticiser uses in different food contact materials in collaboration with the European Food Safety Authority (EFSA).

Helping companies assess chemical safety throughout the supply chain

Actions planned by ECHA to improve extended safety data sheets and the work of the Exchange Network of Exposure Scenarios were suspended in 2021 to refocus on priority areas. The Agency has concentrated on supporting companies in carrying out their chemical safety assessments and improving Chesar[26].

Two new versions of the tool were published in 2021. The first release incorporated a set of harmonised conditions of use resulting from a mapping of worker exposure estimation tools. The second improved chemical safety reports, making information on contributing scenarios for workers and the environment more clear and complete.

ECHA is also developing the Chesar Platform, a chemical risk assessment tool combining Chesar and the EU system for the evaluation of substances (EUSES) that will serve both REACH and biocides. We opened a call to form a chemical risk assessment stakeholder community to discuss scientific proposals, assessment methodologies and the usability of the platform.

The platform is planned to be launched in 2023.

The Agency collaborated with the REACH exposure expert group (REEG), a community of Member State experts, on the levels of use and exposure information needed to swiftly move hazardous substances beyond screening into various risk management processes. This work supports ECHA's integrated regulatory strategy and grouping approach.

We fed ideas on this into a working group led by the Dutch authority Rijksinstituut voor Volksgezondheid en Milieu (RIVM)[27] which is drafting a report setting out a range of hazard-based scenarios on what information is necessary for specific regulatory routes. Independent from REEG, we have also been providing expertise on use and exposure information to the European Commission as it looks to amend REACH under the actions of the Chemicals Strategy for Sustainability, details of which were discussed with REEG and

26 Chesar helps companies carry out chemical safety assessments and prepare chemical safety reports and exposure scenarios to be communicated in the supply chain.

27 https://www.rivm.nl

the Risk Management and Evaluation platform (RiME+) at the end of 2021.

ECHA has also been collaborating with the European Integrated Pollution Prevention and Control Bureau (EIPPCB)[28], providing REACH data and chemicals management advice to enhance the implementation of the Industrial Emissions Directive[29].

On this, the Agency continued to provide informal support to review sectoral best available techniques reference documents (BREFs). For example, in the review of the BREF for the textile sector, we gave input on how chemicals management systems could be structured and described. We also provided information on specific substances mentioned in the descriptions of techniques in the BREFs, together with their regulatory status under REACH and CLP. In the review of the ceramics sector BREF, the Agency provided a list of hazardous substances potentially used in the sector. This was done to support the data collection and identification of key environmental issues during the review process.

For the textiles sector, ECHA has developed a chemicals management system methodology that will help site operators identify the chemicals in their portfolio with emissions that need to be prevented or controlled as a priority. A workshop for textile stakeholders is planned together with the EIPPCB in early 2022.

INFOBOX

INFOBOX: SAFER DRINKING WATER

On 12 January 2021, the revised Drinking Water Directive came into effect. ECHA began setting up EU-wide positive lists of chemicals that can be safely used in materials that come into contact with drinking water. The aim is to protect people from contaminated drinking water, improve their access to safe drinking water, and ensure that safety and hygiene standards are uniform throughout the EU.

The first EU-wide positive lists will be based on existing national lists, provisions and risk assessment reports that were notified by Member States to ECHA in July. These cover around 2 400 substances for different types of materials.

The Agency will compile the lists (e.g. remove duplication) and send them to the European Commission, which will decide on adopting the lists by 2025. Based on the hazardous properties of the substances and the quality of any related risk assessments, ECHA will recommend expiry dates for each entry on the first positive lists.

Companies that want to keep their substance on the lists will need to send a review application to the Agency by the expiry date. ECHA's Committee for Risk Assessment (RAC) will review them and form opinions that will be sent to the Commission. The Commission will decide whether to keep the entry, amend it or remove it from the lists. The review of all entries in the first positive lists needs to be completed within 15 years from the adoption of the lists. ECHA expects that between 50 and 100 opinions per year will have to be issued by RAC between 2025 and 2040.

We will also support the Commission to develop information requirements and assessment methods, in close collaboration with the European Food Safety Authority (EFSA) as these link to food contact materials legislation.

28 https://eippcb.jrc.ec.europa.eu

29 Legislation that aims to prevent or reduce harmful emissions caused by large-scale agro-industrial installations by the identification and application of best available techniques (BATs).

SCIP helps to track products containing substances of very high concern throughout their whole lifecycle including the waste stage, supporting the goals of the EU Green Deal and bringing us closer to a circular economy.

Clara RUEDA

Regulatory officer

Shining a light on chemicals of concern in products through SCIP

Since 5 January 2021, companies have had to submit data to ECHA's SCIP database on articles containing substances of very high concern (SVHCs). This is useful for consumers who want more information about the products they buy and will also help to improve the treatment of waste, namely recycling processes.

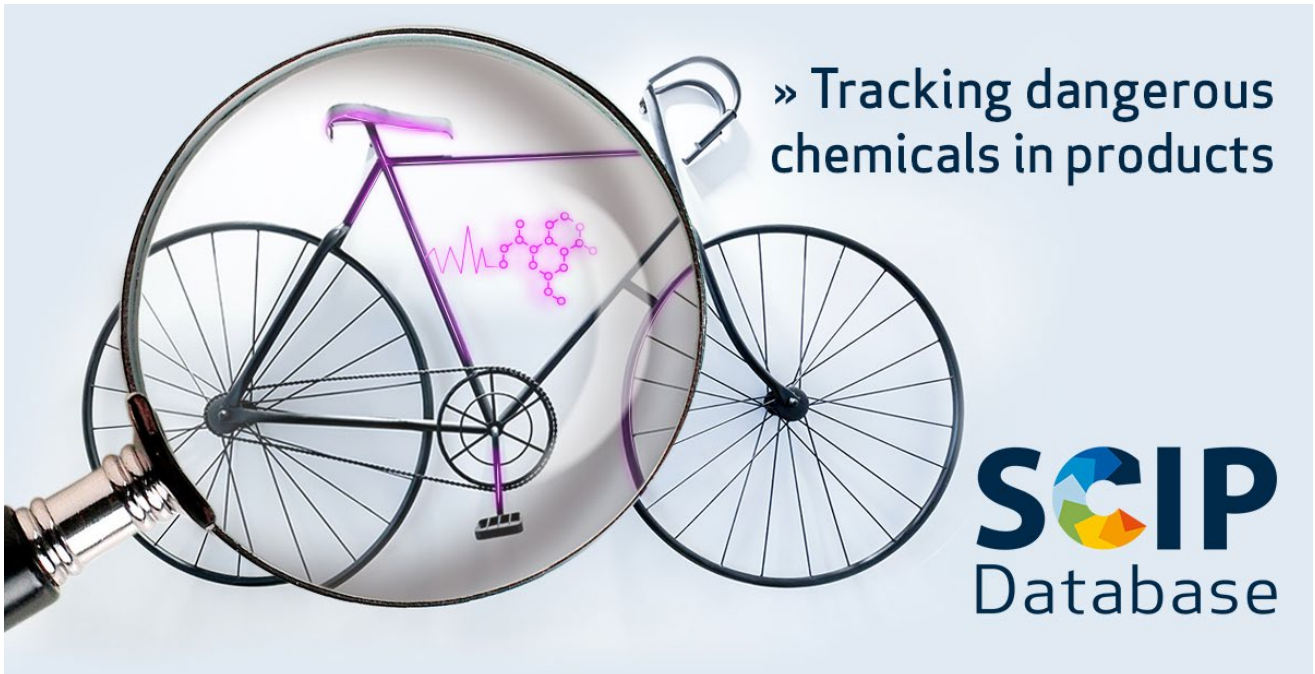
From October 2020 to the end of 2021, around 6 800 companies across the EU successfully submitted more than 15 million notifications to the database.

During 2021, the tools for preparing and submitting SCIP notifications were enhanced to help new duty holders fulfil their legal obligations. For example, they can now submit simplified SCIP notifications by referring to information already successfully submitted to the database, or they can prepare new notifications by referring to data previously submitted for component articles of their product. Through the system-to-system service, users can also now automatically notify directly from their own systems. Various support packages were also published to provide guidance to notifiers.

With the release of the SCIP database in September 2021, users were given access to the first public database on articles and products that contain SVHCs in the Candidate List. They can search the database by article name, chemical name, brand, product category, type of material or by SCIP number, among others. By the end of 2021, approximately 7 million articles[30] were searchable in the database,

30 The difference between the number of submitted notifications (15 million) and the number of results presented in the SCIP database (7 million) comes from the fact that some notifications only make reference to other previously submitted notifications, and do not themselves contain any additional article data.

FIGURE 4: SCIP database social media post



We have come a long way to avoid animal testing and ensure safety and protection where we can. To protect people from more complex diseases caused by chemicals while further limiting the use of animal studies, many parties have to step up and work closer together.

Mike RASENBERG

Director of Hazard Assessment

covering a large variety of products such as rubber and plastic articles, machinery components, furniture, measuring instruments, electronic equipment, vehicles, as well as their components.

The published data allows users to track products containing SVHCs throughout their whole life cycle until they reach the waste stage – which is a significant milestone in the pursuit of a circular economy and zero pollution in Europe. It will enhance the delivery of safe and clean products and secondary materials, in line with priorities on re-use and recycling defined under the European Green Deal. In addition, ECHA has already been able to systematically use the information, confirming whether uses in articles are adequately controlled on the EU market with a focus on restrictions under Article 69(2) of REACH.

Updated packages of reference substances were also released following the updates of the Candidate List[31]. And in December 2021, we organised a webinar to further explain how consumers, waste operators and article suppliers can make the best use of the available data.

Reducing and replacing animal tests without compromising protection

ECHA supports efforts to further reduce animal testing in Europe to the extent possible within our mandate. However, further reduction of animal research and development of alternative approaches not only require time but also significant increases in investment.

Under our mandate, we are responsible for protecting human health and the environment while we also promote alternative methods for hazard assessment. Certain animal tests, particularly for long-term effects, are still required under the current legislation to protect human health and the environment. But ECHA is helping to implement policies and administer processes where alternatives to animal testing play an increasingly important role. Coordinating the development of alternative testing methods is in the hands of the OECD, and industry is responsible for minimising unnecessary testing on animals.

Under REACH, ECHA assesses testing proposals from industry to ensure that animal testing is only done as a last resort. The Agency also runs online consultations to gather information on alternatives, brings companies together to share data and takes binding decisions when companies cannot agree. Furthermore, we publish guidance and support material to help companies understand where they can successfully replace animal tests with alternatives. The focus on groups of substances through the Agency's integrated regulatory strategy also reduces the need for animal testing because tests are only requested for a subset of substances in the groups.

We have also invested heavily in making data public so that predictive models can be developed to further reduce animal tests. To ensure

31 Eight substances were added in July 2021. A further four substances were identified in 2021 and communicated about in January 2022.

data is collected and used in the same format across the EU and globally, we develop and finance IUCLID, which in turn facilitates the sharing of data and development of analytical models and predictions.

In addition, we host and operate the OECD QSAR Toolbox, an IT tool used around the world to predict the effects of chemicals and fill data gaps without further animal testing. This year, ECHA played an active role in the OECD's adoption of an approach to assess skin sensitisation and protect people from skin allergies without testing on animals. The approach includes advice on how to use the computer simulation tools in the QSAR Toolbox to assess this property. ECHA updated its comprehensive guidance for companies on how to reliably apply this non-animal approach when assessing chemicals potential for skin sensitisation.

At international level, the Agency has continued to contribute with peer agencies in US, Canada, Australia and elsewhere to share our experiences on the use of alternatives. We have also formed a working group to accelerate the pace of chemical risk assessment (APCRA) that has several ongoing projects with counterparts in the US and Canada to make progress on the application and acceptance of new approach methods (NAMs) by authorities.

In our everyday work, we look beyond the legal obligations stemming from REACH. It is our vision that the more quickly reliable alternatives become available – particularly for long-term effects such as carcinogenicity, reproductive toxicity and endocrine disruption – the quicker we can move to an animal-free system. Developing alternatives also helps companies incur fewer costs and enables them to make smarter business decisions as they know about the hazards of their substances right away and can invest to make sure their chemicals are safe and sustainable by design.

FIGURE 5: QSAR Toolbox social media post

Assessing chemicals that matter the most

Transparent and predictable evaluation to reduce information gaps

For REACH to function as intended, it is crucial for information gaps on chemical properties to be reduced. ECHA has a responsibility to Europeans to ensure the chemicals data that companies submit complies with information requirements set out in the law.

ECHA has a responsibility to Europeans to ensure that companies submit chemicals data that complies with information requirements set out in the law.

Axel VORWERK

Head of Environmental Health, Chemical Safety Directorate at BMUV

Updates to the REACH annexes clarifying information requirements for companies were written into law in July. The aim is to bring more transparency and predictability to ECHA's evaluation practices. The update affects, for example, general adaptation rules for using existing data, weight of evidence approaches and grouping substances; specific rules for adapting reproductive toxicity studies; and specific requirements for human health and environmental testing[32]. These amendments started to apply in January 2022, so ECHA initiated the update of its guidance to help companies prepare to take them onboard.

Under the grouping approach (see 1.2.1 Faster action on groups of harmful chemicals), the Agency identified around 300 substances for which further regulatory risk management is recommended; 800 for which further data needs to be generated; and 800 for which no further regulatory actions are currently recommended.

In 2021, we conducted a total of 371 compliance checks covering more than 2 100 registrations and addressing 341 unique substances. This is a slight increase compared to 2020. For the vast majority of compliance checks, ECHA verified, as a minimum, the relevant higher-tier hazard endpoints for substances or groups of substances of potential concern[33]. From this total, 300 were full compliance checks addressing all relevant endpoints for 288 unique substances of potential concern. They resulted in 280 draft decisions being sent to companies, requesting more data to clarify long-term effects on human health or the environment. 71 were targeted compliance checks[34].

For the 363 follow-ups to dossier evaluation performed in 2021, around 40 % of dossiers remained incompliant and these have been sent to the Member States for further enforcement actions. When Member States enforce ECHA dossier evaluation decisions, the missing information is ultimately submitted to ECHA in around 92 % of cases, albeit still late and after the legal deadline,.

For substance evaluation, Member States evaluate chemicals listed in the Community rolling action plan to clarify whether their use

32 For the full list, see: https://echa.europa.eu/-/upcoming-changes-to-reach-information-requirements

33 The relevant endpoints checked as a minimum include carcinogenicity, mutagenicity, reproductive toxicity, developmental toxicity, repeated-dose toxicity, aquatic toxicity, biodegradation and bioaccumulation.

34 In a targeted compliance check, ECHA evaluates a specific part of the registration dossier based on specified concerns, for example, substance identity.

poses a risk to human health or the environment. The objective is to request further information from registrants to verify suspected concerns, if necessary.

In August, companies were requested to update their registrations with information about the toxicity of nanoforms of titanium dioxide. The substance is found, for example, in food, pharmaceuticals, cosmetic products, plastic coatings, food packaging materials and printing inks. Workers and consumers can also be exposed to powder forms used in some applications. Further information has been requested as there is a potential risk to human health from inhaling the substance.

We continued to implement measures agreed with Member States and the Commission to improve substance evaluation and reduce the time leading to the adoption of the decisions – draft decisions were further standardised and differences of view on more generic issues are now resolved.

We also published a new version of Instructions to evaluating Member State competent authorities. The instructions contain an update on the practices and policies and aim to help ensure that substances are evaluated consistently across Member States. Bilateral meetings were also held with some evaluating MSCAs, with a double objective: to agree on how to increase efficiency and to get their views on how substance evaluation should look in the future. These fruitful exchanges fed into our proposal on the future of substance evaluation, which was submitted to the Commission at the end of October.

INFOBOX

INFOBOX: SUPPORT TO INDUSTRY INITIATIVES

In line with actions under the REACH evaluation joint action plan, ECHA continued to support industry initiatives that help companies review their chemical safety data.

Close cooperation with Cefic continued and discussions were held on how to streamline the project while still maintaining the best possible support to help companies understand how to improve their registrations.

In the context of the Petroleum and Coal stream substances (PetCo) working group, we supported Concawe and other consortia in defining a strategy for filling data gaps when assessing the environmental impact of petroleum substances. More data is needed to describe the chemical composition in detail and to justify the use of current available hazard data between related petroleum substances.

Support provided in recent years to the non-ferrous industry through the Metals and Inorganics Sectoral Approach (MISA) also started to bear fruit. An analysis of dossier updates for metals indicates that around 60 % of substances under MISA have received updates for human health and environmental endpoints – twice the rate of updates for metals not covered under the approach.

Pursuing a POPs-free future

Persistent organic pollutants (POPs) are regulated by the Stockholm Convention, a global treaty that aims to protect human health and the environment from "forever" chemicals that resist biodegradation in the environment and accumulate in living organisms. Exposure to POPs may lead to severe adverse health effects such as cancers and birth defects.

The Stockholm Convention is implemented in the EU through the POPs Regulation, tasking ECHA to help identify and propose new POPs from the EU.

In May, we published a draft risk management evaluation of methoxychlor, which has been proposed by the European Union for listing as a POP. A consultation was launched for methoxychlor, as well as for the risk profile of UV-328, inviting concerned parties to share scientifically relevant information on these substances. Methoxychlor is an organochlorine pesticide used as an insecticide, and UV-238 is used as a UV stabiliser found

in plastic shrink films and outdoor furniture, and as a light stabiliser in certain coatings and resins.

The final draft risk management evaluation of methoxychlor, taking into account the information received during the consultation, was submitted to the Stockholm Convention's Persistent Organic Pollutants Review Committee (POPRC) for review in July 2021.

In April 2021, the EU proposed listing chlorpyrifos as a POP – a substance that has been phased out in the EU, but which is still used as a pesticide elsewhere and dispersed in the environment globally.

The POPRC is expected to review these proposals and adopt a recommendation as regards their listing once the review process has been finalised, which is expected for methoxychlor in January 2022.

Occupational exposure limits to protecting worker health

In 2021, ECHA's Committee for Risk Assessment issued opinions on the evaluation of occupational exposure limits (OELs) for asbestos, and for cadmium and its inorganic compounds. OELs are regulatory values set at EU and national level that provide a minimum level of protection from exposure to chemical substances in the air of a workplace for all workers in the EU.

ECHA's Committee for Risk Assessment (RAC) proposes health-based occupational exposure limits (OELs) or dose-response relationships (DRRs) and other relevant information to underpin updates under the Chemical Agents (CAD), Carcinogens and Mutagens (CMD) and Asbestos at Work (AWD) directives.[35]

Based on global and national estimates, asbestos-related cancer is currently a leading fatal occupational disease. While the use of all asbestos fibre types is already banned in the EU and stringent control measures apply to asbestos removal or maintenance work, occupational exposure may still occur. So, the scientific opinion of RAC and the review of the OEL are crucial elements in keeping asbestos exposure to a minimum.

The committee's opinion derives an exposure-risk relationship for lung cancer and mesothelioma, describing how the level of excess cancer risk depends on the concentration of mixed asbestos fibres in the air.

Studies on cadmium indicate that it may cause renal, bone and reproductive toxicity as well as cardiovascular effects. RAC's opinion concluded that a combination of an OEL and biomonitoring-based limit value would be most effective in protecting workers.

Both opinions will support the European Commission in its possible review of the respective OELs.

ECHA is also currently evaluating workplace exposure to welding fumes; polycyclic aromatic hydrocarbons; 1,4-dioxane; isoprene; and cobalt and its inorganic compounds.

"OELs help employers to protect their workers from possible risks when using chemicals at work and ensure that workers are not exposed to unsafe levels of hazardous chemicals.

Tim BOWMER

Committee Chair - RAC

35 ECHA provides scientific opinions on toxicological profiles of selected priority chemical substances when requested. This is financed through a service-level agreement with DG EMPL.

Addressing the risks of substances of concern

With each harmonised classification of a substance, workers and consumers become better informed, and human health and the environment are subsequently better protected as a result of the requirements to classify, label and package products appropriately before they can be placed on the market.

Paul RYAN

Head of Hazard I

Harmonised classification and labelling reinforces safety

Once a substance or mixture is classified, its identified hazards must be communicated to all actors in the supply chain, including to consumers. Through labelling and safety data sheets, the hazards can be communicated directly to those using the substances or mixtures to alert them that there are risks and to help them use the substances safely.

In 2021, ECHA received 49 classification and labelling dossiers – covering 32 industrial chemicals and 27 carcinogenic, mutagenic and reprotoxic (CMR) substances. A further 19 active substances used in biocidal and plant protection products were also processed (two of which are industrial chemicals).

With the lingering effects of the COVID-19 pandemic, ECHA's Committee for Risk Assessment (RAC) continued its scientific work uninterrupted with meetings being held remotely. 54 opinions were adopted proposing to give 30 substances an EU-wide harmonised entry – including 9 carcinogens, 5 mutagens, 14 affecting reproduction and 13causing sensitisation. The harmonised entry makes it obligatory for hazards to be communicated consistently throughout supply chains across Member States.

In May, we published a new practical guide giving advice on how to submit a dossier along with a webinar collecting feedback on the experiences of dossier submitters. A follow up webinar later in the year presented the findings and a finalised support package to Member States to help them prepare fit-for-purpose dossiers. A further guide was launched in September to help companies and national authorities understand how mixtures containing titanium dioxide need to be classified and labelled following its classification as carcinogenic if inhaled.

ECHA and the European Food Safety Authority (EFSA) received a draft renewal assessment report and a CLH report proposing harmonised classification and labelling for glyphosate from four Member States – France, Hungary, The Netherlands and Sweden – in June. Parallel consultations were launched on the reports and a total of 416 submissions from within and outside the EU were received through the two consultations. Glyphosate is currently approved in the EU until 15 December 2022, and RAC will review the classification proposal in 2022.

Authorisation has positive health and environmental impacts

The requirement for companies to obtain an authorisation before they can use harmful chemicals has steered them away from using substances of very high concern (SVHCs) according to studies conducted in 2021. Evidence also shows that adding substances to the Candidate List has a sizeable effect in lowering the use of SVHCs and stimulating their replacement with safer alternatives.

In 2021, ECHA's scientific committees agreed on 18 opinions for substances that have endocrine-disrupting properties, and another 31 opinions for substances with other properties. 12 substitution plans were also evaluated.

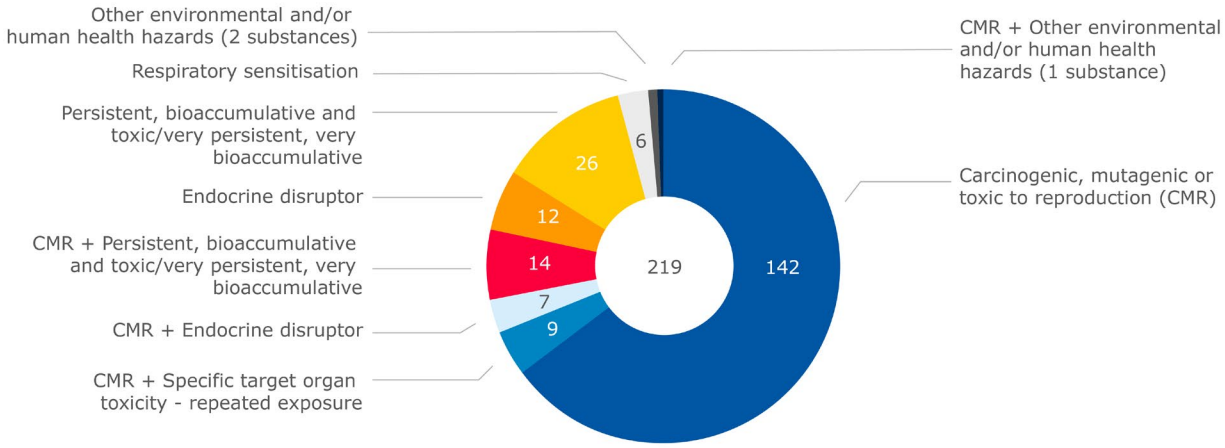
In early 2021, the Agency published its own meta-analysis of the socio-economic impacts of authorisation[36] basing its findings on data and knowledge gathered between 2010 and 2020. The findings indicate that the authorisation system has inbuilt dynamics that inherently promote substitution and significantly reduce the volume of SVHCs over time.

Later in November, we published a further report[37] presenting two case studies on the causal effects that authorisation has had on the use of specific SVHCs. This report found that five years after a substance has been listed in the Authorisation List, Swedish firms have reduced their annual use of SVHCs requiring authorisation by around 40 %. The results are a further indication that both Candidate and Authorisation listing have an impact on reducing the use of SVHCs and their progressive substitution.

In 2021, 12 substances were added to the Candidate List of substances of very high concern. They are used in consumer products such as cosmetics, scented articles, rubbers, lubricants and textiles. Others are used as solvents, flame retardants or to manufacture plastics products. Most have been added to the Candidate List because they are hazardous to human health as they are toxic for reproduction, carcinogenic, respiratory sensitisers or endocrine disruptors. This brought the total number of entries on the list to 223[38].

ECHA also recommended for the Commission to add seven substances from the Candidate List to the Authorisation List – the cyclosiloxanes D4, D5 and D6; terphenyl, hydrogenated; DCHP; disodium octaborate; and TMA.

FIGURE 6: Hazard properties of Candidate list substances - July 2021



36 https://echa.europa.eu/documents/10162/13637/socioeconomic_impact_reach_authorisations_en.pdf/12a126f2-9267-1dcd-75e3-ce0f072918e4

37 https://echa.europa.eu/documents/10162/17231/causal_analysis_reach_authorisation_en.pdf

38 Eight substances were added in July 2021. A further four substances were identified in 2021 and communicated about in January 2022.

ECHA updated its Guidance on authorisation applications in January, clarifying that applicants need to include a substitution plan in their applications if the analysis of alternatives shows that suitable alternatives are available in the EU – regardless of whether these alternatives are technically or economically feasible for applicants.

An updated format for companies that shall be used when applying for authorisation was published, combining the analysis of alternatives, socio-economic analysis and, where relevant, a substitution plan into a single document that makes applying more efficient. The formats of the committee opinions were also revised, and now include a clear conclusion on whether applicants have shown that the costs to society of not granting an authorisation are higher than the monetised risks to human health or the environment from granting an authorisation.

INFOBOX

INFOBOX: CHROMIUM TRIOXIDE USED WIDELY IN PLATING AND SURFACE TREATMENT

By the end of 2021, ECHA had received almost 3 000 notifications from industrial sites, confirming that chromium trioxide is still widely being used in plating and surface treatment with the annual use estimated to be around 7 000 tonnes in the EU.

The substance was placed on the Authorisation List in 2013 and its use has required a specific authorisation in the EU since 2017. As part of the conditions for use set in the authorisation decisions, suppliers informed the Agency by the end of 2021 about the exposure of their workers to the substances.

For the first time ever, worker exposures will be known for all EU surface treaters. And the information can be used to help companies better protect their workers by minimising exposure to the carcinogen. It will also help European authorities carry out joint enforcement actions on functional chrome plating and surface treatment.

With ECHA's scientific opinions as preparatory work, in December 2020, the European Commission granted authorisations for five uses of chromium trioxide, including functional chrome plating and surface treatment. These authorisations expire in September 2024, but authorisation holders can re-apply by submitting a review report to the Agency by March 2023.

Restrictions protect millions of Europeans from serious disease

In February 2021, ECHA published a study[39] that estimates that restricting the manufacture and use of chemicals that pose a risk would result in health benefits amounting to EUR 2.1 billion each year. Such health benefits include the reduced risk of cancers, fewer allergic skin reactions, a decrease in sexual development disorders, and less occupational asthma.

The study found that associated costs to society amount to EU 0.5 billion per year, so health benefits are four times greater than the costs. Once all the restrictions included in the study take effect, at least seven million EU citizens will be less exposed to harmful chemicals at work or in their everyday lives.

The study also estimates that restrictions prevent more than 95 000 tonnes of hazardous substances from being released into the environment annually. For example, the proposed restriction on intentionally added microplastics would prevent 500 000 tonnes of microplastic from being released to the environment over the next 20 years. Reduced emissions bring many benefits to all EU citizens, such as a cleaner environment as well as reduced chemical exposure through drinking water, food and air.

In 2021, four restriction proposals were submitted to ECHA and ECHA's scientific committees agreed on two opinions on restriction proposals.

One restriction proposed in 2021 is to introduce further EU-wide measures to restrict the use of lead in ammunition for hunting, outdoor sports shooting and fishing. Each year, around 100 000 tonnes of lead is estimated to be

39 https://echa.europa.eu/documents/10162/17228/costs_benefits_reach_restrictions_2020_en.pdf

Restricting chemicals that pose a risk reduces the exposure of millions of EU citizens and prevents thousands of tonnes of hazardous substances from being released into the environment each year.

Simone DOYLE

Head of Risk Management I

dispersed into the EU environment from these uses. This results in at least 135 million birds being at risk of lead poisoning and 1 million children significantly at risk of neurodevelopmental effects through the consumption of lead in game meat. The proposed restriction would reduce lead emissions by around 1.5 million tonnes over the two decades following its introduction.

ECHA ran a consultation from March to September 2021, inviting stakeholders to send in scientific and technical information on uses of lead within the scope of the proposal. Further to this, an online information session gave participants the opportunity to hear directly from ECHA's experts as they explained the scope of the restriction. The consolidated opinion of ECHA's Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) on this restriction proposal is expected by end-2022.

In September, RAC released its opinion on a proposal to restrict formaldehyde, polycyclic aromatic hydrocarbons (PAHs), dioxins, furans and polychlorinated biphenyls (PCBs) in single-use baby diapers. None of the chemicals seem to be deliberately added during the manufacture of diapers but are rather residues from raw materials or contaminants from ambient air. However, RAC concluded that the proposal did not provide sufficient scientific evidence to show a risk at EU level. RAC also concluded that it was not possible to completely rule out risks from some of the substances, and as such they should be kept to the lowest possible levels in diapers. ECHA's Committee for Socio-Economic Assessment (SEAC) also adopted its opinion on the costs and benefits of this proposal for society. The committee considered that the evidence available does not demonstrate that the proposed restriction would be proportionate to the risk.

SEAC also adopted its final opinion supporting a proposal to restrict certain uses of undecafluorohexanoic acid (PFHxA), its salts and related substances. This followed an earlier RAC opinion supporting the proposed restriction of PFHxA due to its persistence and mobility in the environment and the damage it can cause to the human reproductive system. PFHxA is a member of the family of environmentally persistent per- and polyfluoroalkyl substances (PFAS).

SEAC concluded that a restriction on certain uses was likely to be proportionate (for example, textiles in consumer apparel, paper and cardboard in food contact materials and cosmetic products.

The Agency also proposed to restrict the use of PAHs in clay targets used for sports shooting, partly based on the authorisation requirement of PAHs in coal tar pitch, high temperature. During preparation of the restriction, it became clear that many of the alternatives also contained PAHs and the scope was enlarged to avoid regrettable substitution. The proposed restriction is estimated to reduce emissions of PAHs (many of which have persistent, bioaccumulative, toxic and carcinogenic properties) by at least 270 tonnes per year. ECHA's scientific committees will give their opinions on this proposal in 2022.

Signs that biocidal active substance review is accelerating

Biocidal products protect humans, animals and materials from harmful organisms, pests and bacteria. The start of 2021 saw a drive to streamline the work of the Biocidal Products Committee (BPC) working groups and a reorganisation of biocides work to steer the focus towards speeding up regulatory outcomes.

With the target to complete the review of all existing biocidal active substances by the end of 2024, there are signs that our efforts to support Member States in accelerating the Review Programme have begun to pay off.

Overall, 18 competent authority reports evaluating active substances were received during the year – almost double the amount received in 2020, including cases under the Review Programme, new active substances, renewal of approval and backlog cases that re-start a peer-review phase. This has started to be reflected in an increased number of BPC opinions for active substance approvals – 18 in 2021 compared to 15 in 2020. While the number of submitted assessment reports is less than the forecast provided by competent authorities, the positive trend is expected to continue in the coming years. Progress is also seen for Union authorisations, with the number of BPC opinions on Union authorisation[40] increasing to 15, compared to 9 in 2020.

Under the Biocidal Products Regulation, scientific criteria have been adopted in 2017 to identify endocrine disruptors and all active substances under examination must undergo a formal endocrine disruptor assessment. ECHA reviewed its earlier opinions on two active substances – DBNPA[41] and cyanamide[42] – due to their endocrine-disrupting properties that had not yet been assessed by the BPC. The committee had noted their endocrine-disrupting potential in its first opinion. The case raises interesting questions on whether it is possible to establish a safe threshold for endocrine disruptors.

ECHA has proposed to bridge the assessment of endocrine-disrupting properties of non-active substances in biocidal products with the integrated regulatory strategy under REACH. Non-active substances (also known as co-formulants) included in biocidal products may also be used in many non-biocidal products and would, therefore, be subject to screening, assessment and data generation under REACH. In line with the 'one substance, one assessment' principle and to simplify actions across legislation, the adoption of this approach concerning non-active substances would avoid the duplication of similar evaluating activities and ensure that assessments of endocrine-disrupting properties are consistent under different legislative frameworks.

To protect human and animal health, and the environment, the BPR promotes the substitution of active substances that are of particular concern. The objective is to ensure that the use of these substances is restricted and they are eventually replaced by better alternatives. To achieve this, the idea of a guidance based on two pilot cases – for borates and hexaflumuron – for Member State authorities and applicants giving them step-by-step advice on how to assess alternatives was investigated in 2021. The guidance is expected to be published in 2022.

Progress also continues in harmonising the environmental assessment of active substances at EU level. In cooperation with the European Food Safety Authority (EFSA), work was initiated to evaluate common substances and draft guidance, for example, on the impact of the water treatment process on residues of active substances in drinking water, and on the risk assessment for bees and other pollinators. This work will also continue into 2022.

To harmonise and integrate risk assessment under biocides and REACH, the Agency continues to develop the Chesar Platform, combining Chesar and the EU system for the evaluation of substances (EUSES) (see 1.2.2 Helping companies to assess chemicals safety throughout the supply chain).

40 The procedure through which companies can apply for permission to place their biocidal products on the market throughout the EU, without needing specific national authorisations.

41 DBNPA is used in the food processing industry as a disinfectant and may be released into the environment when utensils are washed and rinsed. Operators and the general public may also be indirectly exposed.

42 Cyanamide is used in animal husbandry in stables to combat specific disease and prevent the growth of insect larvae.

Management

Management Board

The Management Board provides strategic direction and governance to enable the Agency to deliver its mission and vision and meet its stakeholders' expectations. In 2021, the Management Board led the mid-term review of the multiannual strategy and confirmed that ECHA's strategic direction remains largely valid, while providing guidance to the secretariat for the remaining part of the implementation period[43]. The Board furthermore requested the Commission to initiate the selection and recruitment process of the next Executive Director.

"ECHA is part a network of partners that work on common objectives. Together with our partners, we need to use resources in a smarter way, understand each others' context and ways of working, and be able to adjust where necessary.

Tasoula KYPRIANIDOU-LEONTIDOU
Chair of the Management Board ad hoc subgroup on the strategy review

The Management Board led the strategy review process via its dedicated subgroup. It analysed the status of implementation of the strategy and sought input from ECHA's regulatory partners and stakeholders from EU institutions, Member States and interest groups. On this basis, the Management Board concluded that the Agency's current strategic priorities and their enabling components remain valid. To account for the rapidly evolving policy and operational context and to reflect the learnings from the implementation of the current strategy so far, the Board identified four focus areas – deliver, explain, partner, prepare – for 2022-2023, guiding the secretariat's work to allow ECHA to continue delivering and preparing for future challenges.

Throughout the year, the Management Board closely followed how the Agency delivered additional work to support the Commission in implementing its Chemicals Strategy for Sustainability[44], including the planning for possible new and additional tasks. This allowed the Board to provide steer for the secretariat to ensure that the implementation of the work programme remains on track and that the achievement of the objectives is not jeopardised.

The Management Board adopted all statutorily required documents in line with the applicable rules and regulations, carried out the annual appraisal exercise of the Executive Director and the members of the Board of Appeal, and confirmed the Technically Qualified Member of the Board of Appeal in his functions after his probationary period. Furthermore, the Management Board appointed the new Legally Qualified Member of the Board of Appeal.

When the Executive Director announced his resignation with the intention to retire, the Management Board asked the Commission to take the necessary steps to propose a list of suitable candidates for appointing a new Executive Director. The Board closely followed the pre-selection process, conducted by the Commission, and prepared the Board's decisions with the support of its dedicated subgroup. The selection and recruitment process are expected to be finalised in 2022.

43 https://echa.europa.eu/documents/10162/10340573/final_mb_30_2021_2_report_strategy_review_mb63_en.pdf

44 https://ec.europa.eu/environment/strategy/chemicals-strategy_en

The actions taken in response to audits and evaluations, as well as the Commission's second REACH Review[45] continued to be monitored, the latter as part of the regular planning and monitoring processes.

The secretariat regularly provided the Board with reports on ECHA's activities and gave updates on progress in key operational areas. Upon request from the board, the reporting focused on foresight, risks and reports on areas where progress was less or different than expected.

Financial management

ECHA's finances continued to be managed successfully under lingering COVID-19 conditions. In the REACH/CLP part of the budget, the fee income levels continued to decline, but this was well compensated by savings in meeting and travel costs achieved through virtual meetings. For Biocidal Products Regulation (BPR) fees, the persistently high volatility and unpredictability continued. The Agency met its budget implementation targets reaching a 98 % commitment rate and an 86 % payment rate (estimates were 95 % and 80 %, respectively).

The combination of uncertain fee income and a fixed EU balancing subsidy to finance the Agency's operations again proved challenging. In 2021, ECHA's REACH fee income from industry continued to decline, following the trend observed since the last REACH registration deadline of 2018. For the BPR, after a year of running a deficit, the fee income surged well above the budgeted estimates. At the same time, there were significant expenditure savings stemming from COVID-19. Therefore, a downwards budgetary adjustment during the year was needed for all budget areas (REACH/CLP, BPR, Environmental Directives and International Conventions), and small EU subsidy amounts – EUR 1.7 million, EUR 0.3 million and EUR 0.3 million respectively – were returned to the Commission in autumn 2021.

The split between the overall ECHA fee income and EU subsidies was around 28 % and 72 %, respectively. This is in line with 2020, where the split was 31 % and 69 % but, in stark contrast with the long-term average which has seen over two-thirds of income coming from fees and one-third from EU subsidy. Therefore, ECHA is increasingly relying on the EU subsidy to finance its operations.

The European Parliament[46] and the European Court of Auditors[47] recognised ECHA's financial stability as a key aspect, while the European Commission has also acknowledged the challenges of ECHA's current financing model.[48]

The second REACH Review called on the Agency 'to assess all possible options for financing in the context of projected reduced fee income[49]. In addition to previous proposals to support a review of ECHA's financing model, with an aim to achieve better predictability and stability in its budget planning, the Agency delivered its Fee Options Analysis to the Commission and organised a joint workshop and meetings around the topic.

The initial total budgetary payment appropriations for expenditure of 2021 amounted to EUR 113.1 million (including the separately funded Other tasks amounting to 0.8 million). The final total expenditure need concluded in the second amending budget in September 2021 was EUR 111.1 million. The main reasons for the reduced budget were related to the COVID-19 pandemic that led to, for instance, reduced on-site committee meetings, decreased duty travels, and reduced building costs due to prolonged remote working. Despite the challenging financial environment, ECHA was able to secure efficient use of funds and received a clean audit opinion from the European Court of Auditors regarding its financial and procurement operations.

Details on ECHA's budget information and budget management in 2021 can be found in Appendix II.

45 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:116:FIN

46 European Parliament, Discharge 2017, European Chemicals Agency, adopted 26 March 2019: https://www.europarl.europa.eu/doceo/document/TA-8-2019-0264_EN.html?redirect

47 European Court of Auditors, Annual report on EU agencies for the financial year 2017 (2018/C 434/01 on 30 November 2018): https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2018:434:FULL&from=EN

48 In the REACH Review COM(2018) 116 final, Section 3.4 and in the Chemicals Strategy for Sustainability Towards a Toxic-Free Environment COM(2020) 667 final.

49 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:116:FIN

The commitment and resilience of our staff ensured that we could maintain high levels of performance during the pandemic and, in parallel, we are pleased that our continuous investment in a healthy, collaborative work environment resulted in ECHA being recognised as one of the Finland's most inspiring workplaces.

Shay O'MALLEY

Director of Resources

Human Resources management

Despite the challenges related to the second year of the COVID-19 pandemic, ECHA delivered on its work programme activities in an environment that was predominantly based on remote working. The implementation of the Agency's Human Resources Strategy for 2019-2023 continued, supporting the organisation to achieve its overall strategic priorities. While 97 % of establishment plan posts were filled, the turnover of temporary agents remained low at 2 %. The continuous investment in a healthy work environment that is based on collaboration, agility and a well-developed management culture led to the Agency being recognised as one of the most inspiring workplaces in Finland.

All necessary efforts were taken to maintain a high level of staff health and wellbeing. ECHA's dedicated advisory groups contributed to the changing requirements during the pandemic, whether handling health and safety matters or dealing with the specific challenges of a fully remote working environment. Teleworking was further facilitated by relaunching the reimbursement scheme for home office equipment.

We also continued to work on the priorities of the HR strategy, facilitating a high number of internal mobilities in line with our organisational culture that provides an agile and flexible working environment. A new competency base in designing targeted learning priorities for the organisation was also deployed. ECHA further invested in developing management culture by initiating a new development programme for its heads of unit as well as for its newly established senior management team.

The 2021 staff survey, which was conducted with a new service provider, had a high level of participation by ECHA staff, resulting in a response rate of 96.1 %. The People Power® rating of AA has led to the Agency being recognised as one of the most inspiring workplaces in Finland which 'signals a high employee engagement level' and that 'the organisation is an inspiring workplace where business is developed together with employees'.

As part of a wider inter-agency benchmarking exercise initiated by the Commission, we conducted a job screening exercise that aims to clarify the amount of posts spent on administrative tasks opposed to operations to ensure that there is enough staffing in operational areas.

Corporate Resources management

During 2021, ECHA applied for the EU Eco-Management and Audit Scheme (EMAS) registration, which is a premium management instrument developed by the European Commission for companies and organisations to evaluate, report and improve their environmental performance. It is anticipated that the Agency will be EMAS registered in 2022. The work performed is central to realising ECHA's vision to become an Agency with net-zero greenhouse gas emissions, as articulated in its 2030 climate neutrality pledge.

Due to the ongoing COVID-19 pandemic, the importance in ensuring effective business continuity for ECHA's operations remained high throughout 2021. Under the changing circumstances, the building, facilities and services provided, as well as home-working arrangements focused on safeguarding the health and wellbeing of employees.

While the pandemic raised challenges, there has been a sustained reduced need for building (cleaning and maintenance) and security services, resulting in cost savings, as well as some reductions in greenhouse gas emissions by the Agency.

The audio-visual services were successfully organised for all the events and official meetings in a virtual setting. During 2021, 650 virtual meetings were supported and the number of online Webex participants remained relatively similar to 2020 at 45 000.

Environmental management

Promoting the sustainable use of resources through sound environmental management is an integral part of the Agency's management system.

ECHA's Executive Director made a pledge to the Management Board[50] for the Agency to become net carbon-neutral by 2030. Our environmental work programme sets targets to decrease the consumption of natural resources, to lower waste and to reduce our carbon footprint.

Within the environmental work programme, there are three objectives that determine the actions required during 2020-2022 (2019 as the reference year) to achieve this ambition. The objectives strive for the continuous reduction of greenhouse gas emissions generated by ECHA's premises, travel by meeting participants and staff missions.

In 2021, we exceeded our targets as travel and building-related CO2 emissions were reduced because of COVID-19. This situation is expected to change once pandemic-related restrictions are lifted. Nevertheless, we will continue to take action to meet our set objectives and aim to meet our CO2 emissions reduction targets by the end of 2022. Furthermore, due to the remote working environment, staff engagement was a priority and regular information sessions and online presentations were provided throughout the year.

Finally, ECHA's ISO 14001 certified environmental management system (EMS) underwent a surveillance audit in October. Further to this and to prepare for EMAS registration, the Agency's EMS underwent an internal audit, an external environmental review and an environmental verification audit. All were completed successfully and confirmed that ECHA's EMS is fit for purpose.

IT Resources management

ECHA's IT landscape has been changing rapidly and the number of tools provided to industry, authorities and staff have grown significantly over the years. The third Enterprise Architecture Roadmap (2021-2023) has resulted in an increased integration or modularisation of the IT to support the increased integration of business processes. Dynamic Case is the centre of our regulatory work IT tooling; ECHA Interacts is the platform for interaction with authorities, including the committees; IUCLID is the base for working on chemicals data and will be the centre of a new Dissemination platform for publishing information on chemicals.

The IT tooling has continued to function and adapt to support ECHA's functioning during the COVID-19 pandemic, including providing the tooling for authorities and committees.

As experienced by many organisations during the COVID-19 pandemic, an increase in cybercrime activities has been observed, requiring an equivalent increased vigilance in IT security to keep the Agency safe. We invested in several preventative measures, but also invested further in our detection and response capabilities.

50 See point 4.c in: https://echa.europa.eu/documents/10162/29644884/FINAL_MB_M_03_2020_minutes_MB_58.pdf

In parallel, we have digitalised our workflows, which has further helped to facilitate remote working for staff. At the same time, ECHA's ability to reuse existing systems and efficiently develop them further for new tasks, as demonstrated by the SCIP development in 2020, shows that the IT infrastructure is comprehensive and advanced.

Further cooperation with EFSA also illustrates how our IT competence can be used by other regulatory agencies to manage data and carry out regulatory tasks that are similar to ours.

Litigation, appeals and complaints

Based on REACH and Biocidal Products Regulation, certain ECHA decisions can be appealed to the Board of Appeal. The EU courts decide on legal remedies against ECHA's decisions which cannot be appealed before the Board of Appeal, or decisions taken by the Board of Appeal. In 2021, the European Court of Justice and the General Court delivered 21 judgments and orders where ECHA acted either as a defendant, respondent, or an intervener in support of the Commission.

In 20 out of 21 cases, the judgment was wholly favourable to ECHA. Most importantly, the EU courts confirmed a number of ECHA and Commission decisions identifying substances of very high concern, namely the ECHA decisions concerning;

- PFBS (substance of high mobility and persistence);
- phenanthrene (vPvB)[51] ;
- D4, D5 and D6 (all PBTs/vPvBs)[52];
- Bisphenol A (endocrine disrupter to human health)[53]; and
- the Commission decision concerning the substance 4-tert-butylphenol (PTBP) (endocrine disruptor to the environment).[54]

The General Court also confirmed the Commission decision restricting the substances D4 and D5 because of their PBT/vPvB properties.[55]

In their judgments and orders the EU courts provided clarifications on a number of important issues:

- The public consultation organised by ECHA in the context of the SVHC identification process does not grant any procedural rights to interested parties (such as the right to be heard) apart from the right to provide further information on the substance to ECHA.[56]
- Confirmation of ECHA's approach for assessing the PBT/vPvB and endocrine-disrupting properties of substances in the process for identifying substances of very high concern.[57]
- In the authorisation application process, ECHA is only required to assess the hazardous properties of a substance listed in Annex XIV to REACH. Even if additional hazardous properties have been identified, they should only be considered once included into Annex XIV.[58]
- In the authorisation application process, the Commission is required to verify the absence of alternatives for uses of a substance.[59]

51 Judgment of 9 June 2021 in case T-177/19, Exxonmobil Petroleum & Chemical BVBA v. ECHA.
52 Judgment of 30 June 2021 in case T-519/18, Global Silicones Council and Others v. ECHA.
53 Judgment of 21 December 2021 in case C-876/19 P PlasticsEurope AISBL v. ECHA.
54 Judgment of 10 November 2021 in case T-661/19, Sasol Germany GmbH and Others v. ECHA.
55 Judgment of 30 June 2021 in case T-226/18, Global Silicones Council and Others v. Commission.
56 See judgment in case T-177/19 cited above.
57 See judgments on SVHC identification cited above.
58 Judgment of 6 October 2021 in case C-458/19 P ClientEarth v ECHA.
59 Judgment of 25 February 2021 in case C-389/19 P, European Commission v Kingdom of Sweden.

- In the active substance approval process under biocides, the evaluating competent authority and ECHA are normally not obliged to take into account data submitted late, on the applicant's own initiative.[60]
- In the follow-up process in dossier evaluation, registrants are entitled to submit valid adaptations in response to an ECHA evaluation decision requesting a vertebrate test. ECHA is required to assess such adaptations during follow-up. However, ECHA's follow-up decision is definitive. National authorities are subsequently required to ensure that ECHA's decision is enforced and complied with.[61]
- All acts published by ECHA on its website (including its Board of Appeal decisions and Candidate List decisions) must be challenged within two months and 10 days from the date of publication.[62]

The composition of the Board of Appeal was partially renewed in 2021 with the appointment of a new technically qualified and a new legally qualified member. At the same time, the Board of Appeal adopted 15 decisions in appeal cases brought against ECHA decisions. In those decisions, the Board of Appeal addressed important aspects of ECHA's processes including the following:

- ECHA must take into account a tonnage downgrade during the compliance check process as it may constitute substantial new information that affects the applicable information requirements.[63]
- A registrant who ceases manufacturing or importing a substance remains bound to information requirements of a preceding compliance check decision, but cannot be requested to provide any other additional information.[64]
- Dossier evaluation decisions must be addressed to all registrants of the same substance in the relevant tonnage band who have not opted out of sharing data on the relevant information endpoint.[65]
- Registrants can submit testing proposals based on read-across adaptations, but it remains the responsibility of those registrants to show that the adaptation is valid.[66]
- The lifecycle of a monomer does not include its presence in polymers for registration purposes. However, a registrant of a monomer who seeks to rely on an exposure-based adaptation in its registration has to provide information on exposure to the monomer after polymerisation if it seeks to rely on an exposure-based adaptation in their registration.[67]

The Agency received 23 external administrative complaints in 2021. The work area affected most by complaints was biocides active substance approval (7 complaints). Other complaints concerned data submissions, the Waste Framework Directive, access to documents, SME verification, substance identity assessment, provision of data and data sharing. Within the integrated management system of the Agency, all complaints have been analysed and followed up resulting in corrective actions, where appropriate.

60 Judgment of 15 September 2021 in cases T-337/18 Laboratoire Pareva v. Commission and T-347/18 Laboratoire Pareva and Biotech3D Ltd & Co KG v. Commission.

61 Judgment of 21 January 2021 in case C-471/18 P, Federal Republic of Germany v ECHA

62 Order of 17 March 2021 in case T-160/20, 3M Belgium bvba v ECHA, and Orders of 8 June 2021 in cases T-663/20 and T-664/20, One Voice v. ECHA.

63 A-006-2020 and A-007-2020, BASF Colors & Effects and BASF

64 A-009-2020, Polynt.

65 A-016-2019 to A-029-2019, Lubrizol France and Others.

66 A-016-2019 to A-029-2019, Lubrizol France and Others; A-014-2019, LG Chem Europe; and A-015-2019, Polynt.

67 A-001-2020, SNF.

Audits and evaluations

Internal Audit Service

The Internal Audit Service (IAS) did not conduct a specific audit during the year, focussing on the preparation of the strategic audit plan for 2022-2024.

The follow-up of the past audit on '*Integrated regulatory strategy: screening, evaluation and regulatory management option analysis', from 2020*, assessed the progress in view of the recommendations and concluded that all recommendations can be closed.

The IAS has also closed the remaining open recommendations from the follow-up audit on performance management conducted in 2020, following the review of the processes by the Agency.

Internal Audit Capability

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

The first audit assessed the '*identification and evaluation of environmental aspects at ECHA*' resulting in three desirable recommendations only.

The second audit covered the '*planning, monitoring and reporting (PMR) process of the Agency*', resulting in five important recommendations:

- Re-discuss the purpose, added value and consistent use of the planning, reporting and monitoring process as well as the available tools. Embed planning and monitoring of ECHA's strategic priorities to the PMR process when the strategy indicators are reviewed/agreed.
- Redefine the objectives and usability of the unit level planning (ULP) process according to the organisation's needs.
- Redefine the use of the PPO time-recording tool and enhance acceptance of its use.
- Enhance monitoring of planned vs actual fulltime equivalents (FTEs) and ULP objectives and indicators during the year.
- Develop further ECHA-level main PMR products, reporting to the Management Board and Directors' Meeting.

The third audit regarding the *biocidal active substances approval (under the Review Programme) -process* resulted in 1 very important recommendation – to improve assessment of alternatives – and four important recommendations:

- Contribute to acceleration of the active substance approval process
- Improve working methods during active substance approval process
- Improve data management
- Improve stakeholder feedback mechanisms

The Agency follows up these recommendations with corresponding actions.

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

European Court of Auditors

In their statement of assurance[68], the European Court of Auditors (ECA) concluded that the accounts of the Agency for the financial year 2020 present fairly, in all material respects the financial position of the Agency at 31 December 2020, 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 2020 either. There are two actions of the ECA's audits from previous years (2017-2019) ongoing, that are however, recognised as outside of the Agency's control. These are related to:

- launching a discussion with the Commission and Budgetary Authority about a viable new financing model; and
- the fact that two-thirds of companies do not update the registered information on volumes of chemicals, which however is the responsible of the Member States to verify.

Follow-up of observations from the discharge authority

For the discharge 2020, the Secretariat of the European Parliament Committee on Budgetary Control asked all EU Decentralised Agencies for a follow-up report to the 2019 budgetary discharge to be submitted by 17 September 2021.

The report[69] provides an overview of the relevant observations and recommendations from the European Parliament Resolution of 29 April 2021 on the discharge in respect to the implementation of the budget of ECHA for the financial year 2019, together with the measures ECHA has taken in light of these. For completeness, replies to the comment accompanying the Council's Recommendation of 5 February 2021 on the discharge of the Agency for the financial year 2019 are also included.

On 29 April 2021, the European Parliament also adopted the resolution on discharge in respect of the implementation of the budget of the European Union agencies for the financial year 2019: performance, financial management and control (2020/2194(DEC)). This resolution is a horizontal report containing recommendations and observations that accompanied the individual 2019 discharge reports for each of the agencies and joint undertakings.

The follow-up actions to these recommendations were a collective response from the EU Agencies Network, through which ECHA contributed, and will be presented in a separate report being prepared by the Agency chairing the EU Agencies' Network.

In summary, there were 23 recommendations in total from both the European Parliament and the Council, out of which 8 have been completed.

Ex-ante and ex-post evaluations

In 2021, ECHA performed the strategic assessment of the '*EU Chemicals Legislation Finder (EUCLEF)*', as an external review of the service. The review concluded that EUCLEF is meeting its objectives with a high degree of effectiveness, and that the objectives remain relevant for stakeholders.

68 https://www.eca.europa.eu/lists/ecadocuments/agencies_2020/agencies_2020_en.pdf

69 European Chemicals Agency report on the follow-up to the 2019 budgetary discharge: https://echa.europa.eu/documents/10162/10611501/mb_47_2021_follow-up_discharge_recommendations_2019_en.pdf/f7cbee1a-7271-6b45-27dd-d8b68b1204d0?t=1642577221394

The use of EUCLEF has increased over time and there is a high degree of user satisfaction. It also found strong support for the inclusion of additional pieces of EU legislation in the scope of the finder, which would strengthen its role as a one-stop shop for SMEs in need of information on chemical laws. The review found that the complexity of the project has been carefully managed in terms of the feasibility study and procurement approach and provided recommendations which could contribute to the development of EUCLEF and increase its usefulness.

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

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

Internal control – system effectiveness

Risk management

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

For most risks, the levels remained relatively stable and for some a declining trend was observed. No critical risks materialised during the year.

Transparency, accountability and integrity

Throughout 2021, 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 2021, the first version of the SCIP database was released, providing information on approximately 7 million articles containing substances of very high concern (SVHCs). ECHA also expanded the EU Chemicals Legislation Finder (EUCLEF), adding 16 further pieces of legislation, allowing users to see how their substances are regulated across EU legislation. EUCLEF now covers 56 pieces of chemicals legislation.

Prevention of conflicts of interest

Policy update

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

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

If there is a potential conflict, the case is assigned to a different staff member. The approach is documented in detailed work instructions and guidance is available for those managing the interests to help them deal with individual cases. As a result, no cases of actual conflicts of interest affecting the output of the Agency were identified in 2021.

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.

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 2021, 22 staff members left ECHA: 7 of them went to work for another EU institution, body or agency. One staff member moved to a national public administration or international organisation. Nine staff members moved to the private sector or started self-employment and in three of these cases the Agency deemed it necessary to impose specific conditions due to the nature of the occupational activity or the role of the individual within their new occupation.

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

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

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.

No changes occurred in the composition of the CoIAC in 2021. The Committee comprises three members: Ms Judite Dipane, appointed by the Management Board of ECHA, Mr Julio Bacio Terracino from the OECD ethics department, appointed as an external expert, and Ms Minna Heikkilä, Head of ECHA's Legal Affairs Unit as Chairperson.

At the request of the Executive Director, the CoIAC provided its advice in the context of one specific recruitment process. On 22 October 2021, the CoIAC convened for its annual meeting where this advice to the Executive Director was agreed. The CoIAC in its meeting further took note of the ongoing activity of the European Ombudsman in various 'revolving doors' cases.

At the request of the Chair of the Management Board, the CoIAC has further given advice on two cases relating to the Board of Appeal. In line with the ECHA Procedure on Prevention and Management of Potential Conflicts of Interest, the Chair of the Management Board appointed an ad hoc member to replace the CoIAC Chairperson who does not participate in matters relating to the Board of Appeal.

Ex-post controls

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

A sample check on 36 annual declarations submitted by the members and observers of the ECHA Management Board revealed that all of them were in place, updated during the last year, publicly available and sufficiently complete. For four declarations, the interests of family members were redacted for privacy reasons, but confirmed as available to the secretariat and reviewed by the Chair. For one declaration, a clerical error was detected and addressed.

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[70] 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[71], last revised by the ECHA Management Board in December 2016, includes a focus on maintaining and further developing the anti-fraud culture in the Agency and regularly reviewing key policies and procedures.

Data protection

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

In 2021, the areas of activity concerned mostly contractual arrangements for cloud solutions procured by the Agency, the measures take to address COVID-19, the medical files kept by the Agency, the publication of personal data on the website and the balancing act with transparency obligations, and four personal data breaches that occurred in ECHA or organisations working with 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 2021, fire safety and evacuation training for all corporate services staff was organised. In addition, separate training sessions were organised for service providers in ECHA's premises.

The Emergency Rescue Plan was updated and communicated to the Helsinki Rescue Authorities. ECHA's emergency procedures were audited as part of the preparations for EMAS registration. Radiation safety training was organised for ECHA's Radiation Safety Officer by the Finnish certified training organisation.

Finally, the Agency received two requests for support from the EU Agencies Security Network on security management. The Corporate Services Unit provided input to a request on travel risk management services and provided advice to another Agency about technical support on security scanning devices.

70 https://echa.europa.eu/documents/10162/13559/code_of_good_administrative_behaviour_en.pdf

71 https://echa.europa.eu/documents/10162/2200151/mb_50_2016_echa_anti-fraud_strategy_en.pdf

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

ECHA organised the 18th Security Officers Network (SON)[72] annual meeting on 10th November 2021, where the topics of the new Identity Management Tool, IT and IT-security implications of the Chemicals Strategy for Sustainability, and security challenges and improvements in ECHA were presented and discussed.

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

The objective of the Integrated Management System Strategy[73] is to enable ECHA's strategic priorities to be achieved by ensuring a flexible and performance-based governance, well adapted to its priorities and ECHA's operational structure, while simultaneously recognising the legislative framework within which ECHA operates. It covers the quality and environmental management, conforming to the internationally recognised ISO 9001 and ISO 14001 standards and it is based on the Internal Control Framework of the Commission.

The strategy is supported by the framework, detailing the common principles and characteristics to be implemented in ECHA's operational and governance processes. The progress towards the achievement of the strategy is measured annually, based on the criteria stipulated in the framework. The assessment also ensures the periodic assessment of the sound functioning of the internal control system, required under Article 30 of ECHA's Financial Regulation.

Based on the internal controls assessment of year 2021, overall, ECHA is either fully or mostly compliant with the requirements of the Integrated Management System Framework and is implementing the Integrated Management System Strategy well.

In terms of costing the controls, the Agency follows the definition in the General Financial Regulation[74] of the EU, according to which 'control' means *'any measure taken to provide reasonable assurance regarding the effectiveness, efficiency and economy of operations, the reliability of reporting, the safeguarding of assets and information, the prevention and detection and correction of fraud and irregularities and their follow-up, and the adequate management of the risks relating to the legality and regularity of the underlying transactions, taking into account the multiannual character of programmes as well as the nature of the payments concerned.'*

Controls may involve various checks, as well as the implementation of any policies and procedures to achieve the objectives. Based on an approximation of the resources deployed in the units responsible for governance, HR 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 3.5 %.

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

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

73 ECHA Integrated Management System Strategy and Framework (POL-0001): https://echa.europa.eu/documents/10162/0/pol_0001_07_man_system_strategy.pdf

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

Governance

Mission and vision

- ECHA's mission and vision are well aligned to its strategy and the needs of external stakeholders and communicated to them.
- Ethical and organisational values
- ECHA's management is aware of and upholds the Agency's values through their own behaviour, working methods and decision making.
- ECHA is overall perceived as a transparent organisation.
- Further improvement needed in areas such as "recognition of staff work" and "open communication and involvement".

Management responsibility

- Management is committed to the management system and it continues to achieve its intended outcomes.
- Good progress in meeting the estimates set by the environmental indicators.
- Management needs to further promote a higher risk appetite and ensure further staff empowerment in particular in lower risk areas.

Human resources

- Highly qualified and competent staff in place to carry out the current tasks.
- Decreased staff turnover and high staff motivation.
- Need to invest in organisation development, competences and agility of staff and future-proofing ways of working in particular due to the continuous onboarding of new tasks.

Stakeholder and partner engagement

- ECHA engages well with stakeholders in particular when onboarding new tasks.
- ECHA maintains an open and transparent two-way dialogue with the Agency's regulatory partners and stakeholders.
- Need for better targeting the communication to the key stakeholders' audiences in particular from the perspective of the impact of ECHA activities.
- Good to re-consider communication around sensitive topics, such as animal welfare, generating most of the media negative coverage.

Strategy, planning and risk management

Priorities planning and resources allocation

- Agency's strategic direction, as set out in its Strategic Plan 2019-2023, remains largely valid after the mid-term strategy review led by the Management Board.
- Good to continue enhancing ECHA's collaboration with partner authorities and institutions and share expertise in an impactful manner.
- Need to consider the planning-monitoring-reporting-evaluation cycle in view of ensuring clear priorities on the core work, strengthening the link between strategic and annual priorities and the way they are cascaded

and executed at operational level. Need to re-consider the purpose and benefits of planning-supporting tools, such as PMR tool for managing the ULP, PPO and corporate metrics.

- Need to secure long-term sustainability of ECHA's portfolio of new and existing tasks and ways of working, thus easing the pressure on ECHA and the committees in delivering core regulatory outputs.

Risk management

- Well-structured and integrated corporate risk management exercise.
- Higher risk appetite of Management for further process simplifications.
- Good to continue awareness raising in the area of cost-risk-benefit analysis aiming to increase the risk tolerance of staff and support efficient decision making at the right level.

Operations and operational structure

Activity management

- ECHA's activities and process management allow internal and external synergies.
- Better alignment needed between ECHA's activities, processes and their interactions with ECHA's strategic priorities, thus aiming to clearly define the outcomes, expected performance, efficiency and impact.

Information and data management

- Overall progress under the data strategy; the opportunities and risks with the new EU data platform need to be further analysed.
- ECHA transitioned from on-site to remote work practice without suffering any reduction in the quality of service.
- Synergies within the legislation ECHA already implements, where re-using existing IT platforms for onboarding of new tasks, resulted in economies of scale.
- Increased number of security threats without any major security incident or leakage of confidential information.
- Need to consider alternative ways for contract management in order to prevent drops in the reliability and availability of the IT systems operated by contractors.

Change management

- Flexibility and adaptability demonstrated by the constant onboarding of new tasks often without corresponding resources.
- Need to be ready for changes in ECHA's tasks by making targeted and focused investments in IT, data and processes, as well as in organisation development, competences and agility of staff and future-proofing ways of working.
- Need to re-evaluate and maintain the functioning of the committees, with a view to their current and expected workload.

Evaluation and improvement

Performance management

- Overall, ECHA's performance-based structures ensure reliability of reporting, accuracy, completeness and

timeliness of data.

- Need to re-consider the way ECHA phrases its efforts around efficiency in public documents, especially due to the long-term experience in process improvements, digitalisation of workflows and process measurements at the Agency.
- Need to explore alternative ways, such as using the IRS data on the chemical universe, together with inter-agency data, combined with some general statistics in order to show ECHA's impact on human health and environment.
- Need to consider alternative ways to explore the outcome and impact of ECHA's enablers on the strategic priorities.
- Need to continue raising awareness in particular on the root cause analysis, continue searching for synergies in the management of nonconformities and external complaints and re-assess the process for considering improvement proposals.

Assessments, audits and evaluations

- Overall, Directors and Management Board has adequate tools in its disposal to oversee the effectiveness, adequacy and suitability of the Agency's Integrated Management System.

Strategy for efficiency gains

ECHA's Integrated Management System Strategy and Framework is designed to enable the achievement of ECHA's strategic priorities by ensuring a flexible and performance-based governance. By implementing the framework, ECHA's processes are intended to be effective and efficient by design, taking into account the level of related risks and controls needed. Efficiency is not viewed simply as producing more but producing smarter.

Specific targets have not been seen necessary, as the continual improvement is an integral part of the management system and the Agency is following the efficiencies gained through several means, including:

- Trend in the results for the indicator type 'performance' across activities;
- Outcome of the annual assessment of the Integrated Management Systems Strategy and Framework qualitatively with regard to any potential efficiency initiatives;
- Results from efficiency projects/initiatives in operational activities and IT undertaken throughout the year.

ECHA makes continuous progress also in view of the integrated regulatory strategy, as the grouping approach matures, and respective processes are further developed and there are also ongoing discussions at EU level on how to improve risk management activities, for example, authorisation.

ECHA views IT as key enabler for the regulatory work that it carries out. The availability of all data in digital format ensures accessibility and automation in the processing.

The streamlining of the organisational design and decision making continued and efficiency gains have been achieved by investing in automation and improving workflows, while supporting the introduction of additional pieces of legislation. Efficiency gains have also been delivered through re-engineering and automation of operational and support processes. Almost all workflows have been entirely digitalised, and many have been transformed to self-service, with workflows and controls built into the digital flow.

Concrete achievements in 2021 include, for example, an 'Envelope' feature in the accounting system (ABAC) that significantly facilitates the processing of financial transactions (commitments and payments), as well as budgeting itself, in particular for the administrative expenditure. With this, less time is needed to process individual transactions and at the same time the risk of errors is reduced as the breakdowns do not have to

be calculated manually anymore. The PEPPOL[75] is also used more and more to receive invoices in electronic format so that they are entered automatically in the accounting system, reducing the efforts needed to handle and archive the invoices, as well as facilitating data entry. ECHA has turned its attention to developing means to manage IT, and in 2021 the delivery of a new platform enabled an improved alignment between the different business processes and contractors working on software development projects, and enabled the application of common practices.

Review of the elements supporting assurance - assessment by management

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

The assessment considered a broad range of input[76] and will feed into the Management Review 2022, 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 2022.

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.

75 Pan-European Public Procurement On-Line (PEPPOL) enables trading partners to exchange standards-based electronic documents, like invoices, over the Peppol network

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

Declaration of assurance by the Authorising Officer

I, the undersigned,

Bjorn HANSEN

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 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 31 March 2022

SIGNED

Bjorn HANSEN

Executive Director

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

We, the undersigned,

Shay O'MALLEY
Director of Resources

and

Frank BÜCHLER
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 31 March 2022

E-SIGNED

Shay O'MALLEY
Director of Resources

E-SIGNED

Frank BÜCHLER
Head of Unit Governance, Strategy and Relations

Appendices

Appendix I – Actions, outputs and indicators

Table A. Actions and outputs

In its Work Programme 2021[77], the Agency established the actions and outputs for each of its activities. 214 actions have been carried out and all outputs have been achieved, except for 2. 18 actions and outputs are ongoing or partially met:

Main actions and outputs specified in the Work Programme 2021	Achieved	Additional information/ Explanation
1.1 Registration dossier preparation		
Data generation and compliance		
Update of ECHA's IT tools and support materials in line with regulatory developments, such as the amendment of the REACH information annexes [Joint Action Plan Actions 5 and 6]. [2021, 2022]	Ongoing	Outputs expected in 2022-2023 due to the timing of the REACH Annex amendments and human resource limitations.
Support and promote the implementation of the Commission implementing regulation on dossier updates [REACH Review Action 1] with actions, such as screening and support materials, including screening of dossiers that remained without updates and seek collaboration with the national enforcement authorities on cases of potential breaches of the dossier update obligation. [2021, 2022]	Yes	
Implement actions to improve dossier compliance ahead of submission. [2021, 2022] [REACH Review Action 1] [REACH Review Action 14]	Yes	
Provide advice to registrants related to registration and preparation of complete and compliant registration dossiers taking into account the specific obligations after the end of the transition period of the UK withdrawal from the EU. [2021, 2022]	Yes	
Run a study on circular economy and chemical recycling to better understand current status of the various chemical recycling processes and the potential consequences on registration (or exemptions of registration) and what happens with the presence of SVHCs in these processes. [2021]	Yes	
Data sharing		
Develop and implement an effective policy regarding the possibility for registrants to use data submitted more than 12 years ago without compensation pursuant to REACH Articles 25(3) and 26. [2021]	Yes	
Handle disputes on data sharing. [2021, 2022]	Yes	
IUCLID		
Ensure progressive maintenance of IUCLID to incorporate (international) regulatory requirements (e.g. adaptations to new requirements following the amendment of REACH Annexes, other technical and scientific progress under REACH and CLP such as the PCN format or requirements from our OECD international partners). In close collaboration with the OECD, further position IUCLID at the heart of the Global Chemicals Knowledge Base that is under development. [2021, 2022]	Yes	

77 As part of the Programming Document 2021-2024 available at: https://echa.europa.eu/documents/10162/9930002/final_mb_20_2021_PD_21_24_rev_en.pdf

Main actions and outputs specified in the Work Programme 2021	Achieved	Additional information/ Explanation
Cloud Services		
Finalise by Q1/2021 the assessment of the (financial) feasibility of an approach for ECHA Cloud Services whether it should become the sole delivery model for IUCLID and whether other tools (e.g. Chesar) or services could be added to facilitate and speed up interaction with the registrants in particular on data availability and compliance. The report to the Management Board will be drawn up in cooperation with stakeholders. [2021] [REACH Review Action 14]	Yes	
Chesar and exposure tools		
Maintain version 3 of Chesar so that it remains available to registrants as the mainstream tool for preparing chemical safety reports (CSRs) under REACH, providing support to ensure new CSRs are generated with an appropriate level of quality and updated where relevant. [2021, 2022] [REACH Review Action 1] [REACH Review Action 3]. In parallel, continue developing a new risk assessment tool which harmonises assessments under both REACH and biocides, including the establishment of a scientific governance for the methodologies used by the tool. This development will take place under a merged Chesar/ EUSES project [2021, 2022] and will ultimately replace version 3.	Yes	
Determine which exposure information is used in REACH evaluation to reach a decision and is needed in REACH restrictions and authorisation to obtain an opinion and based on that consider what further exposure tool development work is needed. [2020, 2021	Yes	
Promotion of alternative methods		
Contribute to OECD activities related to further development of alternatives and integration of regulatory relevant alternatives in the OECD test guidelines. [2021, 2022]	Yes	
Jointly coordinate and contribute to an activity together with US EPA and Health Canada to further investigate the use new alternative methods in regulatory processes (jointly with activity 1.3). [2021]	Yes	
Promote alternatives to animal test methods through the OECD QSAR Toolbox, e.g. by integrating developed adverse outcome pathways or extending its applicability to other types of substances (jointly with activity 1.3). [2021, 2022]	Yes	
1.2 Dossier submission		
Process the continuous flow of registration dossiers (new and updates). Perform completeness checks, including manual verifications with a revised scope that covers the chemical safety report; and assess confidentiality requests. [2021, 2022] [REACH Review Action 1]	Yes	
Apply the approach developed in 2019 to the SME size verification to complete the verifications of the 2018 registrations deadline by 2023. [2021, 2022]	Yes	
Provide input to the Commission on the review of the Commission Recommendation concerning the definition of micro, small and medium-sized enterprise. [2021, 2022]	Yes	
Revoke registrations to prevent inactive operators from having access to the EU single market. This is particularly relevant due to the end of the transition period after the UK withdrawal from the EU. [2021]	Yes	
Process PPORD notifications and monitoring high level indications for innovation and new kind of substances.	Yes	
Ensure the further development and maintenance of REACH-IT, including increased usability (migration of online dossiers to ECHA cloud services and C&L automated notifications), the end of the 12-year data protection rule and new functionalities to support Evaluation. Further assess REACH-IT technical upgrade and explore future alternatives. [2021, 2022] [REACH Review Action 1, 2, 14]	Yes	

Main actions and outputs specified in the Work Programme 2021	Achieved	Additional information/ Explanation
Support to Forum in its work assisting inspectors during the operational phase of the pilot project on exemption for recovered substances and preparing the project report. [2021, 2022]	Yes	
1.3 Screening and prioritisation		
Identification and prioritisation of groups of substances for all REACH/CLP processes:		
Identify groups of substances and screen them to identify cases for further information generation and regulatory risk management. [2021, 2022]	Yes	
Prioritise the groups for screening with the view of concluding, without delay, for substances registered above 100 tonnes/y if they are i) of priority for regulatory risk management, ii) currently of low priority for further regulatory action, or iii) need more data for a judgement to be made. The status of this work will be presented through the so-called 'chemical universe' which has for the first time been published end of 2019 and will be refreshed in spring 2021. Automation of the refresh in 2021 to enable more frequent updates from 2022. [2021, 2022] [REACH Review Action 2] [REACH Review Action 8]	Yes	
Based on the experience gained on petroleum stream substances, expand the learnings to progress on further hazard information generation and initiating regulatory risk management actions on other substances of concern due to presence of hazardous constituents and impurities. [2021, 2022]	Yes	
Continue together with Member State competent authorities using the most appropriate approaches to generate hazard information and initiate regulatory risk management action, where necessary, on the groups of substances. Continue targeted collaboration with industry (sectors). [2021, 2022] [REACH Review Action 2]	Yes	
To enhance the implementation of the integrated regulatory strategy continue supporting the alignment of the views and optimising the way the collaboration and sharing of work between authorities is implemented. To this end, continue optimising the collaboration structures (e.g. RIME+). [2021, 2022] [REACH Review Action 2]	Yes	
Publish the annual report on the implementation of the Integrated Regulatory Strategy. [2021, 2022]	Yes	
Development of approaches:		
Further increase transparency and predictability of the authorities work by increasing information on groups of substances on the website. [2021]	Yes	
Based on the experience gained with working on groups of substances since 2019 across tonnage bands, further develop the grouping and group management approaches and harvest the results of the information generated and assessed to adapt the work for the substances registered in lower tonnage bands. [2021]	Yes	
Further develop high throughput new approach methodologies (NAM) in cooperation with ECHA's international partners. This shall allow developing novel, effective regulatory means to inform prioritisation, classification, evaluation, risk assessment and risk management of chemicals and have a positive impact on the level of compliance with information requirements. Following the finalisation of the collaborative project of Tier 1 (in vitro assays and modelling), Tier 2 (NAM enhanced in vivo short-term verification studies) will be initiated followed by preparation for Tier 3 (NAM enhanced in-vivo longer-term regulatory studies). [2021, 2022] [REACH Review Action 2]	Yes	
Augment the registration data with external sources containing in vivo and in vitro (eco)toxicological information, results from predictive models and chemical safety data exchanged with other authorities (e.g. Canada, US EPA). [2021,2022]	Yes	

Main actions and outputs specified in the Work Programme 2021	Achieved	Additional information/ Explanation
Endocrine Disruptor (ED), PBT and Nanomaterial (NMEG) Expert groups work:		
Reach scientific agreement among Member States on general issues and case specific questions, hereby facilitating decision making under REACH, POP, CLP and Biocides. This entails further improvement of interfaces between evaluating Member State Competent Authority, Expert Groups and the MSC. [2021, 2022]	Yes	
ED Expert Group: Gain experience in the implementation of endocrine disruptor identification guidance based on the increasing number of cases in substance evaluation, SVHC candidate listing and biocides. It will align the practice with ED identification for plant protection products in EFSA and assess the need for guidance updates. [2021, 2022]	Yes	
PBT Expert Group: Progress in methodological approaches for PBT testing of difficult and UVCB substances. [2021, 2022]	Yes	
PBT Expert Group: Support development of methodologies for addressing substances that are Persistent, Mobile and Toxic (PMT) substances. [2021, 2022].	Yes	
NMEG: Provide a forum for methodological approaches for testing substances in the nanoform to MSCAs and stakeholders. [2021, 2022]	Yes	
NMEG: Provide support of the nanomaterials guidance updates. [2021, 2022]	Yes	
Other items - Work with industrial sectors to improve the information basis and to support the sustainability efforts of industry as well as authorities' work:		
Continue the work with industrial sectors to address in particular petroleum and coal stream substances and metal UVCBs. [2021]	Yes	
Completion of the postponed work on outstanding technical and methodological issues in line with the agreement signed with the metals sector (MISA). Continue monitoring updates of hazard and risk assessment in registration dossiers and subsequent risk management of metals and inorganics. [2021] [REACH Review Actions 1, 14]	Yes	
Support to the implementation of the action plan of the EU chemical's industry on pro-actively reviewing and updating registration dossiers in line with the cooperation agreement signed. Participate to expert discussions on scientific and technical challenges, support industry in disseminating learnings from these discussions and, for a limited number of cases, provide feedback to testing strategies proposed by industry. [2021, 2022] [REACH Review Action 1]	Ongoing	Cefic-ECHA Dossier Improvement Programme ongoing, ECHA supporting IND in collaboration with Cefic in workshops and providing feedback on selected groups proposed by companies.
1.4 Evaluation		
Compliance check industry dossiers for the higher-tier hazard endpoints for substances of potential concern in the higher tonnage bands (over 1000 tonnes dossiers and 100 1000 tonnes dossiers) or groups of substances of concern containing at least one such substance. [2021, 2022] [REACH Review Action 2; Joint Action Plan Action 4]	Yes	
Examine testing proposals included in the registrations from the 2018 deadline by 1 June 2022 and any new testing proposals within the legal deadlines. [2021, 2022] [REACH Review Action 2]	Yes	
Nanomaterials: Compliance check dossiers updated with the additional requirements for substances in nanoforms with an initial focus on substance identity and justifications for sets of nanoforms, and examine testing proposals within the legal deadlines [2021, 2022].	Ongoing	Assessments of substance ID and justification for sets ongoing, draft decisions under development.

Main actions and outputs specified in the Work Programme 2021	Achieved	Additional information/ Explanation
Examine the compliance of any information submitted in consequence of ECHA's dossier evaluation decisions with the decision. Communicate to the Commission and Member State competent authorities the conclusions made, as well as inform the concerned national enforcement authorities in case of non-compliance with the decision. Where appropriate, draft follow-up decisions. Ensure that the information submitted and any conclusions made are used, through ECHA's integrated regulatory strategy, to identify substances that may need regulatory action to better protect human health and environment. [2021, 2022] [REACH Review Action 2]	Yes	
Ensure, together with Member States, that substance evaluation contributes in an effective manner to the implementation of the integrated regulatory strategy. This entails updating the CORAP with substances for which substance evaluation is the most appropriate tool to generate further hazard information, in line with the outcome of screening and prioritisation based on the grouping approach; it may result in a lower number of substance evaluation cases comparing to previous years, as data relevant for regulatory risk management could be generated to a large extent through compliance check. Applying compliance check in parallel with substance evaluation will be considered where appropriate. [2021, 2022] [REACH Review Action 2, Joint Action Plan Action 10]	Yes	
Ensure together with the Member States that the substance evaluation is concluded as fast as possible to enable initiating appropriate regulatory risk management measures; the aim is to reduce the number of substance evaluation cases currently opened. [2021; 2022]	Yes	
Report on the progress made in evaluation as part of the report on the Integrated Regulatory Strategy and publish the updated recommendations to registrants stemming from evaluation. [2021, 2022] [REACH Review Action 2]	Yes	
Contribute to the Caracal sub-groups in support of the Commission in their policy activities. This concerns: 1) Amendment of the REACH information annexes in accordance with the Joint Action Plan [Joint Action Plan Actions 5 and 6] [2021, 2022]; 2) Information requirements for polymers requiring registration; 3) Legislative and policy issues in relation to endocrine disruptors. [2021, 2022].	Yes	
Continue verification of compliance with good laboratory practice requirements for (eco)toxicological tests analysis. This entails requesting targeted study audits in case a concern about compliance with principles of good laboratory practice is identified by ECHA or a Member State. [2021, 2022] [REACH Review Action 2]	Yes	
Progress the scientific and technical review of the received extended one-generation reproductive toxicity studies in collaboration with the Member State Competent Authorities to inform the Commission on the possible need to revise the relevant REACH information with regard to this issue annexes. [2021, 2022] [REACH Review Action 2]	Yes	
Update ECHA Guidance on information requirements, based on the Commission's decision to revise the REACH information annexes in accordance with the Joint Action Plan [2022]. When updating reflect the latest developments in methodologies for substances in nanoforms. (Human health [2021]; Environment [2021, 2022])	Yes	
Provide regulatory advice to registrants and other interested parties on information requirements including on nanoforms of the substances and on dossier and substance evaluation processes. [2021, 2022] [REACH Review Action 2, Joint Action Plan Action 15]	Yes	

Main actions and outputs specified in the Work Programme 2021	Achieved	Additional information/ Explanation
1.5 Authorisation		
MSC decides on the identification of SVHCs. An increasing proportion of SVHC dossiers are expected to cover groups of substances, substances with a complex composition and PBTs and EDs. An increased involvement by the respective expert groups and the MSC is therefore expected. The identification process is adapted to make further use of the identified improvements in the interfaces between dossier submitters, Expert Groups and the MSC. [2021, 2022]	Yes	
Provide a well-founded Annex XIV recommendation. [2021]	Yes	
RAC and SEAC deliver fit-for-purpose quality opinions, providing sufficiently detailed scientific justification of all elements as requested by REACH with about 50 opinions for substances that have endocrine-disrupting properties, another 50 opinions for substances with other properties as well as evaluate the substitution plans of 12 applicants if they have suitable alternatives available in general. The opinions will be sent to the Commission. [2021, 2022]	Yes	
Work with the Commission and Member States in implementing the results of the improvement activities identified under Action 6 of the REACH Review (simplification for a more workable authorisation process) and other suggestions for improvement in the subsequent Review. [2021, 2022]	Partially	ECHA implemented the work process for "legacy spare parts". However, there was no work carried out to improve the so called "upstream" applications
Taking into account the feedback received from the Commission, Member States, European Parliament, General Court as well as industry and non-governmental stakeholders continuously improve the authorisation process. This comprises, inter alia, the updating of application and opinion formats to ensure fit-for-purpose quality and consistency, provision of technical and scientific support to RAC and SEAC rapporteurs during opinion making, the assessment of the suitability of alternatives in general and for the applicant as well as active participation in Application for Authorisation Task Force. [2021, 2022] [REACH Review Actions 6, 10]	Yes	
Support the Commission during the decision making on authorisations. [2021, 2022]	Yes	
Carry out market research to estimate the substitution effort taken and the likely number of applications to be received to plan well the opinion making process. [2021, 2022]	Yes	
Develop further the analysis of alternatives activities under the Network of REACH SEA and Analysis of Alternatives Practitioners (NeRSAP) and hold one or two meetings to improve the knowledge and skills of European applied economists, providing analysis in regulatory settings for restrictions or in applications for authorisation. Hosting NeRSAP in 2021. Joint activity between restrictions and applications for authorisation. [2021, 2022] [REACH Review Actions 8, 9]	Ongoing	Due to COVID-19, ECHA was not able to host NeRSAP in 2021. It plans to do so in 2022.
Provide web-based training to interested stakeholders on analysis of alternatives and informed substitution from substances subject to regulatory risk management. Joint activity between applications for authorisation and restrictions supporting substitution [2021, 2022] [REACH Review Action 5]	No	Due to constraints in staff resources, this activity was not completed.
Provide timely notes on methodological questions, including socio-economic issues. [2021, 2022][REACH Review Action 6]	Yes	
ECHA will provide timely and transparent support to applicants and authorisation holders through a streamlined process, including teleconference-based information sessions, updated information documented in, for instance, updates of the Guidance document, practical guide, application formats, 'reference' DNELs and dose-response relationships of substances. [2021, 2022]	Yes	

Main actions and outputs specified in the Work Programme 2021	Achieved	Additional information/ Explanation
Support to Forum in preparing the ninth coordinated enforcement project (REF-9) on authorisation and supporting inspectors during the operational phase. The lessons learnt will be communicated, including those learnt from the downstream user notifications. [2021, 2022]	Yes	
1.6 Restrictions		
Work with the Commission in implementing various improvement activities identified under Actions 8 to 11 of the REACH Review to improve the restriction procedure as such and enhance the Member State involvement in it. Continue to speed up the screening of substances on the Authorisation List (Annex XIV) for REACH for action under Article 69(2). [2021]	Yes	
Submit fit-for-purpose restriction proposals or restriction reports to address the identified concerns for (groups of) substances, as requested by the Commission, or for substances of very high concern used in articles, addressing the specific aspects of groups of substances where appropriate. Support to the Member States to identify candidate and prepare restrictions, for example, in pre-restriction information and support meetings and in restriction workshops. [2021, 2022] [REACH Review Actions 8, 9, 10, 11]	Yes	
Timely, targeted and fit-for-purpose opinions on submitted restriction proposals. Consider further options on how to better express uncertainties in the RAC and SEAC opinions. [2021, 2022] [REACH Review Actions 8, 10]	Yes	
Provide web-based training to interested stakeholders on analysis of alternatives and informed substitution from substances subject to regulatory risk management. Joint activity between applications for authorisation and restrictions supporting substitution. [2021, 2022] [REACH Review Action 5]	Partially	The RTF has worked on a paper on best practice in Analysis of Alternatives during 2021. The final paper has been integrated in the Fit-4-Purpose guidance document, which will be made available on ECHA's website during early 2022.
Additional capacity building for Member States, RAC and SEAC on regulatory impact assessment, in particular on methods used in socio-economic analysis relevant for restrictions or in applications for authorisation. [2021, 2022] [REACH Review Actions 5, 9]	Partially	See above
Develop further the analysis of alternatives activities under the Network of REACH SEA and Analysis of Alternatives Practitioners (NeRSAP) and hold one or two meetings to improve the knowledge and skills of European applied economists, providing analysis in regulatory settings for restrictions or in applications for authorisation. Hosting NeRSAP in 2021. Joint activity between applications for authorisation and restrictions. [2021, 2022] [REACH Review Actions 8, 9]	Ongoing	Due to COVID-19, ECHA was not able to host NeRSAP in 2021. It plans to do so in 2022.
Further develop methodologies related to socio-economic analysis in particular in the context of the OECD. This comprises both the valuation of health and environmental endpoints and learning lessons from regulatory risk management cases in different OECD member countries. [2021, 2022]	Yes	
Based on initial work carried out in 2020 of indicators that would allow for an ex-post evaluation of the most relevant impacts of restrictions further develop these and find ways of getting annual information of substances based on the EU market. The insights will help in improving the preparation of restriction proposals by ECHA and Member States and in making the restriction process more effective. [2021, 2022]	Yes	
Continue to provide input to the opinion making processes of other EU agencies or committees with a view to explaining ECHA's opinions and understanding the reasons for any differences. [2021]	Yes	

Main actions and outputs specified in the Work Programme 2021	Achieved	Additional information/ Explanation
Together with the Commission and Member States, compare ECHA's guidance on socio-economic analysis of restrictions with the Commission's Better Regulation guidelines and adapt where possible and necessary. [2021]	Ongoing	Due to staff resource constraints this was not carried out.
When developing new restriction proposals, ECHA integrates better, where relevant, circularity and sustainability aspects, including possible trade-offs, to the analysis with view of learning from this experience. [2021, 2022]	Ongoing	This was planned relative to an expected dossier to follow up the lead in PVC restriction, which is now due on 2022.
Support the Commission, stakeholders and enforcement authorities to clarify the existing restriction entries by developing public Q&As. [2021]	Yes	
1.7 Classification and Labelling		
Process incoming CLH dossiers and the upward trend in industrial chemicals from the outcome of screening and prioritisation based on the grouping approach as well as the continued high number of PPP and Biocides dossiers resulting from the joint Commission, EFSA and ECHA efforts to encourage timely submission of dossiers. [2021, 2022]	Yes	
Continue to develop the CLH dossier submitter support package with a guidance document and a Workshop to help Member States in preparing fit-for-purpose dossiers in an efficient manner. [2021]	Yes	
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 the work of selected GHS working groups, notably the working group on the use of non-animal testing methods for classification. [2021, 2022]	Yes	
Improve the visibility and clarity of the information in the C&L Inventory to make the C&L data more accessible and facilitate the analysis of the data for any purpose (see also Dissemination section (1.9)). [2021, 2022]	Ongoing	The re-design of the C&L Inventory was postponed in the context of the overall decision to halt any major integration and investment into the current Dissemination platform. The work will be resumed under a new Data availability platform. See activity 1.9.
Update the CLP guidance, to reflect changes in information requirements as well as updates to reflect revised practises in applying criteria and to ensure consistency in decision making; starting with the environmental sections and then the human health sections. [2021, 2022]	No	The guidance work was put on hold to be able to support CSS work.
Poison Centres Notification portal		
Consolidate standard formats and tools (product categorisation system) and notification (PCN) format) and revise guidance for the poison centres notifications according to the new Commission Regulation amending the CLP Regulation adopted in 2020. [2021, 2022]	Yes	
Maintain the Unique Formula Identifier (UFI) generator [2021, 2022]	Yes	
Ensure further development and maintenance of the notification portal and system-to-system submission channel to provide the features to support the reception and processing of the notifications received with the 2021 first compliance date as well as communication, including the development of group submission, removal of product, support multi-component submissions and alignment with IUCLID. [2021, 2022]	Yes	

Main actions and outputs specified in the Work Programme 2021	Achieved	Additional information/ Explanation
Continue to develop the searchable central database, to be used by the national appointed bodies and Poison Centres, based on the Commission's mandate, the outcome of the consultation initiated in 2019 and the feedback from national authorities on the use of the database. [2021]	Yes	
Continue the promotion of the PCN activities with duty holders and consumers. [2021, 2022]	Yes	
1.8 Safe and sustainable use of chemicals		
Concerning substances in articles:		
Work further on the strategy to support a safer use of chemical substances in articles, including any specific questions arriving via the Commission in relation to the development and implementation of the Circular Economy policy [2021, 2022]	Partially	Relevant progress made via related work on the SCIP database, Assessment of Regulatory Needs (for articles) and Article 69(2) restrictions' screening. Strategy development postponed due to human resource constraints.
Based on the activities carried out in 2020 , define further work for 2021. [2021, 2022]	Yes	
Concerning substitution, ECHA will, subject to the availability of resources, carry out its substitution activities coordinated with the Commission as well as any other activities of EU in this field:	Yes	
Help Member States and other stakeholders in the organisation of substitution collaborative supply chain workshops. [2021, 2022] [REACH Review Action 5]	Yes	
Continue providing input to the work performed at the OECD level on safe and sustainable chemistry and disseminate the outcomes. [2021, 2022]	Yes	
Support the relevant services of the Commission, when requested, to promote the enhancement of EU financial and technical support for substitution and safe and sustainable innovation. [2021, 2022]	Yes	
1.9 Data management and dissemination		
Data management		
Identify a data strategy and implement actions prioritised in it, which includes integrating different data sources and facilitating the re-use of REACH, CLP, and BPR data as well as other sources as relevant. [2021, 2022]	Yes	
Further invest in the consistency of substance identity information to allow for unambiguous reference of registration data and making links to other legislations and data sources, among other for dissemination of regulatory lists and in the EU Chemicals Legislation Finder (EUCLEF). [2021]	Yes	
Promote the common usage of data by interested parties, in cooperation with other EU agencies, particularly EFSA, aiming for a higher level of consistency. [2021, 2022]	Yes	
Continue to provide data analysis services as a response to internal and external requests for example supporting the implementation of the Implementing Regulation on dossier updates or the review of information requirements for low tonnage substances [2021, 2022]	Yes	
Dissemination		

Main actions and outputs specified in the Work Programme 2021	Achieved	Additional information/ Explanation
Implement the Data availability roadmap according to agreed priorities and resources. Integrate new and existing data sources into the dissemination portal such as the revamp of the C&L inventory, PIC data, and the public version of the SCIP database, to achieve a robust and sustainable publication solution. Increase visibility of substances in regulatory processes and implement the reviewed publication policy of registration data. [2021, 2022]	Partially	The majority of the activities foreseen by the Data availability roadmap were postponed following the overall decision to halt any major integration and investment into the current Dissemination platform due its continuous failures. In this context the re-design of C&L Inventory was postponed; the PIC dissemination solution is ongoing with limited scope; the public version of the SCIP database went live; very limited integrations from regulatory processes only to support IRS work. Work is ongoing to establish a new Data availability platform where planned developments can be taken up.
Pursue the analysis and development of approaches to make data available in machine-readable formats for effective data exchange across systems, facilitating on-boarding of new tasks and integrated data management and collaboration. [2021, 2022]	Yes	
Maintain and further develop the OECD Global Portal to Information on Chemical Substances (eChemPortal). Maintain the synchronisation of the eChemPortal with ECHA's dissemination website. [2021, 2022]	Partially	Access to ECHA's Biocidal Active Substance dissemination data from the OECD eChemPortal was established end of October 2021. Submission of REACH data to the eChemPortal is stopped since the end of 2020 but work is ongoing to resume the process in 2022.
2. Biocides		
The support provided by ECHA to MSCAs to accelerate the review programme include: specific advice and guidance with special attention to the assessment of ED criteria, direct or indirect support in different sections of the assessment (e.g. exposure, substance identity, toxicological assessment), best practices and simplification of approaches (e.g. focused assessment of safety and efficacy, improved synergy with REACH and CLP), guidance to harmonise confidentiality assessment. ECHA also contributes to the MSCAs capacity building by providing training and may provide advice in priority setting, planning and relationship with applicants. [2021, 2022]	Yes	
Support the Member State competent authorities in the preparation of complementary BPC opinions on the endocrine-disrupting properties of active substances evaluated before June 2018 following the request by the Commission. Ten such opinions have been adopted in 2020 and the remaining 6 opinions are foreseen for in 2021. [2021, 2022]	Ongoing	ECHA has supported MSCAs in the evaluation phase. MSCAs have submitted only two assessment reports for opinion making in late 2021 for adoption in 2022.
Support the Member State competent authorities in the preparation of BPC opinions on the early review of already approved active substances (according to Article 15) following the adoption of the endocrine-disrupting criteria. Such opinions are foreseen to be requested by the Commission for at least three active substances. [2021, 2022]	Yes	
Improvements in the analysis of alternatives as part of BPC opinions based on the experience gained in a pilot project started in 2020. [2021]	Yes	

Main actions and outputs specified in the Work Programme 2021	Achieved	Additional information/ Explanation
Support the Member State competent authorities in the preparation of BPC opinions on the renewal of the approval of active substances. [2021, 2022]	Yes	
Support the Member State competent authorities following the requests from Commission for Article 75(1)g opinions on active substances and Union Authorisation. [2021, 2022]	Yes	
Support the Member State competent authorities with the identification of potential endocrine-disrupting properties for biocidal active substances and biocidal products under evaluation, including scientific advice from the Endocrine Disruptor Expert Group and the provision of training. [2021, 2022]	Yes	
Support the Member State competent authorities in the preparation of BPC opinions on Union authorisation of biocidal products, with a special emphasis on the efficiency of the opinion-forming process and the coordination between Member States competent authorities dealing with related applications. In addition to enabling the evaluating competent authorities to deliver their assessment in a timely manner, identifying and addressing issues during this phase and ECHA proposing harmonised approaches, facilitates the finalisation of the peer review phase within the challenging 180-day timeline. [2021, 2022]	Yes	
Set up a functional interface and synergies between the assessment of endocrine disruptor properties of non-active substances in biocidal product authorisation and the screening and assessment of same substances in a group approach under REACH. [2021]	Yes	
Prepare ECHA's opinions on Union authorisation of same biocidal products and on administrative and minor changes to Union authorisations. [2021, 2022]	Yes	
Timely perform assessments of applications for technical equivalence, inclusion in the Article 95 list and classification for changes. [2021, 2022]	Yes	
Support the Member State competent authorities in the checking of the translations of summaries of product characteristics for the Union authorisation of biocidal products. [2021, 2022]	Yes	
Support the Member State competent in preventing and resolving disagreements in the mutual recognition process and in harmonising the practices for biocidal product authorisation. [2021, 2022]	Yes	
Prepare the BPC opinions requested by the Commission according to Article 38 BPR on scientific and technical questions related to mutual recognition disagreements and derogations to mutual recognitions. [2021, 2022]	Yes	
Support in the development of a new tool combining EUSES and CHESAR to harmonise assessments under both REACH and BPR (see REACH Activity 1.1) that was started in 2020 is foreseen to continue until 2022. [2021, 2022]	Yes	
The development of IT support tools (in particular ECHA Interact) and their integration to facilitate the work of Member States competent authorities during the peer review phases for active substances and Union authorisation is foreseen to be resumed in 2022 after a pause in 2021. Notwithstanding the possibility to address short term critical needs that will be considered in 2021. [2022]	Yes	
Assess the feasibility of extending dissemination to cover the full assessment reports of active substances. [2021]	Ongoing	The feasibility assessment has been initiated and is ongoing, foreseen to be finalised in 2022.
Revision of BPR guidance Volume I to IV in line with the amendments to the Annexes II and III of the BPR. [2021, 2022]	Yes	

Main actions and outputs specified in the Work Programme 2021	Achieved	Additional information/ Explanation
Cooperation with EFSA where appropriate and in particular within the framework of the assessment of endocrine disruptors to seek high level of harmonisation and alignment, including cooperation in related procurements. [2021, 2022]	Yes	
Cooperation with EFSA with the aim to develop common guidance document (e.g. impact of water treatment processes on residues of active substances in drinking water) and complementary guidance documents (e.g. guidance document on bees for biocides). [2021, 2022]	Yes	
Handle disputes on data sharing. [2021, 2022]	Yes	
ECHA will provide input to the Commission for its report to the European Parliament and Council on the implementation of the Biocidal Products Regulation (2021).	Yes	
Support to BPRS in preparing the manual and assisting inspectors in the operational phase of the second Forum-coordinated BPR enforcement project (BEF-2) on approved substances in biocidal products. [2021, 2022]	Yes	
3.1 Prior Informed Consent		
Process a continuously increasing number of notifications and related tasks such as stakeholder support. [2021, 2022]	Yes	
Produce and publish the annual report on PIC exports and imports. [2021, 2022]	Yes	
Provide scientific and technical support to the Commission as regards the listing of substances in the PIC Regulation and in notifying the Rotterdam Convention Secretariat. [2021, 2022]	Yes	
Support the Commission in their participation to the 10th Conference of the Parties to the Rotterdam Convention [2021], the regular meetings of the designated national authorities and the international capacity building activities. [2021, 2022]	Yes	
Based on the outcome of the stakeholders' consultation on PIC dissemination, further adapt PIC data publication to ECHA's dissemination portal improving the visibility and clarity of the information published and performing the necessary technological upgrades. [2021, 2022]	Yes	
Maintain ePIC and further develop it to increase the efficiency of the process by facilitating the work of DNAs, exporters, Commission and ECHA secretariat. [2021, 2022]	Yes	
Manage the changes arising from the UK withdrawal from the EU and the implementation of Protocol on Ireland and Northern Ireland. [2021, 2022]	Yes	
3.2 Persistent organic pollutants		
Support to the Commission when the EU or another party proposes substances for inclusion in the Stockholm Convention and related work. [2021, 2022]	Yes	
Ensure that the platform for data submission and reporting by the Member States is provided in a timely manner [2021]	Partially	The completion of the platform is postponed, while the Agency has obtained data from Member States.
3.3 Waste Framework Directive		
In close interaction with the Commission, Member States and interested parties establish a database of articles containing Candidate List substances that industry will need to notify to ECHA as from 5 January 2021. This may include exploring the possible exchange of non-confidential data in a structured format with the AskREACH project that focusses on final, off-the-shelf products for consumers once the SCIP database has been filled with data. [2021]	Yes	

Main actions and outputs specified in the Work Programme 2021	Achieved	Additional information/ Explanation
Raise awareness and provide support to duty holders to allow any EU suppliers of articles to submit the required information to ECHA. [2021]	Yes	
Plan for and implement the necessary tools for providing access to information in the database to "waste treatment operators" and to consumers once this has been made available by industry. [2021]	Yes	
3.4 Drinking Water Directive		
Compile the existing national positive lists based on the notification by competent authorities. [2021]	Yes	
Develop an approach to prioritise the substances on the existing national lists for review under the operational phase. [2021, 2022]	Yes	
Draft the information requirements for and the risk assessment methods used in preparing the applications. [2021, 2022]	Yes	
Prepare a proposal for the procedure from the submission of the applications until the opinion of the Risk Assessment Committee is submitted to the Commission. Develop the IT infrastructure needed to support the process. [2021, 2022]	Ongoing	A high-level process model has been developed and IT contractors have been onboarded. Work will intensify in 2022
3.5 Support to the 8th Environmental Action Programme of the EU		
Management and consolidation of databases. [2021, 2022]	Yes	
Provision of chemical data in order to complete the respective emerging risk reports and contribution to chemical policy indicators and other inputs to EEA's work. [2021, 2022]	Yes	
4.1 EU Observatory for Nanomaterials		
Update the EUON website, incorporating feedback from the ongoing customer insight project [2021]	Yes	
Update the EUON search tool with new search features to further integrate the content from national nanomaterial inventories and improve integration with data from REACH dossiers. [2021]	Yes	
Continue to promote the EUON via different channels to increase its outreach to a wide variety of audiences. [2021, 2022]	Yes	
Perform a technology upgrade to the NanoData knowledge base. [2021, 2022]	Yes	
4.2 EU Chemicals Legislation Finder		
Launch version 1.2 of EUCLEF covering 16 additional pieces of legislation. [2021]	Yes	
Run the corresponding helpdesk. [2021, 2022]	Yes	
Run external review on whether EUCLEF meets its original objectives and suggest a way forward. [2021]	Yes	
4.3 Support to occupational health legislation		
At the Commission's request and based on a service level agreement, RAC issues opinions, based on the preparatory work by the Secretariat, to underpin the Commission's possible proposals for occupational exposure limit (OEL) values. [2021, 2022]	Yes	
Process the two opinions on OELs received in the second request and initiate the process for a further five opinions foreseen in the third request. [2021, 2022].	Yes	
4.5 Interaction with other legislation		
Sustaining active input to the review of the Best Available Techniques Reference documents (BREF) under the Industrial Emissions Directive [2021, 2022]	Yes	

Main actions and outputs specified in the Work Programme 2021	Achieved	Additional information/ Explanation
Continue supporting the Commission services in implementing the chemicals related parts of the ecolabel and eco-design schemes. [2021, 2022]	Yes	
Contribute to EFSA's work to re-evaluate the risks related to plasticisers used in food contact materials, in particular, by identifying, grouping and prioritising substances for further work. [2021]	Yes	
4.6 IUCLID for EFSA		
Agree on the follow-up of the pilot on IUCLID for plant protection products. [2021]	Yes	
Assess applicability of IUCLID to other food regulated products [2021, 2022].	Ongoing	This will be further assessed as part of the shared project work with EFSA in 2022 (specifically for food contact materials as synergies are expected with the Drinking Water Directive activities).
Support EFSA in defining the target IT architecture and level of support required by EFSA to perform its regulatory work. Estimate resources and compensation mechanisms. Establish and start the execution of a new Service Level Agreement for implementation and regular service accordingly [2021, 2022].	Yes	
4.7 Partnership for the Assessment of Risk from Chemicals (PARC)		
Develop and implement 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. [2021, 2022]	Yes	
Contribute to the development of a framework with clear decision criteria to enable transparent decision making for the prioritisation of activities within PARC. [2021, 2022]	Yes	
Support the development of annual work plans by steering the process of review of the projects submitted. [2021, 2022]	Yes	
5.1 Support to Forum		
Continue preparing, executing and reporting on Forum-coordinated REACH enforcement projects described in other sections of this document. In particular select the subject of eleventh Forum-coordinated REACH enforcement project (REF-11). [2021]	Yes	
Prepare the report of the eighth Forum-coordinated REACH enforcement project (REF-8) focusing on internet sales of chemicals and a guide for enforcement based on the experience gathered in that project. [2021, 2022]	Yes	
Prepare the manual for the tenth Forum-coordinated REACH enforcement project (REF-10), on REACH and POP restrictions on hazardous substances in various mixtures and articles, and support inspectors during implementation phase. [2021, 2022]	Yes	
Continue establishing best practice in enforcement and testing enforcement approaches by running Forum pilot projects. [2021, 2022]	Yes	
Continue to examine enforcement proposals and deliver advice on enforceability of restrictions. [2021, 2022]	Yes	
Continue to ensure efficient and timely enforcement of ECHA decisions, such as non-compliance with ECHA's dossier evaluation decisions. Make best use of data and expertise to maintain interlinks between ECHA regulatory processes and national enforcement. [2021, 2022]	Yes	
Continue to support enforcement authorities by developing and delivering training programmes for national trainers and inspectors. [2021 (BPR only), 2022]	Yes	

Main actions and outputs specified in the Work Programme 2021	Achieved	Additional information/ Explanation
Continue to support enforcement by the national enforcement authorities via improvement and thereafter maintenance of the IT tools available to inspectors (modules of ECHA Interact Portal for National Enforcement Authorities). [2021, 2022]	Yes	
Prepare a guide for enforcement focusing on imported substances and articles in cooperation with customs authorities. [2021]	Yes	
5.2 Board of Appeal		
Process and decide on appeals following decisions of the Agency related in particular to dossier evaluation and substance evaluation, as well as decisions adopted under the BPR. [2021, 2022]	Yes	
Adopt procedural decisions in appeal cases, as needed. [2021, 2022]	Yes	
Publish a robust body of high-quality decisions online, thereby facilitating proper implementation of REACH and BPR, and strengthening the trust of different ECHA stakeholders in that regard. [2021, 2022]	Yes	
Provide clear, accurate and timely communication to the parties in appeal proceedings and to the interested public in relation to appeal process. [2021, 2022]	Yes	
5.3 Management		
Complete the follow-up of the actions and recommendations relevant to the Agency arising from the Commission's 2018 REACH Review evaluation that remained open. [2021]	Yes	
Support the Management Board in performing its duties, through the preparation of plenary and working group meetings and the administration of all relevant procedures. [2021, 2022]	Yes	
Prepare and coordinate the activities of the senior management team, including management strategies, decisions, delegations and policies. [2021, 2022]	Yes	
Support strategic alignment with Member States' priorities on policies relevant to ECHA's mandate. [2021, 2022]	Yes	
Develop the Agency's relationship with institutional (policy) stakeholders of the European Parliament and the Commission. [2021, 2022]	Yes	
Seek synergies and align, where appropriate, on strategic and/or work programme level with peer agencies working in the area of health and environmental protection. [2021, 2022]	Yes	
Steer relationships with peer agencies on strategic matters, including active participation and leadership of the EU Agencies' Network. [2021, 2022]	Yes	
Coordinate the Agency's international activities. [2021, 2022]	Yes	
Continue to develop and implement ECHA's change management agenda following the organisational review process, to continue adapting and improving ECHA's performance. Streamline ECHA's integrated management and internal control systems to support ECHA operations while successfully maintaining relevant ISO standards [2021, 2022]	Yes	
Complete a mid-term review of the Strategic Plan 2019-2023 to take account of ECHA's current operating environment and new EU strategies taking into account stakeholder perceptions. [2021]	Yes	
Review external communication channels for better targeted communication and activate inter-institutional collaboration to maximise outreach. Revamp ECHA websites to take into account the various needs of different stakeholder groups. [2021, 2022]	Yes	

Main actions and outputs specified in the Work Programme 2021	Achieved	Additional information/ Explanation
Manage the Agency's reputation by: gathering feedback on the Agency's performance, including on new activities, from stakeholders through surveys and by daily media and social media monitoring; and acting on the feedback received. [2021, 2022]	Yes	
Maintain sound managerial overview of the various implemented regulations and delegated tasks, to achieve maximum integration, synergy of shared services and transparency of performance. Support activities initiated under Strategic Priority 3 ensuring recognition of ECHA's competences, knowledge and expert advice, as well as data held to support the efficient on-boarding and implementation of other pieces of legislation and policy areas related to the safe use of chemicals. [2021, 2022]	Yes	
Perform audits and evaluations in line with the annual audit plan, and act on the feedback generated. [2021, 2022]	Yes	
Complete preparation for ECHA's five-year report on the operation of the REACH Regulation under Article 117(2) as input to the Commission's five-year general report. [2021]	Yes	
Follow-up and bring to maintenance mode ECHA's relations with the UK as a third country after its withdrawal from the EU. [2021, 2022]	Yes	
Review and refine in Q1/2021 in consistency with establishing a new monitoring and reporting framework under the 8th EAP (see section 3.5 above) performance indicators for chemicals with a view of measuring effectiveness, efficiency and impact for priorities and activities allowing for a quantitative and qualitative assessment. [2021]	Yes	
5.4 ICT		
Plan and prepare the establishment of replacement framework contracts for HR management system as well as for REACH-IT, ECOMOD, IUCLID, SPC Editor, R4BP, ePIC, ECHA Cloud Services, IDM, Data Management Platform, Scientific Data Analysis Platform, Text Analytics, Printing Services and others. An important focus is to ensure continuity in operations in the most cost-effective manner. [2021]	Yes	
Continue to evolve the workplace service to ensure an appropriate service for ECHA staff, adjusting to the demands of a more mobile workforce, triggered by COVID-19 situation. [2021, 2022]	Yes	
Complete the overhaul of the Identity and Access Management solution in order to prepare for the continued expansion of ECHA's user base. [2021]	Yes	
Managing and maintaining IT security on ECHA infrastructure, systems and data while worldwide IT threats are continuously increasing, becoming more sophisticated and are more difficult to remediate. Ensuring appropriate security is in place for an increasingly mobile workforce. [2021, 2022]	Yes	
Updating the approach to IT business continuity service to the needs of ECHA, addressing the changes in ICT infrastructure and increased use of cloud services. [2021]	Yes	
Implement the targets agreed in Enterprise Architecture 2020-2023 and IT Master Plan. [2021]	Yes	
Prepare the roadmap for the future of the ICT infrastructure services, including an analysis of the use of public cloud as an approach to be more cost efficient. [2021, 2022]	Yes	
Ensure that services can continue to be run at the required level of quality, in an efficient and cost-effective manner, by continuously investing in evolving the tools and practices. [2021, 2022] [REACH Review Action 15]	Yes	
5.5 Financial resources		

Main actions and outputs specified in the Work Programme 2021	Achieved	Additional information/ Explanation
Prepare the Agency's budget and manage its implementation, including budget amendments and transfers, revenue collection and cash management, procurement and contracting, financial accounting and reporting. [2021, 2022]	Yes	
Continue regular exchange with Commission partner services, including reporting on actual budget implementation, communicating revenue and expenditure estimates for the future and discussing ways of handling any shortfall or surplus during the budget year. [2021, 2022]	Yes	
Examine, with the European Commission, alternative options for ensuring sustainable financial model for ECHA in particular with a view to the Multiannual Financial Framework of the EU (2021-2027). [2021, 2022] [REACH Review Action 15(1)]	Yes	
Monitor and report on transfer of fees to Member States and prepare updates to the related Management Board rules. [2021, 2022]	Yes	
Implement further efficiency measures, including automation and financial process re-engineering as part of the financial management information system development. [2021, 2022]	Yes	
Working with the Commission, and based on the available data since 2007, conduct a thorough analysis on the correlation between the fees and charges paid registrants and the workload of the Agency per regulatory activity and propose scenarios of adjustments to the current fees and charges systems to the Commission in Q1/2021. [2021]	Yes	
5.6 Human resources		
Implement ECHA's human resources strategy to continue to ensure high-quality services to staff and optimal use of its human resources. [2021, 2022]	Yes	-
Provide relevant competence development activities to ensure continuous capacity-building of staff and support more flexible deployment of staff. [2021, 2022]	Yes	
Ensure efficient allocation of resources by providing sufficient staffing to the identified priority areas. [2021, 2022]	Yes	
Support the Agency staff in adapting to the new ways of working. [2021]	Yes	
Conduct the job screening exercise as part of a wider inter-Agency benchmarking exercise initiated by the Commission. [2021, 2022]	Yes	
Maintain positive relations and dialogue with ECHA's Staff Committee, the European School of Helsinki and other key stakeholders. [2021, 2022]	Yes	
Conduct necessary management development actions to ensure a high level of people management by ECHA and to maintain a healthy working culture throughout the Agency. [2021, 2022]	Yes	
Implement the agreed action plan to advance gender balance in ECHA's management team and at organisational level. [2021, 2022]	Yes	
Implement, in close consultation with senior management, the agreed approach to decrease the number of interims engaged by the Agency [2021, 2022]	Yes	
5.7 Corporate services		
Ensure operations under the responsibility of Corporate Services continue to run smoothly following the transition to the new premises and investigate alternative modes of service delivery, while striving to reduce building and other service-related costs and environmental impact. [2021, 2022].	Yes	
Implement further efficiency measures and improvements in services delivery models following the move to the new building. [2021, 2022].	Yes	

Main actions and outputs specified in the Work Programme 2021	Achieved	Additional information/ Explanation
Monitoring the settling-in phase in the new building. [2021]	Obsolete	Maybe required post COVID as we adapt to new ways of working.
Developing and implementing approaches to new ways of working and related infrastructure and service needs. [2021]	Yes	
Implement environmental aspects of ECHA's integrated management system. [2021]	Yes	

Table B. Indicators

Work Programme 2021 workload drivers and performance indicators	Type	Estimate	Actual
1.1 Registration dossier preparation			
Effective working time for processing inquiries	Performance	0.35 person day/ inquiry	0.27 person day/ inquiry
Inquiries received and concluded	Output	4 200	4 611
1.2 Dossier submission			
Number of PPORD notifications	Input	340	335
Number of C&L notifications received	Input	25 000	31 151
Registration dossiers received (incl. updates)	Input	13 500	14 928
Effective working time for processing a registration dossier (first submission)	Performance	0.60 – 0.70 person days	0.33 person days
Registrations stopped for manual verification at technical completeness check	Input	5 800	5 716
Number of registrations failing first technical completeness check	Output	1 860	1 388
Share of registration dossiers over 100 tonnes in the database that has passed the enhanced technical completeness check	Outcome	48 %	52 %
1.3 Screening and prioritisation			
Number of substances registered above 100 t/y for which a conclusion on potential regulatory follow up was drawn	Outcome	tbd	410
Number of groups of substances taken into the screening process	Outcome	70	71
1.4 Evaluation			
Compliance checks concluded: draft decisions or no action[78]	Output	300	300
Final decisions on dossier evaluation (testing proposals and compliance checks)	Output	300	443 TPE: 165 CCH: 278
Number of substances for which a conclusion was reached in the follow-up to dossier evaluation	Outcome	200	327
Substance evaluation final decisions issued	Output	15	10

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

Work Programme 2021 workload drivers and performance indicators	Type	Estimate	Actual
Number of substances for which a conclusion was reached in substance evaluation	Outcome	15	31
1.5 Authorisation			
Number of new entries in the Candidate List	Output	15	12
Recommendation for inclusion of substances in the authorisation list	Output	1	1
Cumulative number of downstream user notifications of authorised uses of SVHCs	Outcome	3 000	3 448
Number of RAC and SEAC opinions adopted on applications for authorisation (number of uses)	Output	50	53
Effective working time of ECHA staff per opinion	Performance	38-46 person days	37.5 person days
Applications for authorisation received (number of uses)	Input	60	22
1.6 Restrictions			
Number of RAC and SEAC opinions on restriction proposals	Output	2	2
Restriction proposals 69(1) or reports developed under Article 69(2)	Output	4	2
Effective working time of ECHA staff per opinion (ECHA dossier)	Performance	240-290 person days	n/a[79]
Effective working time of ECHA staff per opinion (Member State dossier)	Performance	Approx. 200 person days	Approx. 185 person days
1.7 Classification and labelling			
Number of RAC opinions on proposals for harmonised classification and labelling	Output	65	61
Decisions made on requests to use alternative (Article 24)	Output	40	22
Effective working time for processing RAC opinions	Performance	45-55 person days	49.7 person days
Proposals for harmonised classification and labelling	Input	70	49
1.9 Data management and dissemination			
Number of user page views for published information on chemicals	Outcome	48.0 M	32.9 M
Description and number of data requests	Outcome	Internal:60	
External:30	Internal: 73		
External: 19			
Average time taken for publication (days)	Performance	3	3[80]
2. Biocides			
Number of BPC opinions on active substances approval	Output	38	18
Number of BPC opinions on the renewal of active substances approval	Output	4	0
Number of BPC opinions on Article 15, Article 38 and Article 75(1)(g) requests	Output	20	3
Number of BPC opinions on Union authorisations for biocidal products	Output	26	15
Number of ECHA opinions on Union authorisations (same biocidal products, administrative and minor changes)	Output	36	21

79 ECHA did not submit own opinions in 2021.

80 To 14 Oct 2021, after which publication was stopped due to the annual adaptation to the IUCLID format changes. Publication is planned to resume in February – March 2022.

Work Programme 2021 workload drivers and performance indicators	Type	Estimate	Actual
Support actions on evaluation of Active substance approvals	Output	23	11
Support actions on evaluation of Union authorisation applications	Output	3	3
3.1 Prior Informed Consent (PIC)			
Scientific and technical support provided to the Commission, EU and non-EU DNAs	Output	3 600	3 550
Export notifications processed (validated, rejected, resubmissions)	Output	13 200	10 699
Share of notifications validated/accepted by ECHA	Outcome	90 %	95 %
4.1 EU Observatory for Nanomaterials			
All traffic to EUON websites	Input	70 000[81]	125 287
4.3 Support to occupational health legislation			
Number of OEL requests received under SLA	Output	3-5	5
Number of RAC opinions on OELs completed	Output	2	2
5.1 Forum			
Number of enforcement trainers trained by the Forum	Output	25[82]	365[83]
5.3 Management			
Areas where audits and evaluations results (including prevention of conflicts of interest and fraud) have been taken into account in future strategic decisions	Intermediate impact	4	4
Combined neutral and positive feedback monitored in media publications	Outcome	>90 %	93.7 %
Website unique visitors/traffic to the web content	Outcome	4.0 million	13.3 million
5.5 Financial resources			
Level of budget implementation: commitment rate and cancelled carry-over rate	Performance	Min. 95 %, max. 5 %, respectively	98 % and
2 %, respectively			
Processing of payments within legal deadlines	Performance	No less than 99 %	99 %
5.6 Human resources			
Percentage of Establishment Plan posts filled	Performance	95 %	97 %
Turnover of Temporary Agents	Performance	<5 %	2 %
Turnover of Contract Agents	Performance	<10 %	3 %

Appendix II - Budget implementation reports and statistics on financial management

Budget overview

The initially budgeted total payment appropriations for the Agency's expenditure in 2021, as concluded by the Management Board in December 2020, amounted to EUR 113.1 million, which included c. EUR 0.8 million for the separately budgeted Other tasks, and the final total expenditure, concluded in the amending budget in September 2021, amounted to EUR 111.1 million. The primary reason for this net budget reduction during the year was the REACH expenditure savings of c. EUR 3.3 million, primarily relating to the COVID-19 pandemic, leaving room for reducing the REACH subsidy need by EUR 1.7 million, even after projecting a decline in fee

81 Traffic to the EUON's main site.

82 25 is the estimate of BPR trainers. Estimate assumed that onsite training could be organised in Helsinki.

83 365 covers both BPR trainers and inspectors who attended the online BPR training in 2021.

income by EUR 1.6 million. Similarly, there were also BPR expenditure savings, which led to reducing the EU subsidy need by EUR 0.3 million. Furthermore, the budget and the EU subsidy was reduced by c. EUR 0.3 million for the 'Environmental directives and international conventions', as the adoption the legal basis for the 8th Environmental Action Programme (8EAP) took longer than originally foreseen. Finally, the budget for the Other tasks was increased by almost EUR 2.0 million.

Revenue	Initial voted budget	Amending budgets	Final voted budged
Total revenue	113 053 087	(1 961 796)	111 091 291
Expenditure	**Initial voted budget**	**Amending budgets**	**Final voted budged**
Commitment appropriations	111 434 085	(705 259)	110 728 826
Payment appropriations	113 053 087	(1 961 796)	111 091 291

Revenue

The budget funding of ECHA in 2021 consisted of the following (amounts in EUR):

Description	Initial voted Budget 2021	Budget Amendments 2021	Final voted Budget 2021	Entitlements established 2021	Revenue received 2021
Fees and charges from Registrations & Updates	24 374 616	(428 330)	23 946 286	24 669 712	24 669 712
Fees and charges from Authorisations	2 400 000	(1 200 000)	1 200 000	1 123 928	1 123 928
Fees SME Administration	1 200 000	-	1 200 000	1 176 050	1 176 050
Fees and charges from CLP	156 000	-	156 000	90 385	90 385
Fees and charges from Appeals	-	-	-	71 760	71 760
Total REACH Fees & Charges Income	**28 130 616**	**(1 628 330)**	**26 502 286**	**27 131 835**	**27 131 835**
Fees relating to Biocidal Active Substances	522 146	-	522 146	651 020	651 020
Fees for Union Authorisation of Biocidal products	461 120	-	461 120	1 026 990	1 026 990
Miscellaneous fees	1 268 395	-	1 268 395	1 386 100	1 386 100
Fees and charges from Appeals	-	-	-	2 500	2 500
Total BPR Fee & Charges Income	**2 251 661**	**-**	**2 251 661**	**3 066 610**	**3 066 610**
REACH EU Contribution	63 614 564	(1 700 000)	61 914 564	61 914 564	61 914 564
BPR EU Contribution	10 348 160	(300 000)	10 048 160	10 048 160	10 048 160
PIC/POPs/DWD/WFD EU Contribution	5 607 100	(322 000)	5 285 100	5 285 100	5 285 100
EFTA Contribution - REACH	1 681 047	-	1 681 047	1 681 047	1 681 047

Description	Initial voted Budget 2021	Budget Amendments 2021	Final voted Budget 2021	Entitlements established 2021	Revenue received 2021
EFTA Contribution - BPR	275 755	-	275 755	275 755	275 755
Confederation of Switzerland Contribution - BPR	372 348	-	372 348	460 852	460 852
Total EU Contributions	**81 898 974**	**(2 322 000)**	**79 576 974**	**79 665 478**	**79 665 478**
Contribution Agreement EUON	-	-	-	600 000	600 000
Contribution Agreement EUCLEF	-	-	-	1 026 000	1 026 000
Contribution Agreement IPA	-	-	-	-	-
Contribution Agreement OELs	-	600 000	600 000	600 000	600 000
SLA with EFSA	771 836	1 388 534	2 160 370	2 123 206	2 123 206
Total Contribution Agreements and SLAs	**771 836**	**1 988 534**	**2 760 370**	**4 349 206**	**4 349 206**
Total Other income - miscellaneous	**-**	**-**	**-**	**403 837**	**326 505**
Total	**113 053 087**	**(1 961 796)**	**111 091 291**	**114 616 966**	**114 539 634**

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 2021, in terms of cash received, amounted to EUR 27.06 million (EUR 29.69 million in 2020). In addition, EUR 0.07 million (EUR 0.05 million in 2020) was recorded in relation to REACH appeal fees[84] giving a total of fees and charges of EUR 27.13 million (EUR 29.74 million in 2020).

During 2021, ECHA cashed in a total of 6 473 invoices related to REACH registrations and update fees, compared to 7 102 invoices in 2020. This translates into EUR 24.7 million REACH Registrations and Updates income for 2021, while the corresponding amount collected in 2020 was EUR 25.6 million (in 2019 the corresponding amount collected was EUR 28.4 million while in the final registration deadline year of 2018, EUR 79.1 million was collected). This declining trend characterises the new era for the REACH registration fee income, after passing of the registration deadlines as defined in the REACH legislation that used to generate peaks in the fee income.

In 2021, the Agency received payments for 23 applications for REACH authorisation (55 in 2020). The total REACH authorisation income collected in 2021 amounts to EUR 1.1 million (EUR 3.0 million in 2020). The Agency received payments for 34 applications under the CLP Regulation (20 in 2020). The total receipts under CLP for 2021 amount to EUR 0.09 million (EUR 0.07 million in 2019).

84 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.

The additional registration fee income generated through the SME size verification process (included in the REACH registrations and updates income) in 2021 amounted to EUR 0.72 million (EUR 1.37 million in 2020). A total of 373 enterprises were verified for their company size in 2021(504 in 2020). On top of the additional registration fees, the Agency generated EUR 1.18 million in administrative charges (EUR 1.05 million in 2020) levied on companies who were not eligible for the already received rebates.

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

During 2021, the Agency received an EU balancing contribution for REACH/CLP of EUR 61.91 million (EUR 61.88 million in 2020) and a European Free Trade Association (EFTA) contribution of EUR 1.68 million (EUR 1.44 million in 2020).

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 2021, in terms of cash received, amounted to EUR 3.07 million (EUR 2.55 million in 2020).

B) BPR contributions from the General Budget of the EU

During 2021, the Agency received an EU balancing contribution of EUR 10.05 million (EUR 7.00 million in 2020) and an EFTA contribution of EUR 0.28 million (EUR 0.16 million in 2020). In addition, the Agency received a contribution from the Confederation of Switzerland of EUR 0.46 million (EUR 0.25 million in 2020).

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)(No 2019/2021), Waste Framework Directive (WFD) (EU) 2018/851 amending Directive 2008/98/EC, and the revised Drinking Water Directive (DWD) Directive (EU) 2020/2184, ECHA is fully financed by an EU contribution for these activities. In 2021, the EU contribution amounted to EUR 1.16 million for PIC (EUR 1.15 million in 2020), EUR 0.23 million for POPs (EUR 0.26 million in 2020), EUR 2.20 million for WFD (EUR 1.64 million in 2020) and EUR 1.69 million for DWD, totalling EUR 5.29 million (EUR 3.06 million in 2020).

Other tasks (Contribution and Service Level Agreements)

The Agency has signed contribution agreements with the European Commission to implement the European Union Observatory for Nanomaterials (EUON) and the European Union Chemicals Legislation Finder (EUCLEF), as well as for work with respect to the Instrument for Pre-Accession Assistance (IPA). ECHA has also signed a Service Level Agreement with the European Commission to provide opinions for occupational exposure limits (OELs). Additionally, the Agency signed a Service Level Agreement with the European Food Safety Authority (EFSA) for developing and implementing IUCLID software solution for plant protection products. In 2021, ECHA received an amount of EUR 4.35 million in aggregate for these tasks (EUR 3.85 million in 2020).

Other miscellaneous income

The table below shows other miscellaneous income received by the Agency in 2021 (amounts in EUR).

Description	Entitlements established 2021	Revenue received 2021
Legal recoveries	93 465	64 016
Recovery of 2020 Building Maintenance costs	270 355	222 472

Description	Entitlements established 2021	Revenue received 2021
Late interest income	1 844	1 844
Recoveries from other EU agencies	28 728	28 728
Other cost recoveries	9 445	9 445
Miscellaneous income	**403 837**	**326 505**

Fee Invoicing

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

A) REACH Fees and Charges

The total net invoiced by the Agency in 2021 amounted to EUR 26.63 million (EUR 28.64 million in 2020 and EUR 35.53 million in 2019). The table below depicts the breakdown of the net invoiced REACH fees during the years.

REACH	2021		2020		2019	
Description	No of Invoices	EUR	No of Invoices	EUR	No of Invoices	EUR
Invoices issued	6 588	28 295 673	7 383	31 360 367	8 969	37 795 088
Credit Notes	215	(1 161 459)	257	(1 857 253)	227	(1 579 220)
Unpaid	118	(505 526)	154	(867 424)	167	(681 689)
Considered paid	29	(488)	18	(274)	38	(2 622)
Net Invoiced		**26 628 200**		**28 635 416**		**35 531 557**
Write offs	29	(458 573)	-	-	-	-

On 31 December 2021, the amount to be recovered for REACH fees and charges, before any year-end Accounting adjustments, stood at EUR 2.41 million relating to 376 open invoices (On 31 December 2020, the amount to be recovered for REACH fees and charges, before any year end Accounting adjustment, stood at EUR 3.28 million relating to 552 open invoices).

B) Biocidal Products Fees and Charges

The total net invoiced by the Agency in 2021 amounted to EUR 3.00 million (EUR 2.60 million in 2020). The table below depicts the breakdown of the net invoiced BPR fees during the year.

BPR	2021		2020		2019	
Description	No of Invoices	EUR	No of Invoices	EUR	No of Invoices	EUR
Invoices issued	730	3 383 700	1 126	3 350 000	1 085	9 904 600
Credit Notes	39	(363 700)	67	(518 800)	66	(635 300)
Unpaid	14	(13 700)	23	(230 500)	66	(127 900)
Considered paid	2	(110)	2	(25)	4	(752)
Net Invoiced		**3 006 190**		**2 600 675**		**9 140 648**

On 31 December 2021, the amount to be recovered for Biocidal product fees and charges before any year end accounting adjustments, stood at EUR 0.05 million relating to 39 open invoices (On 31 December 2020, the amount to be recovered for BPR fees and charges, before any year end Accounting adjustment, stood at EUR 0.1 million relating to 38 open invoices).

Expenditure

ECHA's expenditure budget consists of commitment appropriations (CA) and payment appropriations (PA). The initial CAs totalled EUR 111.9 million and the initial PAs totalled EUR 112.3 million, while the figure concluded in the final budget is EUR 108.0 million for CAs and EUR 108.3 million for PAs. These commitment and payment appropriations consist of C1 funds. It is to be noted, that 2021 initial budget includes EUR 0.5 million to compensate for the negative financial result in 2020 in the area of BIOCIDES.

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

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

The initially adopted budget for the Agency in 2021 was EUR 111.9 million and the overall net decrease during the year, including 17 transfers and two amending budgets, was EUR 3.9million, to arrive at EUR 108.0 million as the final budget.

The main reason for the reduction in the budget was the reduced meeting expenditure needs due to continued travel restrictions related to the COVID-19 pandemic together with the reduced building expenditure due to extensive remote working mode.

The final executed amount totalled EUR 106.2 million corresponding to an execution rate of 98.4 % for the appropriations.

Carry over of appropriations to 2022

The commitment and payment appropriations carried over to 2022 totals EUR 13.2 million, corresponding to 12.4 % of the committed amount.

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

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

The operational expenditure required to implement the Work Programme for the different regulations is budgeted in Title 3 for REACH and CLP, in Title 4 for Biocides and in Title 5 for the Environmental Directives and International Conventions (PIC, POPs, Waste Framework Directive (SCIP) and Drinking Water Directive). The carry over in operational titles totalled EUR 11.1 million and is mostly related to IT projects.

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

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

The amount carried over from 2020 totalled EUR 11.6 million and the finally executed amount was EUR 11.4 million, corresponding to 98 %. The cancelled 2 % relates mostly to IT projects in Title 2, lower than anticipated costs for legal services related to collection of administrative charges, as well as a scientific contract which was not delivered in due time.

Late interest payments

During 2021, ECHA did not pay late interest for commercial invoices.

Procurement procedures

In 2021, in implementing its budget, ECHA signed 336 contracts and purchase orders. To note that due to the exceptional situation created by Covid-19, the Agency issued no catering orders and only 1 travel order, through the electronic ordering tools of the relevant framework contract (FWC), which represents a very substantial drop when compared to previous years.

Out of the 336 signed contracts, 265 were specific contracts and orders under FWC, 71 were contracts resulting from tendering procedures.

Out of the 71 contracts following procurement, ECHA concluded 3 new FWCs for IT services - two for ECHA's bespoke applications and one in the field of Oracle Peoplesoft - a FWC for scientific consulting services for EOGRTS projects and a FWC for medical services, and joined 8 inter-institutional FWCs for IT services - Microsoft ILA (DI-7880), NATACHA IV (DI-7890-93) and for Oracle licenses (DI-7870); for communication-related services - for strategic communication services, for digital communication and social media services and projects, for quantitative and qualitative social research methods in support of an audience-first approach & enhanced user experience in risk communication -; for HR - for advertising senior management vacancies in the International Media and for e-learning services -; and for IPR legal advice. A total of 20 contracts were signed following negotiated procedures without prior publication based on the relevant rules of the Financial Regulation (Annex 1–11.1), seventeen of which refer to legal services; and three for technical reasons for a subscription to a scientific database, publication of scientific reports, and renewal of an IT software.

In 2021, 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 adequately addressed by ECHA. The main arrangements/ amendments implemented in 2020 to tackle the consequences of the COVID-19 pandemic on the contracts (such as reduced presence on-site, reduced volumes of services, etc) continued in 2021.

Green Public Procurement (GPP) continued to be a priority and an integral part of the Agency's management system. ECHA plans to use the guidelines published by the EU Commission in 2022 in the forthcoming procurement of IT infrastructure and IT standard workplace services. The Agency also carried out staff awareness-raising actions on GPP, like training and presentations.

The annual list of contractors is published by ECHA by 30 June of each year for the previous year to ECHA website[85].

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 they are responsible for in line with their activities.

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

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

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

Statistics on Financial Management and Budget (Expenditure)

Budget 2021: Breakdown and changes in commitment appropriations and implementation of the appropriations for the current year (C1) per Title* (EUR)

Title	Description	Budget 2021 (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	75 274 991	-1 310 443	73 964 548	72 555 493	98.1%	73 964 548	72 284 371	97.7%	271 123	0.4%	1 409 055
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	14 823 572	-1 115 498	13 708 074	13 578 918	99.1%	13 708 074	11 774 944	85.9%	1 803 973	13.3%	129 156
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	15 180 494	-1 311 886	13 868 608	13 732 428	99.0%	14 231 073	7 491 717	52.6%	6 603 168	48.1%	136 180
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	2 433 576	477 751	2 911 327	2 894 058	99.4%	2 911 327	754 868	25.9%	2 139 190	73.9%	17 269
B0-5	OPERATIONAL EXPENDITURE - ENVIRONMENTAL DIRECTIVES AND INTERNATIONAL CONVENTIONS	2 949 616	80 707	3 030 323	2 981 036	98.4%	3 030 323	622 362	20.5%	2 358 674	79.1%	49 287
B0-9	OTHER EXPENDITURE - RESERVE - BIOCIDES	1 200 000	-714 424	485 576	485 576	100.0%	485 576	485 576	100.0%	0	0.0%	0
		111 862 249	**-3 893 793**	**107 968 456**	**106 227 509**	**98.4%**	**108 330 921**	**93 413 839**	**86.2%**	**13 176 128**	**12.4%**	**1 740 947**

**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 2021: 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 2021 (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	65 196 822	-1 009 279	64 187 543	62 981 529	98.1%	64 187 543	62 747 190	97.8%	234 339	0.4%	1 206 014
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	12 629 909	-950 628	11 679 281	11 569 016	99.1%	11 679 281	10 032 160	85.9%	1 536 855	13.3%	110 265
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	15 180 494	-1 311 886	13 868 608	13 732 428	99.0%	14 231 073	7 491 717	52.6%	6 603 168	48.1%	136 180
		93 007 225	**-3 271 793**	**89 735 432**	**88 282 972**	**98.4%**	**90 097 897**	**80 271 068**	**89.1%**	**8 374 362**	**9.5%**	**1 452 460**

BIOCIDES

Title	Description	Budget 2021 (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	7 909 603	64 979	7 974 582	7 836 921	98.3%	7 974 582	7 812 934	98.0%	23 987	0.3%	137 661
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	1 704 745	-128 306	1 576 439	1 561 749	99.1%	1 576 439	1 354 284	85.9%	207 465	13.3%	14 690
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	2 433 576	477 751	2 911 327	2 894 058	99.4%	2 911 327	754 868	25.9%	2 139 190	73.9%	17 269
B0-9	OTHER EXPENDITURE - RESERVE - BIOCIDES	1 200 000	-714 424	485 576	485 576	100.0%	485 576	485 576		0		
		13 247 924	**-300 000**	**12 947 924**	**12 778 304**	**98.7%**	**12 947 924**	**10 407 662**	**80.4%**	**2 370 642**	**18.6%**	**169 620**

ENVIRONMENTAL DIRECTIVES AND INTERNATIONAL CONVENTIONS

Title	Description	Budget 2021 (1)	Transfers / amendments (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (6)/(5)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
A-1	STAFF	2 168 566	-366 143	1 802 423	1 737 044	96.4%	1 802 423	1 724 246	95.7%	12 797	0.7%	65 379
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	488 918	-36 564	452 354	448 153	99.1%	452 354	388 500	85.9%	59 653	13.3%	4 201
B0-5	OPERATIONAL EXPENDITURE - ENVIRONMENTAL DIRECTIVES AND INTERNATIONAL CONVENTIONS	2 949 616	80 707	3 030 323	2 981 036	98.4%	3 030 323	622 362	20.5%	2 358 674	79.1%	49 287
		5 607 100	**-322 000**	**5 285 100**	**5 166 233**	**97.8%**	**5 285 100**	**2 735 108**	**51.8%**	**2 431 124**	**47.1%**	**118 867**

Budget 2021: Implementation of differentiated appropriations (EUR)

Budget line		Available commitment appropriations	Commitments made	%	Available payment appropriations	Payments made	%
B3-111	Substance evaluation and Rapporteurs (Multiannual)	1 423 485	1 369 260	96%	850 792	850 507	100%
B3-801	Cooperation with international organisations for IT programs	1 071 315	1 071 315	100%	591 815	591 815	100%
Total		**2 494 800**	**2 440 575**	**98%**	**1 442 607**	**1 442 321**	**100%**

Out of the total available commitment appropriations, EUR 1 414 658 was stemming from commitments made in earlier financial years. The available commitment appropriations for 2021 totalled EUR 1 1 080 142 out of which EUR 1 079 864 (100 %) were committed. The amount of commitments carried forward to 2021 totals EUR 998 254.

Budget 2021: Implementation of assigned revenue (C4, C5, R0) (EUR)

Title	Description	CD/ CND	FS	Commitments Appropriations	Commitments Established	Com %	Payments Appropriations	Payments Executed	Pay%	Carried over commitment appropriations	Carried over payment appropriations
A-1	STAFF	CND	C4	29 128	0	0%	29 128	0	0%	29 128	29 128
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	CND	C4	231 092	0	0%	231 092	0	0%	231 092	231 092
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	CND	C4	59 721	0	0%	59 721	0	0%	59 721	59 721
			C4	**319 941**	**0**	**0%**	**319 941**	**0**	**0%**	**319 941**	**319 941**

Title	Description	CD/ CND	FS	Commitments Appropriations	Commitments Established	Com %	Payments Appropriations	Payments Executed	Pay%	Carried over commitment appropriations	Carried over payment appropriations
A-1	STAFF	CND	C5	31 357	30 477	97%	31 357	30 477	97%	0	880
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	CND	C5	129 273	129 273	100%	129 273	129 273	100%	0	0
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	CND	C5	85 756	76 481	89%	85 756	61 721	72%	0	24 035
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	CND	C5	7 909	7 487	95%	7 909	0	0%	0	7 909
			C5	**254 296**	**243 719**	**96%**	**254 296**	**221 472**	**87%**	**0**	**32 824**

Title	Description	CD/ CND	FS	Commitments Appropriations	Commitments Established	Com %	Payments Appropriations	Payments Executed	Pay%	Carried over commitment appropriations	Carried over payment appropriations
B6-000	IPA programme	CND	R0	502 002	341 811	68%	502 002	271 660	54%	160 191	230 341
B6-010	EUON	CND	R0	1 850 861	1 021 616	55%	1 857 043	702 060	38%	829 246	1 154 982
B6-011	EUCLEF	CND	R0	2 714 887	1 329 403	49%	2 708 706	894 433	33%	1 385 484	1 814 273

Title	Description	CD/ CND	FS	Commitments Appropriations	Commitments Established	Com %	Payments Appropriations	Payments Executed	Pay%	Carried over commitment appropriations	Carried over payment appropriations
B6-020	Occupational exposure limits	CND	R0	750 029	574 375	77%	750 029	401 312	54%	175 655	348 717
B6-021	Further development of IUCLID (w/ third parties)	CND	R0	2 763 597	2 244 577	81%	2 763 597	1 772 178	64%	519 020	991 419
			R0	**8 581 376**	**5 511 782**	**64%**	**8 581 376**	**4 041 644**	**47%**	**3 069 595**	**4 539 733**

Budget 2021: Implementation of the appropriations carried forward from previous year (C8) Per Title (EUR)

Title	Description	Carried Forward from 2021	Paid	Cancelled	% Cancelled
A-1	STAFF	322 596	311 931	10 665	3%
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	2 390 375	2 294 430	95 945	4%
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	6 921 360	6 760 567	160 793	2%
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	623 194	621 776	1 417	0%
B0-5	OPERATIONAL EXPENDITURE - ENVIRONMENTAL DIRECTIVES AND INTERNATIONAL CONVENTIONS	1 381 268	1 381 262	6	0%
		11 638 792	**11 369 967**	**268 825**	**2%**

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

Last establishment plan adopted

Category and grade	Establishment plan in voted EU Budget 2021				Posts filled 31 December 2021*			
	TA				TA			
	REACH/CLP	Biocides	ENV	TOTAL	REACH/CLP	Biocides	ENV	TOTAL
AD 15	0	0	0	0	0	0	0	0
AD 14	6	0	0	6	4	0	0	4
AD 13	15	1	0	16	7	0	0	7
AD 12	19	2	0	21	5	2	0	7
AD 11	30	2	0	32	23	1	0	24
AD 10	41	5	0	46	33	4	0	37
AD 9	55	10	0	65	49	4	0	53
AD 8	52	9	1	62	58	6	1	65
AD 7	53	8	1	62	58	11	0	69
AD 6	27	5	3	35	46	9	0	55
AD 5	12	1	0	13	20	5	3	28
Total AD	**310**	**43**	**5**	**358**	**303**	**42**	**4**	**349**
AST 11	0	0	0	0	0	0	0	0
AST 10	0	0	0	0	0	0	0	0
AST 9	4	0	0	4	0	0	0	0
AST 8	8	0	0	8	5	0	0	5
AST 7	9	1	2	12	8	0	0	8
AST 6	19	1	0	20	14	0	0	14
AST 5	19	3	1	23	25	2	1	28
AST 4	20	3	2	25	13	3	2	18
AST 3	11	1	1	13	8	2	2	12
AST 2	4	0	0	4	17	1	1	19
AST 1	0	0	0	0	0	0	0	0
Total AST	**94**	**9**	**6**	**109**	**90**	**8**	**6**	**104**
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**	**393**	**50**	**10**	**453**

** Under recruitment (included in figures): REACH: 6 TAs, Biocides: 2 TAs, ENV: 1 TA (PIC)*

	CA estimated need of FTEs 2021					CA posts filled 31 December 2021*				
	REACH/ CLP	Biocides	ENV	Other tasks	TOTAL	REACH/ CLP	Biocides	PENV	Other tasks	TOTAL
CA FG IV	24	7	11	13	55	18	7	7	10	42
CA FG III	52	6	2	1	61	49	4	4	3	60
CA FG II	18	2	0	0	20	23	4	1	1	29
CA FG I					0					0
Total	**94**	**15**	**13**	**14**	**136**	**90**	**15**	**12**	**14**	**131**

** Under recruitment (included in figures): Other tasks: 1 CA*

Percentage of posts filled on 31 December 2021

	REACH/CLP/PIC	Biocides	ENV
TA posts	97.28 %	96.15 %	90.91 %
CA posts	95.74 %	100.00 %	92.31 %

Geographical and gender balance (as per 31 December 2021)*

		TA			CA			OVERALL	
Nationality		Male	Female	Total	Male	Female	Total	Sum	%
FI	Finnish	55	86	141	11	27	38	179	31.2 %
IT	Italian	23	20	43	5	4	9	52	9.1 %
DE	German	18	12	30	3	0	3	33	5.8 %
FR	French	19	14	33	2	8	10	43	7.5 %
UK	British	4	2	6	1	0	1	7	1.2 %
ES	Spanish	13	10	23	6	6	12	35	6.1 %
GR	Greek	14	6	20	6	6	12	32	5.6 %
BE	Belgian	11	9	20	1	0	1	21	3.7 %
PL	Polish	7	8	15	1	3	4	19	3.3 %
RO	Romanian	1	4	5	3	7	10	15	2.6 %
IE	Irish	11	3	14	0	2	2	16	2.8 %
BG	Bulgarian	0	8	8	3	4	7	15	2.6 %
PT	Portuguese	5	5	10	0	4	4	14	2.4 %
SE	Swedish	3	3	6	1	0	1	7	1.2 %
NL	Dutch	14	4	18	1	1	2	20	3.5 %
HU	Hungarian	2	6	8	0	3	3	11	1.9 %
LT	Lithuanian	1	5	6	0	0	0	6	1.0 %
EE	Estonian	0	6	6	1	0	1	7	1.2 %
SK	Slovakian	1	2	3	0	2	2	5	0.9 %
SI	Slovenian	3	3	6	1	0	1	7	1.2 %
CZ	Czech	0	2	2	1	0	1	3	0.5 %
LV	Latvian	1	6	7	1	1	2	9	1.6 %
AT	Austrian	2	3	5	0	1	1	6	1.0 %

		TA			CA			OVERALL	
Nationality		Male	Female	Total	Male	Female	Total	Sum	%
DK	Danish	2	1	3	0	0	0	3	0.5 %
MT	Maltese	0	3	3	0	0	0	3	0.5 %
IS	Iceland	1	0	1	0	0	0	1	0.2 %
CY	Cypriot	0	0	0	1	0	1	1	0.2 %
LU	Luxembourger	0	0	0	0	0	0	0	0.00 %
NO	Norwegian	0	0	0	0	1	1	1	0.2 %
LI	Liechtenstein	1	0	1	0	0	0	1	0.2 %
Other	Other	0	0	0	0	0	0	0	0.00 %
	TOTAL	212	231	443	49	81	130	573	100 %

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

Middle and senior management – gender and nationality overview*

NATIONALITY		MALE	FEMALE	TOTAL	%
FI	Finnish	5	4	9	27.3 %
FR	French	2	0	2	6.1 %
BE	Belgian	2	0	2	6.1 %
NL	Dutch	5	0	5	15.2 %
UK	British	1	0	1	3.0 %
IT	Italian	2	0	2	6.1 %
ES	Spanish	0	1	1	3.0 %
DE	German	2	0	2	6.1 %
IE	Irish	3	0	3	9.1 %
SI	Slovenian	1	0	1	3.0 %
DK	Danish	1	0	1	3.0 %
GR	Greek	1	0	1	3.0 %
PT	Portuguese	1	0	1	3.0 %
RO	Romanian	0	1	1	3.0 %
SI	Slovenian	1	0	1	3.0 %
TOTAL	OVERALL	27 (82 %)	6 (18%)	33	100 %

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

Results of the screening / benchmarking exercise

Key functions	Type of contract (official, TA or CA)	Function group, grade of recruitment *(or bottom of grade bracket if published with such bracket)*	Indication whether the function is dedicated to administrative support or operations *(subject to definitions used in screening methodology)*
Core functions			
Executive Director	TA - 5 + 5 years	AD 14	Management-Operations
Deputy Executive Director	TA - 5 + 5 years + indefinite	AD 14	Management-Operations
Director (Head of Directorate) (Level 2)	TA - 5 + 5 years + indefinite	AD 12	Management-Operations
Head of Unit (Level 3)	TA - 5 + 5 years + indefinite	AD 9	Operations/Administration
Administrator	TA - 5 + 5 years + indefinite	AD 5 and higher depending on profile	Operations/Administration
Administration			
Head of Administration (Head of Directorate) (Level 2)	TA - 5 + 5 years + indefinite	AD 12	Management-Administration
Head of Human Resources (Level 3)	TA - 5 + 5 years + indefinite	AD 9	Administration
Head of Finance (Level 3)	TA - 5 + 5 years + indefinite	AD 9	Administration
Head of Communication (Level 3)	TA – 5 + 5 years + indefinite	AD 9	Administration
Head of IT (Level 3)	TA - 5 + 5 years + indefinite	AD 9	Administration
Assistant	TA - 5 + 5 years + indefinite	AST 1 and higher depending on profile, up to AST 4	Operations/Administration
Special functions			
ECHA Committee or Board of Appeal Chair	TA - 5 + 5 years + indefinite	AD 10	Operations
Data Protection Officer	TA - 5 + 5 years + indefinite	AD 6	Administration
Accounting Officer	TA - 5 + 5 years + indefinite	AD 8	Administration
Internal Auditor	TA - 5 + 5 years + indefinite	AD 10	Administration

Benchmarking against previous results

ECHA undertook the benchmarking (job screening) exercise in 2021, in accordance with the Commission's requirements. The 2021 results indicate a decrease of 0.1% in the percentage of administrative support and coordination staff, an increase of 0.7% in the percentage of the operational staff and a decrease of 0.6% in the percentage of neutral staff in comparison to 2020.

Job type (sub) category	2020	2021
Administrative support and Coordination	**15.1**	**15.0**
Administrative Support	12.1	12.1
Coordination	3.0	2.9
Operational	**80.1**	**80.8**
Top level Operational Coordination	2.5	2.6
Programme management and Implementation	52.7	55.6
Evaluation & Impact assessment	4.1	3.4
General operational	20.8	19.2
Neutral	**4.8**	**4.2**
Finance/ Control	4.6	4.0
Linguistics	0.2	0.2

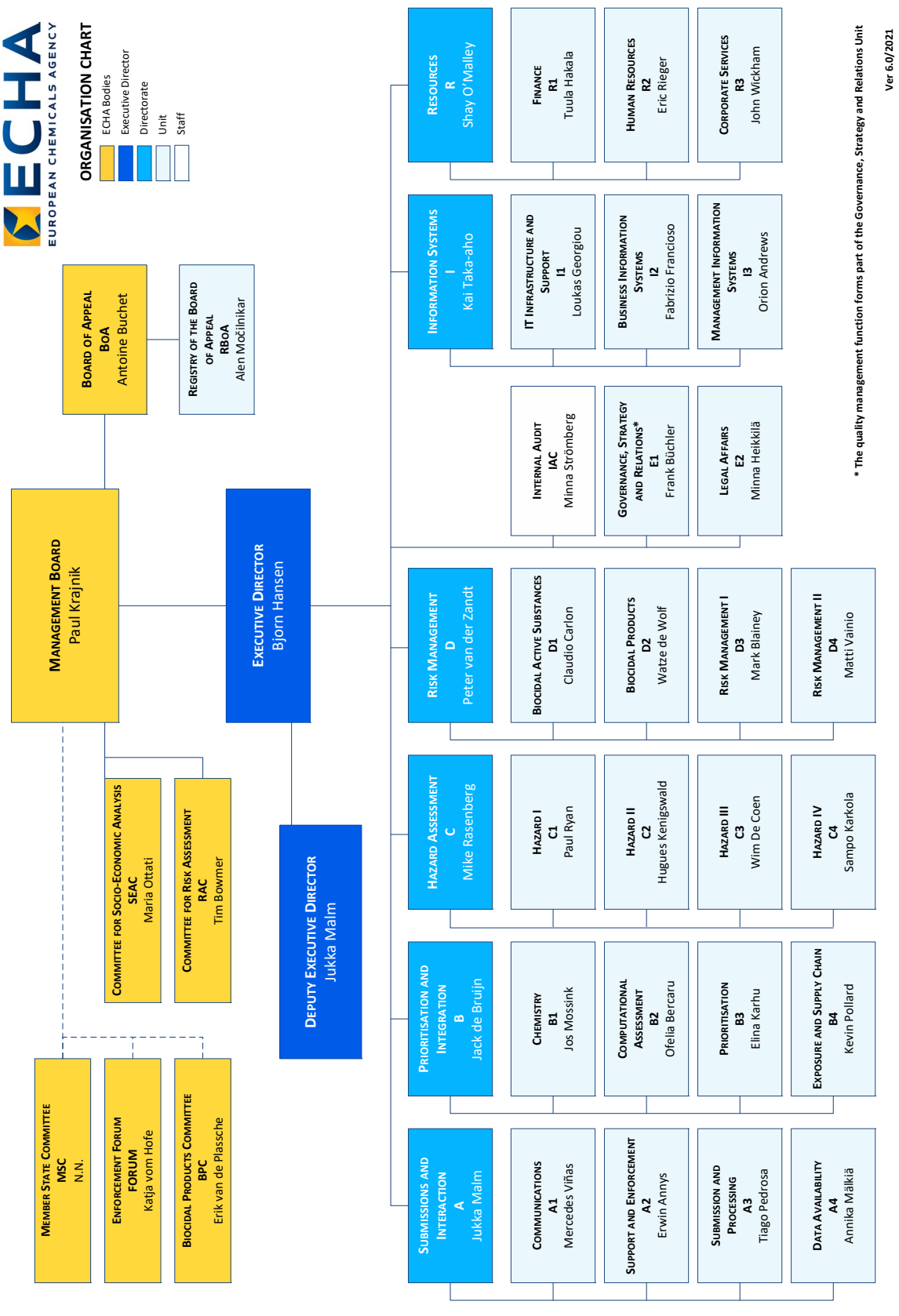
Appendix IV – Human and financial resources by activity

WP Activity	Actual consumption of the human resources	Executed budget 2021
1.1 Dossier preparation	30	7 758 427
1.2 Registration and dossier submission	37	7 520 126
1.3 Identification and prioritisation	53	8 358 160
1.4 Evaluation	104	16 995 996
1.5 Authorisation	32	5 934 260
1.6 Restrictions	29	5 495 361
1.7 Classification and labelling	34	7 242 769
1.8 Safe and sustainable use of chemicals	8	1 532 470
1.9 Data management and dissemination	22	6 487 812
2. Biocides	49	9 752 436
3.1 Prior Informed Consent	7	1 714 809
3.2 Persistent organic pollutants	1	225 678
3.3 Waste Framework Directive	7	1 714 809
3.4 Drinking Water Directive	4	1 037 776
3.5 8th Environmental Action Programme*		
4.1 EU Observatory for Nanomaterials	3	1 021 616
4.2 EU Chemicals Legislation Finder		1 329 403
4.3 Support to Occupational health legislation	4	574 375
4.4 Instrument for Pre-Accession assistance (IPA)	1	341 811
4.5 Support to other legislation		
4.6 IUCLID for EFSA	4	2 244 577
4.7 Partnership for the Assessment of Risk from Chemicals**	2	
Governance and enablers	155	23 971 044
Overall TOTAL	**586**	**111 253 715**

** The posts for the 8th EAP were not filled in 2021, pending the approval of the Programme.*

*** Financed with REACH/CLP resources.*

Appendix V – Organisational chart



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