ECHA
EUROPEAN CHEMICALS AGENCY

Annual Report 2019

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Annual Report 2019

Reference: ECHA-20-R-04-EN
ISBN: 978-92-9481-399-2
Cat. number: ED-BF-20-001-EN-N
DOI: 10.2823/40779
ISSN: 2600-0849
Publ.date: April 2020
Language: EN
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Foreword

ECHA commenced the implementation of its five-year Strategic Plan in 2019 with a focus on its core regulatory processes, maximising its impact and laying the groundwork for its long-term future.

To support this, we restructured the Agency at the beginning of the year bringing together and aligning staff competencies and operational tasks to capitalise on efficiency gains and make our work more impactful. As a result, the Agency is operating with increased levels of cooperation and staff engagement resulting in real and substantial progress in the work we do with our partners to ensure chemicals are used safely.

The more than 300 full compliance checks carried out last year exemplifies the efficiencies we have gained by prioritising and simplifying decision making. This is an area that we will continue to prioritise in the coming years: checking the extent to which registrants submit data that meets the information requirements is necessary to conclude whether substances are safe or of concern for human health or the environment and to initiate risk management measures where needed.

This work follows up on the second REACH Review by the European Commission, and together, we have set up an ambitious Joint Evaluation Action Plan. The plan foresees that, by 2027, the Agency will have screened all registrations between 1 and 100 tonnes submitted by the final registration deadline, and that the compliance of all substances where data gaps prevent us from concluding on possible concerns will have been checked.

For substances of very high concern, the authorisation process is an important and impactful tool for managing risks. In 2019, we received guidance on the authorisation process from the General Court and followed up on feedback from our stakeholders and the European Parliament. The Management Board played an active role in supporting and implementing a range of improvement actions. As a result, there are now revised formats on how ECHA's committees should present their opinions, with the aim of making them more concise and consistent.

For biocides, we developed an action plan to proactively re-accelerate the Review Programme. The plan proposes to prioritise substances, provide support to Member States, and streamline assessments and peer reviews.

ECHA also made significant progress in taking on new tasks: developing a database for substances of very high concern in articles, getting ready to launch an online service that gives companies an overview of EU legislation relevant to their substances (EUCLEF), and preparing to assess substances that come into contact with drinking water.

We restructured the Agency at the beginning of the year bringing together and aligning staff competencies and operational tasks to capitalise on efficiency gains and make our work more impactful.

Bjorn HANSEN

Executive Director

For ECHA to deliver on its growing legal mandate and its vision there is a need to identify and assess upfront what resource requirements are needed to ensure that the Agency has the means to perform all new tasks.

Sharon McGUINNESS

Chair of the Management Board

The seamless integration of these new legislative mandates and tasks into the Agency's growing portfolio is encouraging and shows that ECHA is delivering on its vision to be the centre of knowledge on the sustainable management of chemicals, serving a wide range of EU policies and global initiatives, for the benefit of citizens and the environment.

However, for ECHA to deliver on its growing legal mandate and its vision there is a need to identify and assess upfront what resource requirements are needed to ensure that the Agency has the means to perform all new tasks.

In the mid-term, the next Multi-Annual Financial Framework of the EU and the remaining uncertainty about the financial implications of the UK's withdrawal need our attention.

With our new organisation and committed staff, we believe we are prepared for the coming years. The political agenda of the EU, more explicitly the Commission's Green Deal and upcoming Chemicals Strategy are areas that ECHA can and will contribute and add value to – based on what we have achieved not just in 2019 but over the past 12 years.

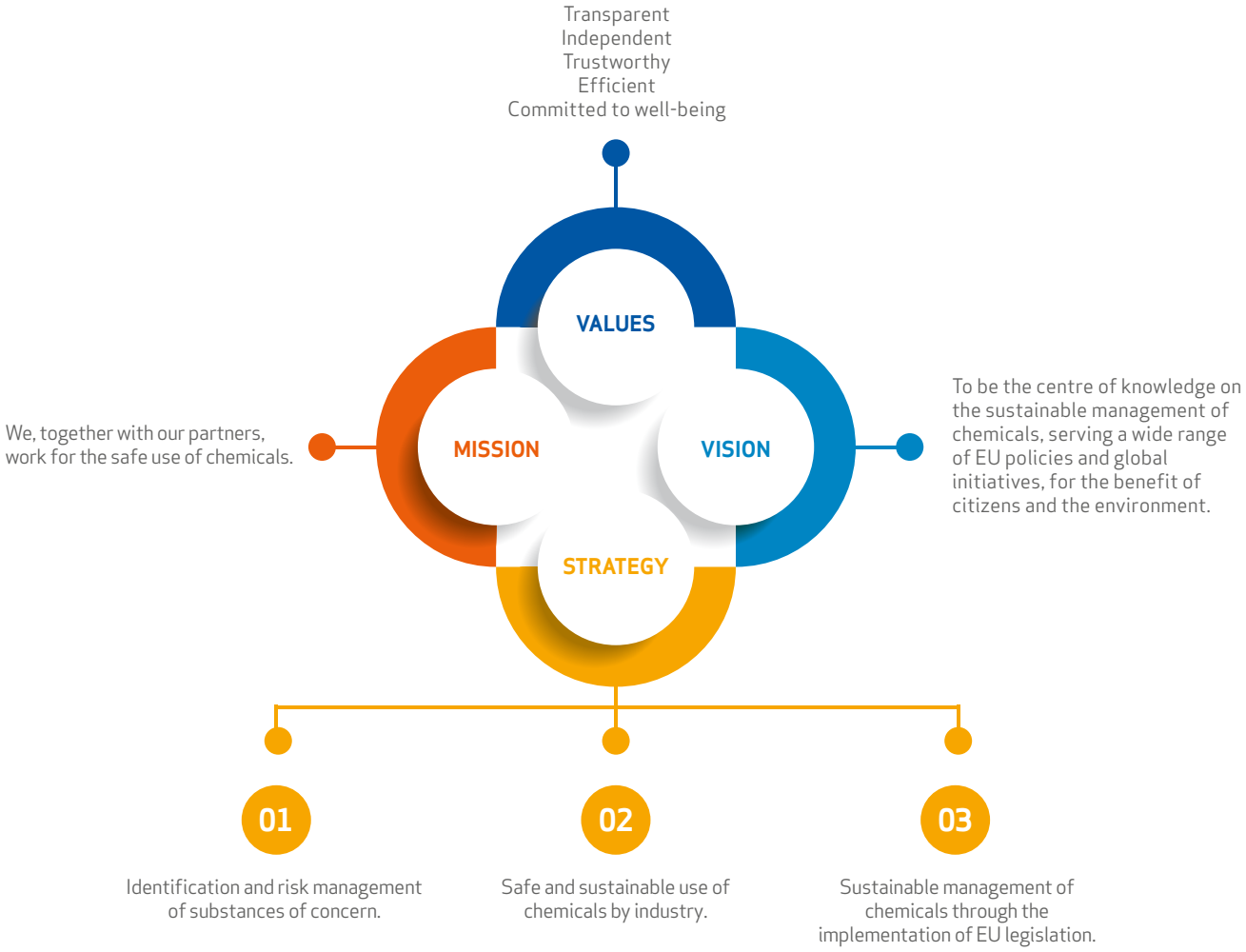
Working for the safe use of chemicals

Executive summary

2019 marked the start of new political priorities with the Green Deal for Europe, the growth strategy for Europe, under the von der Leyen Commission, the start of ECHA's five-year strategic plan for improving chemical safety, preparations for the move to new premises for the Agency and the uncertainty for ECHA's stakeholders related to the withdrawal of the UK from the EU.

With valuable input from the second REACH Review[1], we have focused our priorities on where they matter most for protecting human health and preventing damage to the environment. This shaped ECHA's **new strategic plan for 2019-2023** with its three strategic priorities enabled by staff competencies and the data held by the Agency.

FIGURE 1: ECHA mission, vision, values



Under the first priority, we implement our tasks, integrating them into our work and doing so consistently. Under the second, we use our tasks to foster safer and more sustainable use of chemicals by industry. And, under the third, we ensure the consistency of our tasks with that of other EU chemicals legislation and provide scientific and technical support to international activities. Achievements in all three areas support progress towards the United Nations' sustainable development goals[2].

1 Commission General Report on the operation of REACH and review of certain elements, COM(2018) 116 final

2 https://www.un.org/sustainabledevelopment/sustainable-development-goals

They show:

- a robust baseline in identifying which substances require further work to manage the risks associated with them;
- substances for which we need more information;
- how industry is taking steps forward to ensure safe and sustainable use of chemicals; and
- where the Agency has contributed to a higher level of coherence for EU chemicals legislation.

Our reorganisation took effect in 2019 bringing processes closer together, capitalising on efficiency gains, and enabling ECHA to be more impactful[3]. With this, ECHA has proven to be agile and capable of undertaking major significant organisational changes. With the limited resources available to the Agency, we had to shift resources to priority work, mostly to identifying and managing the risks of substances of concern (strategic priority 1), meaning that we had fewer resources to allocate to other priority areas.

Results on strategic priorities

1. Identification and risk management of substances of concern

ECHA's screening and prioritisation work for over 21 000 substances[4] shows good progress towards acceleration of data generation, identification of and regulatory action on chemicals of concern for human health or the environment. As of 2020, we will be able to compare the results and report on progress made with the figures in 2019 as a baseline.

The substances in the higher tonnage bands that are not yet assigned will be allocated to a specific priority group based on whether they are of priority for regulatory risk management; currently of low priority for further regulatory action; or need more data for a judgement to be made. Where further data is required, substances will undergo dossier or substance evaluation. Currently, there are around 1 500 substances registered above 100 tonnes per year that need more data before authorities can allocate them to a group[5].

During 2019, eight more substances were identified and included in the Candidate List of substances for eventual inclusion in the Authorisation List. ECHA also recommended 18 substances for the Commission to include in the Authorisation List. With three proposals for restriction submitted by Member States and ECHA, and one restriction being adopted by the Commission, tangible progress has been made in improving risk management within the EU. Finally, the Committee for Risk Assessment (RAC) adopted 51 opinions on classification and labelling dossiers.

2. Safe and sustainable use of chemicals by industry

Establishing effective communication up and down the supply chain is critical to ensuring safe use of chemicals. ECHA has worked with key stakeholders to identify necessary improvements to the current system for providing fit-for-purpose safety information on hazardous substances and mixtures. Our work has been endorsed by key policy stakeholders and we are moving into the development phase. These changes also aim to help companies make use of this information to effectively meet their obligations under related occupational safety, health and environmental legislation.

3. Sustainable management of chemicals through the implementation of EU legislation

The work towards this objective showed how ECHA's information, knowledge and competences on safe use of chemicals support the implementation of EU legislation. This resulted in synergies both internally when

3 See further: Workload drivers and performance indicators of ECHA's performance management model (Appendix I).

4 See further in the section 'Generating, monitoring and regulating information that matters on groups of chemicals of concern.'

5 ECHA's annual Integrated Regulatory Strategy report provides detailed information.

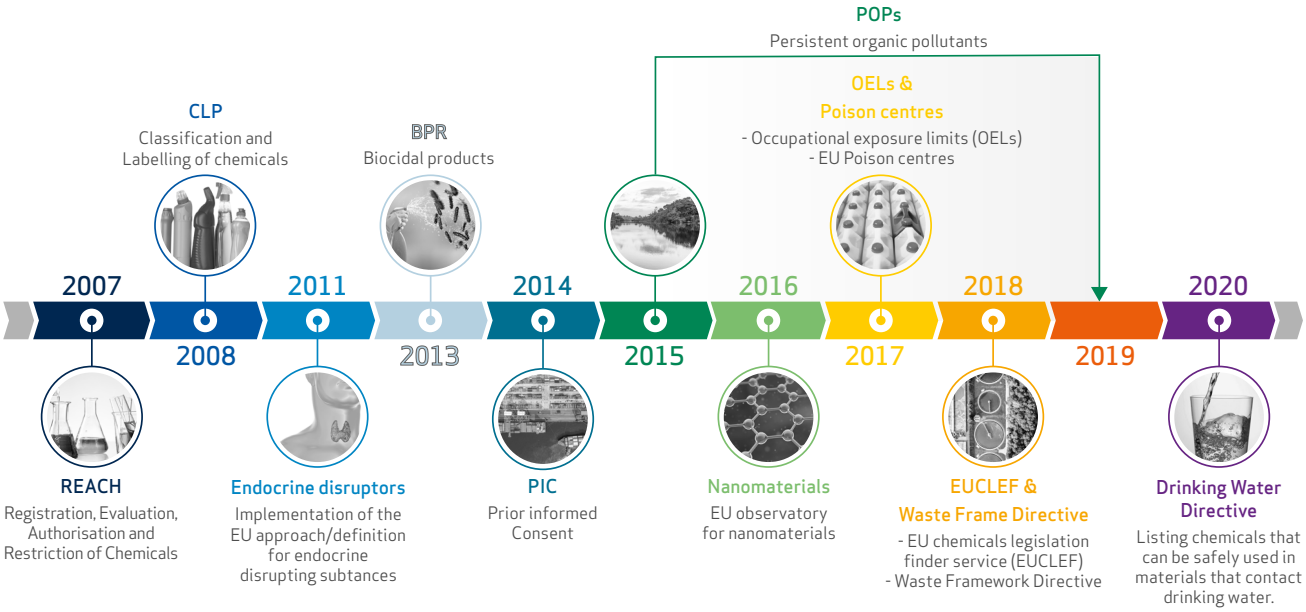
implementing new regulatory tasks and externally in cooperating with partners. By integrating new tasks into our portfolio, such as the SCIP database or preparations for assessing substances used in materials that may come into contact with drinking water, we showed that we have the competence and expertise to leverage the experience achieved through working with REACH, CLP, BPR, PIC and POPs. ECHA can apply its knowledge in new areas while re-using existing IT platforms, creating economies of scale. Long-term projects, such as sharing IUCLID-as-a-service with the European Food Safety Authority (EFSA) have started.

ECHA provided short-term support to the Consumers, Health, Agriculture and Food Executive Agency for data protection services and a peer review of common risks with the environmental agencies of the EU intensified cooperation and the exchange of good practices.

ECHA's outreach activities support sustainable chemicals management on a global level. We started developing a systematic approach for capacity building in third countries that helps them develop chemical management systems that can benefit from European chemicals management and risk assessment approaches.

Overall, we efficiently and effectively carried out our tasks under REACH, CLP, BPR, PIC and POPs together with new areas of work on poison centres, occupational exposure limits, the Waste Framework Directive, the EU Chemicals Legislation Finder and the EU Observatory on Nanomaterials.

FIGURE 2: ECHA's new areas of work during the years



For 2019, we have identified the following main **operational areas of achievements**:

- We have tackled non-compliant information on chemicals head on and recorded significant progress in generating needed hazard information. We have sped up dossier evaluation and put further measures in place to raise the percentage of the dossiers we check. We have conducted 50 % more full compliance checks[6] of substances compared to 2018. We carried out 301 full checks covering 274 unique substances and 89 targeted checks on 64 unique substances. The full checks focused on the long-term effects of chemicals, with most

6 A full compliance check focuses on the most relevant information requirements for identifying substances of concern. Such checks cover as a minimum genotoxicity, repeated-dose toxicity, pre-natal developmental toxicity, reproduction toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation and bioaccumulation

carried out for properties that are important for health, such as mutagenicity and pre-natal developmental toxicity, and for the environment, such as long-term aquatic toxicity. With the Commission and ECHA's Joint Evaluation Action Plan[7], we prepared the basis for obtaining information on substances where it is unclear whether they are safe or not.

- ECHA has taken steps to clarify how companies apply for authorisation to continue marketing and using their substances once they are listed in the Authorisation List. This includes explaining to applicants when they need to provide substitution plans and developing more consistent and concise opinions that define the boundaries of the scientific opinion making of ECHA's committees. We have started to put these opinion formats into practice and have adapted our working practices to allow a high number of authorisation applications to be processed, while ensuring proper control of risks to human health and the environment, and that substances of very high concern are substituted with safer alternatives.
- ECHA worked on four restrictions in 2019 that allow us to target how we are addressing risk to human health and the environment. There are two standout cases. Firstly, there may be smarter alternatives to microplastics that are intentionally added to some products and ultimately released into the environment in large volumes where they stay for a very long time. Secondly, the proposal to restrict hazardous chemicals in tattoo inks and permanent make-up aims to reduce the risk of cancer, as well as negative effects on fertility and skin irritation.
- In view of the delays at EU level on the implementation of the review programme for biocides active substances, ECHA has developed an action plan aiming to increase the number of dossiers submitted for peer review by the Member States. As part of this action plan, ECHA has increased the collaboration with Member States and provides them with concrete support to finalise their dossiers for decision making.

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GREEN DEAL OF THE COMMISSION – ECHA'S SUPPORT

The Commission's Green Deal gives steer on how to contribute to improving air and water quality, to reduce risks of hazardous chemicals, industrial emissions, pesticides and endocrine disrupters plus a New Circular Economy Action Plan.

ECHA's knowledgebase and high quality, scientific and operational work as set out in its Strategic Plan provides a basis to support sustainable innovation that will contribute to the goals of the Green Deal. This can be in critical areas, such as circular economy, sustainability, climate change or ensuring a toxic-free environment.

In 2019, we set out how ECHA can strategically support the Commission for the Green Deal. We believe that our work can deliver synergies and efficiencies in scientific and technical tasks under various EU laws. This would not only simplify but also strengthen the legal framework by:

- bringing transparency to how the EU coherently legislates chemicals and product safety in Europe;
- evaluating the potential application of a 'one substance – one assessment' approach;
- assessing groups of similar chemicals to speed up risk management and add consistency; and
- establishing ECHA's scientific work as the basis for defining safe values for chemicals and protecting workers from cancer and other harmful effects.

ECHA can play a stronger role in promoting the competitiveness of European industry, by assuming a more robust stance on checking and controlling that chemical safety laws are followed and complied with at the EU's borders, for example, by sharing information with customs authorities.

7 https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en

- ECHA has formed a framework for on-boarding new tasks, such as the European Chemicals Legislation Finder and currently, for instance, the ad hoc tasks for occupational exposure limits. This framework takes into consideration how well it can do so based on existing capabilities, structures and how well new tasks can be integrated into ECHA's activities to support a more holistic approach for safer chemicals.
- The Management Board conducted a comprehensive review of its functioning and ways of working, to continue providing strategic direction and strong governance to the Agency.
- We revised the Integrated Management System Strategy and Framework to support the Agency to deliver on its strategic priorities in a more coherent way. The strategy sets high-level commitments that will direct the Agency in the coming years, as well as consolidating and integrating the different elements of ECHA's management system.

The new organisational structure introduced at the start of 2019 has increased our interconnectivity and facilitated more collaborative ways of working, shifting our focus to our existing competences in tasks where we have developed synergies over the past years. A significant amount of resources has been invested in analysing our structure and finding ways to improve it to better serve the needs of our stakeholders.

Since consumers are becoming more and more conscious of the effects that chemicals have on their everyday lives, we have developed our communications strategy to help us reach out to interested audiences and meet our stakeholders' needs with fact-based information in a relevant and easy-to-use language.

As a centre of knowledge on chemicals safety and relevant EU legislation, the strategy guides us on creating content that will be picked up by mainstream media and interested audiences, and multiplied, spreading awareness of the important work we undertake.

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This annual report consists of two parts:

- Part 1 'Achievements of the year' is ECHA's General Report under the REACH Regulation for **adoption** by the Management Board;
- Parts 2, 3 and 4 are the report of the Executive Director for **assessment** by the Management Board.

Achievements of the year

Our advice to companies on handling their registrations has never been more important especially given the uncertainties caused by Brexit. We've equipped them with all the tools and support they need to cope with the situation.

Jukka MALM

Director of Submissions and Interaction

Advancing the understanding of and the access to information on chemicals

Offering continued registration support for companies

ECHA and the Commission worked together to clarify the rules for registering "phase-in" substances[8] following the completion of the last registration deadline in 2018. 16 053 incoming dossiers (including updates) were received in 2019, and they continued to be processed on time. From these, 30 % were manually verified for completeness in 2019.

The Commission set 31 December 2019 as the cut-off date after which **transitional conditions for "phase-in" substances no longer apply**. ECHA provided a support package for companies to help clarify the rules for registering "phase-in" substances after this date. From 1 January 2020 onwards, companies that want to register a substance can no longer use the pre-registration route to register. Instead, they have to submit an inquiry to ECHA to get information on other registrants.

Industry needs to continue sharing data for dossier updates and also with newcomers through the informal communication platforms used for registering "phase-in" substances.

ECHA redesigned the inquiry process to help speed up data-sharing negotiations for potential registrants. The redesign enabled ECHA to handle more than 4 000 inquiries in 2019.

The **completeness check process** was also extended to include chemical safety reports. The extension enables substances to be prioritised for regulatory action by authorities, enhances information on uses that are disseminated and improves the starting point for appropriate supply chain communication. The revised approach will be launched in 2020 together with the release of the new version of IUCLID.

FIGURE 3: Brexit social media campaign

8 Phase-in substances are already listed on the European market in the European Inventory of Existing Commercial Chemical Substances (EINECS). Under REACH, rules for these substances were established for a transitional period.

After the last registration deadline, there was a marked increase in the number of notifications for the registration exemption for product and process oriented research and development (PPORD). In 2019, ECHA handled around 350 notifications, roughly 35 % more than before the deadline.

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USEFUL INFORMATION FOR COMPANIES DURING BREXIT UNCERTAINTY

During on-going political uncertainty over the UK's withdrawal from the EU, ECHA developed an extensive communication package to support companies and minimise disruptions to the EU market. The Agency continued to urge companies to act to ensure they comply with their obligations under the EU's chemicals legislation and to prepare for a "no deal" scenario.

To avoid disruptions in supply, a **list of substances registered by UK companies only**[9] was published so that downstream users could take action, if necessary. Those who were planning to receive their supply from the UK after its withdrawal needed to register the substances themselves as an importer, unless an only representative based in one of the remaining 27 EU Member States or an EEA country had been appointed for the registration process.

Registrations made by UK manufacturers, importers and only representatives will become invalid if they are not transferred before the UK withdrawal. **Step-by-step instructions on how to transfer registrations**[10] were published in February 2019. Consequently, by the end of 2019 transfers had been made for 531 substances only registered in the UK, but there were still 650 UK-only substances not yet transferred.

A temporary procedure was put in place until the UK left the EU to ensure that companies that want to export PIC chemicals to the UK after the withdrawal could still comply with their obligations to notify their trades, 35 days before the expected date of import.

All industry-facing IT systems also had to be adjusted to handle the challenges faced due to the UK's withdrawal.

Making data more accessible to all users

Users of ECHA's chemicals database were given enhanced possibilities to identify the stage their substances were under different regulatory processes, whether they had properties of concern or whether they were present in nanoforms on the market.

New features to the chemicals database became available in July 2019, improving access to the first layer of information in the **substance Infocards**. The new elements allowed users to search for substances based on their hazard properties. For instance, if a substance is considered as an endocrine disruptor in the EU, or is under assessment, users would see a small icon displaying this.

The registration data is now structured based on relevant chemical regulations. The respective regulatory activities for each substance now include simple explanations of why substances appear in specific regulatory lists. More **multilingual information** was also made available than ever before with translated names released for around 6 000 substances in 22 EU languages.

Furthermore, we implemented **quick links to key datasets** for each substance, helping users to search beyond the basic information into more rich sets of data, such as the Brief Profiles, REACH registered substance factsheets, the Classification and Labelling (C&L) Inventory, biocides data and the public activities coordination tool (PACT). Under the work of the EU Observatory for Nanomaterials (EUON), users now also have access to **a new nanomaterial section** that shows whether substances are on the EU market in nanoforms.

9 https://echa.europa.eu/documents/10162/13552/uk_only_reg_en.xlsx
10 https://echa.europa.eu/documents/10162/13552/how_to_transfer_uk_reach_registrations_en.pdf

As well as the free public access to information on chemical properties available in ECHA's chemicals database, REACH registration data is now also automatically linked to the OECD's eChemPortal[11] and has been integrated into the QSAR Toolbox.

These steps will help European governmental institutions, industries and stakeholders fill data gaps for assessing chemical hazards, particularly for aquatic toxicity, sensitisation, irritation and corrosion.

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HARMONISED HELPDESK SUPPORT FOR COMPANIES ACROSS THE EU

ECHA continued to keep national helpdesks updated on relevant legislative changes that impact the Agency's work, particularly for new tasks added to our portfolio. The yearly meetings of the network of national REACH, CLP and Biocidal Products Regulation helpdesks – **HelpNet** – demonstrate European-wide collaboration, and ensure that the same advice is communicated to all concerned companies regardless of the Member State they are from.

The HelpNet replied to more than 40 000 enquiries on REACH, CLP and biocides from companies across the EU during 2019. The network is a key multiplier of ECHA's messages and provides advice to companies – many of which are SMEs – in their own languages.

The hot topics that companies asked about in 2019 included Brexit, the "phase-in" period for registrations and the submission of poison centre notifications. Responses to these and other enquiries were discussed at the network meeting in April 2019. Information exchange in the network also happens through the web-based IT application **HelpEx**.

In November 2019, a CLP Workshop gave an update on the changes to timelines and development plans for ECHA's submission portal for poison centre notifications.

Strengthening enforcement together with Member States

Enforcement authorities were urged to prioritise and tighten cooperation in enforcing evaluation decisions to help tackle insufficient information in registrations. Measures have been recommended to improve supply chain communication for substances in articles, address safety data sheet deficiencies and ensure that mixtures are classified and labelled correctly.

ECHA works with Member State enforcement authorities through the Enforcement Forum on REACH, CLP, PIC, POPs and the Biocidal Products Regulation.

Since January 2019, ECHA's evaluation decisions have been individually sent to all co-registrants of the same substance whose registration dossiers were found to be incompliant. With this approach, enforcement authorities have been encouraged to prioritise evaluation decisions in their activities. The Forum is working to establish a way for authorities in different countries to collaborate to address multiple registrants in joint submissions. This should bring a welcome boost for driving companies to fill in information gaps in their registration dossiers.

The findings of the Forum's pilot project checking substances in articles were published in November 2019, revealing that **companies need to improve their communication about hazardous substances in products**. Candidate List substances of very high concern were found in 12 % of inspected products and, for these, 88 % of suppliers failed to communicate sufficient information to their customers. This lack of information flow hinders

11 https://www.echemportal.org/echemportal/index.action

the safe use of imported products and articles and may undermine the protection of European consumers.

Around 44 % of nearly 3 400 hazardous mixtures were found to be incompliant during the sixth EU-wide enforcement project on **classification and labelling obligations of mixtures**. Shortcomings were also found in one third of safety data sheets, and industry has been encouraged to address these to aid the flow of information throughout the supply chain.

FIGURE 4: Post from Enforcement Forum social media campaign

The operational phase of several other enforcement projects ran through the year. In January 2019, the **first enforcement project for biocides kicked off, focusing on the illegal use of non-approved active substances in treated articles** used in children's and sports clothing, building products and for swimming pools and personal safety equipment.

Checks on whether importers and manufacturers are complying with their **obligations to register their substances** were also launched in the Forum's seventh enforcement project. In parallel, enforcement authorities and customs began a pilot project **checking whether importers were complying with certain restrictions** for hazardous substances like cadmium, nickel and lead. The Forum also prepared for the launch of its eighth enforcement project on **controlling the online sales of chemicals**.

Under the joint evaluation action plan[12], the Forum launched a questionnaire surveying Member States about the **measures they have in place for enforcing dossier evaluation decisions** and drafted an **annual reporting template** for collecting information on national enforcement actions. The idea is to collect high-level information about the focus of inspections and to allow Member States to report more granular information. The template is expected to be finished by early 2020.

Authorisation was announced as the topic of the Forum's upcoming ninth major enforcement project, with the focus on provisions related to REACH authorisations that are meant to protect the safety and health of workers and the environment.

12 https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en

Supporting non-EU countries to make better use of information on traded chemicals

In spring 2019, ECHA collaborated with the Commission and Member States at the Conference of the Parties to the Rotterdam Convention to present to non-EU countries how the Convention is implemented by the EU. This gave attendees a chance to discuss the challenges they face with information provided by EU importers for chemicals that need to be administered under the Prior Informed Consent (PIC) Regulation.

Authorities in non-EU countries emphasised that the **lack of accuracy of importer details** in certain PIC export notifications prevents them from contacting importers. ECHA already took measures, including communicating through the ePIC tool, to raise awareness about the lack of information and to enable authorities to check the importer's identity, activities and capabilities for handling PIC chemicals.

ECHA also supported other initiatives to increase the knowledge and capacity of non-EU countries, participating in a workshop in June 2019 organised by the Rotterdam Convention Secretariat in Rabat, Morocco.

To allow importing countries to make informed decisions and ensure safer use of PIC chemicals, ECHA has continued to improve the clarity of information provided in export notifications on regulatory actions taken by the EU for those chemicals.

In late 2019, we published the report on the amount of PIC chemicals exported and imported in 2018. While the total amount of **exported PIC chemicals had dropped significantly** by around 120 000 tonnes compared to 2017 figures – from approximately 829 000 tonnes in 2017 to less than 708 000 tonnes in 2018 – the **amount of PIC chemicals imported into the EU rose** by more than 246 000 tonnes compared to 2017, reaching approximately 547 500 tonnes in 2018.

Benzene – a substance that is predominantly used to make plastics, resins, synthetic fibres, rubber lubricants, dyes, detergents, drugs and pesticides – was the most traded PIC chemical, both for exports and imports. More than 228 000 tonnes were exported from the EU to non-EU countries, but more than 445 000 tonnes entered the EU in 2018.

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INTERNATIONAL OUTREACH AND CAPACITY BUILDING

For EU pre-accession countries, we provided capacity building under the instrument for pre-accession and supported the worldwide development of standards and tools for risk assessment.

ECHA's international outreach in 2019 included contributing to the **worldwide development of standards and tools for risk assessment** of chemicals, offering technical and scientific support to the Commission and the EU agenda for international chemicals management and capacity building in third countries.

ECHA continued to contribute to the international development and harmonisation of tools and methods needed to effectively implement EU legislation. This has mainly been done through the **OECD Chemicals Programme** and driving agreements on international standards and tools that not only benefit the EU, but also authorities and industry beyond its borders.

ECHA supported the implementation of the **Rotterdam and Stockholm Conventions** and the United Nations Globally Harmonised System for Classification and Labelling of Chemicals (**UN GHS**), notably in work to develop the use of non-animal testing methods for classification.

In close cooperation with the Commission, we started developing a more systematic approach for **capacity building** towards third countries and supported (potential) EU accession candidate countries through the Instrument for Pre-accession assistance (**IPA**) with an in-depth study on **Montenegro** and **Serbia** to assess their readiness for EU membership.

Generating, monitoring and regulating information that matters on groups of chemicals of concern

The chemical universe becomes more clear

Over 21 000 registered substances have been mapped in a 'chemical universe' assigning each of them to a pool based on regulatory actions that were initiated or under consideration.

In early December 2019, we published a **list of more than 21 000 substances registered under REACH**[13], divided into five pools based on regulatory activities for each substance. The list also highlights that possible actions have not yet been determined for thousands of substances. The allocation is divided into:

- **Regulatory risk management ongoing:** regulatory risk management measures in place based on confirmed hazards for human health or the environment, and considering exposure.
- **Regulatory risk management under consideration:** substances that are currently being considered for regulatory risk management.
- **Data generation:** substances that require additional information to conclude whether further regulatory action is needed.
- **Currently no further actions proposed:** substances for which authorities have not proposed further regulatory action at the moment.
- **Not yet assigned:** substances currently registered under REACH but not yet assigned to any of the other pools.

The mapping brings transparency to ECHA's regulatory risk management and helps authorities plan and execute their work better. Additionally, we collaborated with authorities to pursue the goals of the UN's World Summit on Sustainable Development 2020.

This common approach is embedded in ECHA's Integrated Regulatory Strategy, which is the **backbone of ECHA's data generation and risk management**. As part of the strategy, structurally similar substances are grouped to address them together rather than individually - increasing coherence on how similar substances are regulated within the EU, the predictability of authorities' work and ensuring that all hazard information can be used effectively to fill data gaps. Grouping the substances into pools supports the development of sustainable alternatives and helps to remove the most harmful substances from the market through informed substitution.

So far, we have focused on the substances registered for volumes over 100 tonnes per year and aim to conclude on their allocation to the pools by the end of 2020. The work should be concluded for all registered substances by 2027.

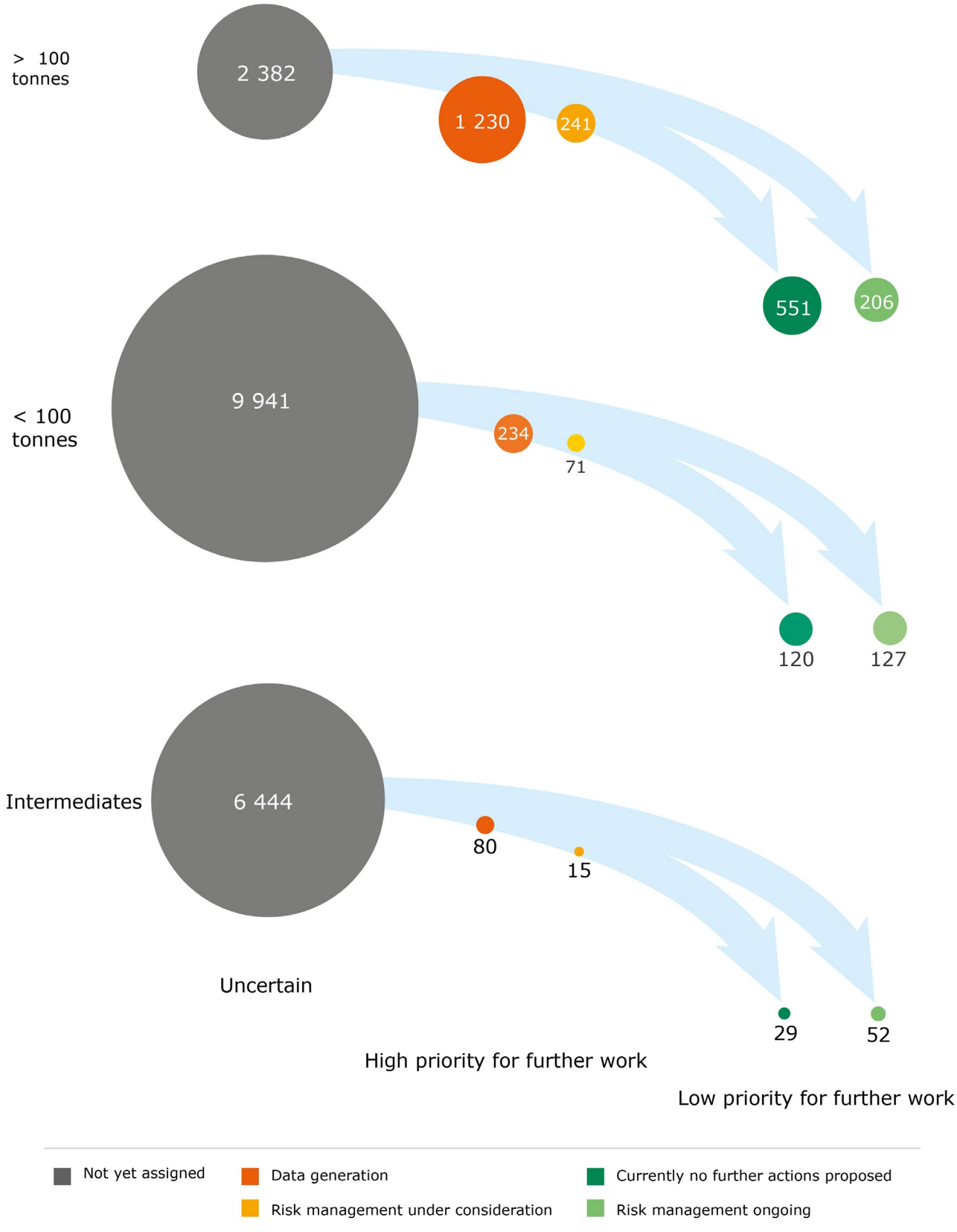
"The more we know about the 21 000 registered substances, the better authorities can focus their work and concentrate on protecting EU citizens, and the better choices industry can make in producing and using safer products.

Jack DE BRUIJN

Director of Prioritisation and integration

13 https://echa.europa.eu/universe-of-registered-substances

FIGURE 5: Mapping of the REACH chemical universe



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ACHIEVEMENTS IN SUPPORTING NANOMATERIAL REGISTRANTS

ECHA supported companies to submit more relevant data for their substances in nanoform, as required by the revised REACH annexes.

Companies manufacturing or importing nanoforms of substances within the scope of REACH, had to register them with ECHA by 1 January 2020.

To support registrants with this task, we published two guidance documents in December 2019 on submitting specific information for (sets of similar) nanoforms. One explains the specific characterisation information that needs to be reported and provides advice on how to build and justify sets of nanoforms. The second clarifies the differences between creating a set of nanoforms and read-across for justifying the use of hazard data between different (sets of) nanoforms.

In November 2019, our webinar explained both guidance documents and introduced the new IUCLID fields for reporting characterisation parameters of nanoforms together with practical examples. The webinar gave companies the chance to receive specific information from ECHA's experts on what they need to meet their obligations by the deadline. It was attended by over 500 participants and the recording has been viewed over almost 1 000 times. More than 150 questions were received and a comprehensive Q&A document was made available to further support companies.

In parallel, the manual on dissemination and confidentiality under REACH was revised in October 2019 and guides registrants on how they should submit sensitive information.

By 1 January 2020, only 36 substances covering nanoforms had been registered according to the updated REACH requirements – 10 % of what the Agency had expected. ECHA is working closely with key industry associations and Member States to better understand the actions needed to raise awareness on the legal obligations.

Our advice on safe use of chemicals along the supply chain

ECHA has made a proposal to improve the workability and quality of safety data sheets based on the direction emerging from the REACH Review Action 3[14] and from our second strategic priority that aims for safe and sustainable use of chemicals by industry.

Under REACH, suppliers have to provide information to recipients on the safe use conditions of their substances and mixtures. They communicate this information along the supply chain through safety data sheets and relevant exposure scenarios.

Throughout 2019, ECHA and the Commission organised two major workshops addressing **REACH Review Action 3** on improving safety data sheets and exposure scenarios. Several more specific projects were also done under the umbrella of the Exchange Network on Exposure Scenarios – ENES – coordinating and involving a complex community of stakeholders including industry, Member State authorities and the Commission. In particular, ENES created a platform for industry-led activities to **enhance sector use maps**, which demonstrate how information can be used under real life conditions and how uses apply across different market sectors. This is useful for registrants during their chemical safety assessment.

ECHA has invested more than a decade in testing ways of working, developing and implementing different IT tools to facilitate appropriate distribution channels. Information on safe use of chemicals is of the utmost importance and requires proper handling through methods such as the safe use of mixtures information (SUMI)

14 REACH Review Action 3: Improving the workability and quality of extended safety data sheets (eSDSs).

approach and lead component identification (LCID) methodology.

Based on these investigations, ECHA carried out a major gap analysis during 2019 to find out what the main obstacles are that block successful communication in chemical supply chains. These obstacles include ambiguous requirements for exposure scenarios for mixtures, the need to better fit exposure scenarios to the recipients' needs and a lack of harmonisation enabling IT support. We also identified the scope of a broader technical system that illustrates the workflow of risk management communication. The **supply chain flowchart**[15] shows the information flow from a bottom-up perspective while connecting three main actors – end users, formulators and REACH registrants.

This approach highlighted, on the one hand, which IT tools should be further fine-tuned to better support the flow of exposure scenario-related information and which methods and tools would still need to be created. Related to this, in November 2019, ECHA included a functionality that allows suppliers to enter substance information directly into the Chesar tool without linking it to IUCLID. The scoping phase for this work has allowed us to compare the crossovers between REACH and the occupational, safety, health and environmental legislation to propose a common and synchronised grounds for minimum requirements for exposure scenarios.

ECHA has also supported the Joint Research Centre Seville under the **Industrial Emissions Directive** and their work to develop Best Available Technique reference documents (BREFs) for ceramics and textiles. In this context, we have outlined how the information on substances required by REACH can support and achieve the fulfilment of occupational, safety, health and environmental obligations in the European Union.

Collecting data for safer chemicals in products, sustainability and a circular economy

Under the Waste Framework Directive, ECHA received a task to set up a database including information on substances of concern in articles and products (SCIP). The information will help waste operators sort and recycle articles that contain substances of very high concern, and will support consumers to make informed choices when buying articles and consider how to best use and dispose them.

The **information requirements for the database** were finalised and made available in September 2019, taking on board input from the Commission, Member States and stakeholders. Key data models have also been produced ahead of the launch pf the prototype of the database in February 2020.

After securing the necessary resources, the development of the SCIP database took off in May 2019 with the delivery of the **technical notification format for substances of very high concern in articles**, launched with the updated version of IUCLID in October 2019.

In November 2019, ECHA set up an IT user group and organised a workshop on SCIP to engage with stakeholders. It was attended by more than 400 participants and a large amount of outreach activities were organised to raise awareness on this new legal obligation.

The SCIP database, together with other processes under REACH, including authorisation and restrictions, provides a broad knowledgebase that will allow ECHA to contribute to EU action on chemicals that damage the environment and human health, and develop safer and sustainable alternatives that progressively substitute substances of concern in articles. These steps will improve the interface between products, waste and chemicals and will contribute towards a European circular economy and a higher level of protection for human health and our environment.

15 See page 19 of: https://echa.europa.eu/documents/10162/13563/report_2nd_reach_review_action_3_ws_en.pdf

How we improve the impact and increased the efficiency of dossier and substance evaluations

Significant progress in the number of substances checked for compliance

ECHA and the Commission published a joint action plan in 2019 with 15 actions to improve dossier compliance – increasing the minimum target of dossiers checked from 5 % to 20 % in each tonnage band. This new target will reduce information gaps and result in approximately 30 % of all registered substances being checked by 2027. By the end of 2019, more than 20 % of the substances above the 100 tonnage band were checked for compliance.

ECHA has a responsibility towards European citizens and stakeholders to ensure that the data on chemicals provided by industry complies with REACH information requirements. We have taken several initiatives to act upon the agreed commitments made in the joint action plan[16]. Moreover, we have tackled non-compliant information on chemicals head on this year, sped up dossier evaluation and significantly raised the percentage of dossiers checked.

The Agency discussed the possibility of **simplifying the wording and clarifying the REACH annexes** with the Commission. This action will help industry better understand how to conduct their testing to meet the information requirements. The wording of compliance check decisions was also standardised so industry can see which specific information is incompliant and how to proceed with the next steps of the dossier evaluation process.

We also looked in detail at how efficiently we carry out compliance checks and launched a series of projects aimed at **generating decisions faster**. Since early 2019, we have worked to simplify evaluation decisions aiming to provide more focused justifications on why information is still required from registrants to compel them to comply with their obligations. Feedback from companies has indicated that the justifications in our decisions could still be clearer and we are working to further simplify them.

As of 2019, decisions are sent to all registrants with incompliant dossiers within a joint submission – a change to the earlier practice when only the lead registrant was contacted. This change of practice has been welcomed by stakeholders as it facilitates collaboration and data sharing within the joint submission and increases the impact of our decisions.

“The health of Europe’s citizens is in industry’s hands and companies must do all they can to fill in the remaining information gaps and take risk management actions. We are determined to do our part: based on a comprehensive screening of all substances, the selection of about 30 % of substances for compliance check is expected to address the data gaps that matter most for safety.

Christel MUSSET

Director of Hazard assessment

16 https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en

2019

YEAR IN NUMBERS

390
compliance checks performed on 3 750 dossiers covering 338 unique substances.

From these, 301 full checks focused on information relevant for clarifying PBT and CMR properties and were performed on 2 958 dossiers covering 274 unique substances.

99
testing proposals examined

207
follow-up evaluations concluded

31
new substance evaluations performed

22
substance evaluations finalised with 15 decisions issued requesting further information

In 2019, we carried out **301 full checks** covering 274 unique substances – an increase of more than 50 %[17] compared to the 2018 figures (where 196 full checks covering 182 substances were done). The full checks focused on the information relevant to clarify the long-term effects of chemicals.[18] In addition, we also performed 89 targeted compliance checks. Overall, this means a total of 390 checks on 3 750 dossiers covering 338 unique substances.

Compliance of dossiers, their systematic review and updates of registrations based on new information remains industry's responsibility. In 2019, we continued to support industry associations' initiatives to develop programmes for helping registrants review chemical safety data. ECHA's experts presented the Agency's views at a number of webinars and workshops organised by different industry associations at national or European level. Examples of these programmes include the **CEFIC Action Plan** launched in June 2019 or the **metals and inorganics sectoral approach** (MISA) – a collaborative programme that addresses technical and scientific issues facing the metal and inorganics sector and covering 300 substances – almost all of the metals in large volumes.

Evaluating dossiers and substances more effectively

To better integrate dossier and substance evaluation and progress on generating data, ECHA discussed the feasibility of a "combined approach" (COMBO) with Member State authorities. From the discussions, ECHA considered that a COMBO approach was feasible and could be done on a voluntary and case-by-case basis, although some Member States have asked for more flexibility.

We launched several projects analysing multiple groups of substances, on **whether compliance checks and substance evaluations could be done at the same time**. While the results are not yet final, the progress showed that a COMBO approach is possible. Compliance checks and substance evaluation can run in parallel and doing so can speed up data collection, so that necessary information can be obtained faster and used to quickly decide on the most appropriate ways to manage chemical risks.

ECHA also prepared an **improved substance evaluation draft decision template** and an illustrative example. The example showed concisely how we justify our requests for more information and address the comments of registrants in a substance evaluation decision. With new templates in place, the instructions were also updated accordingly.

We have also strengthened collaboration with Member States by updating materials and offering webinar trainings encouraging them to carry out their assessments more quickly.

17 A full compliance check focuses on the most relevant information requirements for identifying substances of concern. Such checks cover, as a minimum: genotoxicity, repeated-dose toxicity, pre-natal developmental toxicity, reproduction toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation and bioaccumulation.

18 Concerns for carcinogenicity, mutagenicity, reproductive toxicity (CMR) and persistency, bioaccumulation and toxicity (PBT).

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SMARTER DECISION MAKING IN EVALUATION

We have further increased the efficiency of decision making both in dossier and substance evaluation. A decreasing proportion of draft decisions required the involvement of the Member State Committee (MSC). Agreement seeking in the MSC is triggered when Member States submit proposals for amendment to a draft decision. These proposals are a welcome quality control, however, they trigger the need for further discussions within the MSC and further consultations with registrants, which requires additional work and time.

In 2019, Member States proposed amendments to 16 % of the draft decisions notified to them. The corresponding number was 22 % in 2018 and 46 % in 2017.

Improving collaboration between ECHA, the MSC and competent authorities, to ensure that the path forward is clarified before decision making, will further reduce and better focus proposals for amendments. These efficiency gains will also enable the MSC to concentrate more on resolving general scientific-regulatory issues.

Working for harmonised classification, labelling and packaging of chemicals

Classification and labelling of products containing hazardous substances is one of the most powerful incentives for companies to reduce their use of hazardous substances. The Committee for Risk Assessment (RAC) adopted 51 opinions on the harmonised classifications of substances.

RAC members contributed during 2019 with expertise on classification for physical, human health and environment hazards. The committee adopted 51 opinions on classification and labelling dossiers throughout 2019, which included 31 for active substances used in plant protection products. This year there has been a shift back to the earlier trends, with over 60 % of the CLH dossiers submitted for industrial chemicals.

Companies are **obliged to self-classify hazardous substances that do not have a harmonised classification under CLP** and must notify ECHA accordingly. In 2019, we recorded 6 000 new notifications with information on classification and labelling of substances to the Classification and Labelling (C&L) Inventory.

For ensuring transparency on how substances are classified and labelled, also the EU-wide harmonised classification form part of the Inventory. The Commission updates the legislation with harmonised classification and labelling of hazardous substances through Adaptations to Technical Progress (ATPs) of the CLP Regulation. For the Inventory, in 2019, we integrated two ATPs, adding 16 new harmonised classifications, updating 18 entries and deleted one. The update includes translations in all EU languages for more than 4 000 substances.

In Europe, the CLP Regulation implements the internationally agreed Globally Harmonised System for classifying and labelling chemicals. During 2019, ECHA actively supported this global work by:

- contributing to the revision of the chapter on skin corrosion and irritation to include non-animal testing methods;
- assisting in the development of "additivity" in health hazards; and
- participating in the discussions of a global list of chemical substances.

2019

YEAR IN NUMBERS

51
RAC opinions on CLH proposals

60
CLH dossiers submitted

152 000
substances notified
(C&L Inventory total number)

TABLE 1: Selected hazard classes included in the RAC opinions. Note that one opinion can cover multiple hazard classes

Hazard Class	No.	Percentage on total
Carc. 1B	4	8 %
Carc. 2	8	16 %
Carcinogenicity	**12**	**24 %**
Muta. 1B	1	2 %
Muta. 2	3	6 %
Mutagenicity	**4**	**8 %**
Repr. 1B	8	16 %
Repr. 2	8	16 %
Reproductive toxicity	**16**	**32 %**
Sensitisation	**15**	**30 %**

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COMMITTEE CLASSIFICATION OPINIONS MAKE STRONGER RISK MANAGEMENT POSSIBLE

In June 2019, ECHA's Committee for Risk Assessment (RAC) adopted its opinion on the classification of **6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol (DBMC)** as a substance that is presumed to damage sexual function and fertility.

Many registrants and several notifiers (although not all) had classified the substance as **suspected** of damaging fertility or the unborn child. But RAC's stricter opinion on harmonised classification makes more stringent risk management measures possible, including restriction for supply to the general public.

The substance is an antioxidant and stabilising additive that is used both by professional workers and consumers. Industrial uses include in rubber and non-rubber polymers, fuels, hydraulic and metal working fluids, adhesives, process regulators and in laboratory chemicals. Consumer applications include fuels, lubricants and greases, metal working fluids, adhesives and sealants (such as in floor coverings), paints and coatings, paper products, and plastic and rubber products.

Addressing and focusing on groups of substances of concern

Taking steps towards more consistent applications for authorisation

In 2019, ECHA included eight substances of very high concern in the Candidate List for authorisation and recommended 18 substances for the Commission to include in the Authorisation List. ECHA changed how opinions are documented and, consequently, the requirements for applicants were also adapted. ECHA received[19] 62 applications for authorisation for 95 uses, which is the second highest amount received in a year.

In 2019, two substances were added to the list of substances of very high concern (**Candidate List**) because of identified endocrine disrupting properties, and four due to reprotoxic properties. This brought the Candidate List to 205 substances of very high concern.

The Member State Committee (MSC) also made milestone decisions by identifying HFPO-DA and perfluorobutane sulfonic acid (PFBS) and its salts as substances that are of **equivalent level of concern** to other substances of very high concern. These substances are characterised by high persistence, high mobility and potential for long-range transport, difficulty of technical control and probable serious effects for human health and the environment. They were, therefore, also added to the Candidate List.

ECHA continued to prioritise substances from the Candidate List for inclusion in the **Authorisation List**. If companies need to use substances included in the Authorisation List in their products, they have to apply for an authorisation to ECHA. The authorisation requirement aims to ensure that substances of very high concern are properly controlled and progressively replaced by less dangerous substances or technologies, where they are technically and economically viable.

In October 2019, ECHA recommended to include 18 substances of very high concern in the Authorisation List – the recommendation contained 13 substances that are toxic for reproduction, one of which also had endocrine-disrupting properties. The other substances included an endocrine disruptor, a cancer causing substance, two respiratory sensitisers and one very persistent, very bioaccumulative substance. The substances were prioritised either because their high volume and widespread use may pose a threat to the environment or to human health, or because they may be used to replace other substances already on the Authorisation List.

We value delivering quality opinions that are fit for purpose. We can only gain the trust of applicants and decision makers when they get clear and consistent opinions from our committees and we've done a lot this year to improve this.

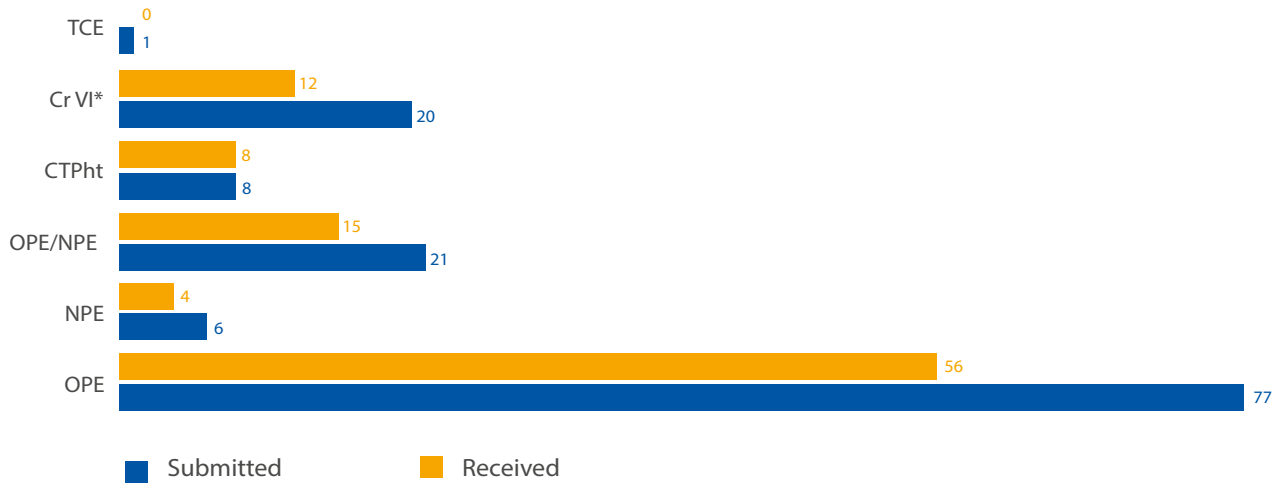
Peter VAN DER ZANDT

Director of Risk Management

We received 62 applications for authorisation for 95 uses in 2019. ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) began working on these applications, notably on **ethoxylated nonyl- and octylphenols**, and **coal tar pitch high temperature**. The committees concluded and sent 14 opinions on nine applications for authorisation and one review report to the Commission for decision making.

19 Applications are only considered received when the application fee has been paid.

FIGURE 6: Number of uses submitted/ received in 2019 per substance



* 8 uses submitted in 2018 but received (application fee received) in 2019.

Based on feedback from stakeholders and the European Parliament, as well as the General Court's judgment on a lead chromate authorisation[20], we have **updated the formats for RAC and SEAC opinions** on application for authorisations, adapting them to make them more concise and consistent.

The **second REACH Review concluded that the authorisation system is delivering on its objectives** on substituting harmful substances and reducing risk. The Commission has identified where we still need to improve, in particular, when companies high up in the supply chain apply for authorisation.

ECHA is discussing with the Commission to improve the system by providing clearer opinions as well as by clarifying how RAC and SEAC would evaluate the risks related to ethoxylated nonyl- and octylphenols – which are environmental endocrine disruptors – and how these would be communicated in the over 100 opinions in 2020.

During the discussions on the **UK's withdrawal** from the EU, ECHA was in close contact with about a dozen European and UK companies regarding their authorisations or applications. We informed them about the consequences of withdrawal and learned about their intentions, which enabled us to understand the full picture, and communicate this to the Commission in an effort to minimise disruption to the EU market at withdrawal.

Restricting chemicals of concern: microplastics, tattoo inks, lead in shot and PAHs in rubber granules

To support policy makers in addressing citizen's concerns, ECHA developed four restriction proposals including one for intentionally added microplastics, where the proposed restriction is estimated to reduce emissions by 400 000 tonnes over 20 years. ECHA's scientific committees also adopted opinions supporting restrictions for hazardous substances used in tattoo inks and permanent make-up, and for eight polycyclic aromatic hydrocarbons in granules and mulches. A call for evidence on a potential restriction of lead in shot, bullets and fishing tackle was also published.

In January 2019, we proposed to restrict **microplastics that are intentionally added to products** that will inevitably be released to the environment. Once released, microplastics can remain in the environment for

20 Judgment of the General Court T-837/16 of 7 March 2019 annulled a decision authorising certain uses of lead chromate pigments. The Commission has appealed this on 20 May 2019 (C-389/19 P).

thousands of years, and be practically impossible to remove. A consultation was launched in September 2019 and received nearly 500 individual comments. The comments are considered by ECHA's committees when they prepare their opinion.

Another proposal to restrict **hazardous chemicals in tattoo inks and permanent make-up** was supported by ECHA's committees in March 2019. The restriction covers substances that can cause cancer, mutations and are toxic to reproduction; sensitise or irritate skin; corrode or damage the eye; as well as metals and other substances regulated in cosmetic products.

In September 2019, ECHA's scientific committees backed a proposal from the Netherlands to restrict **eight polycyclic aromatic hydrocarbons (PAHs) found in granules and mulches** used in synthetic sports pitches and on playgrounds. The restriction proposal will reduce the total concentration limit of the eight PAHs to 20 mg/kg, and ensure that the cancer risk for professional footballers, workers installing the pitches and children playing on the surfaces remains low.

In October 2019, we launched a call for evidence on the **risks posed by lead to the environment and wildlife, and to human health** when they consume game meat. The Agency will use the information to prepare a restriction proposal for lead in shot outside of wetlands, bullets used in any terrain and fishing tackle.

Further restriction work was carried out in 2019 related to lead in consumer articles, **worker exposure to formaldehyde and to N,N-dimethylformamide (DMF)**, and on two restrictions submitted by Member States on **skin sensitisers in textiles** and **PFHxS**.

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USING WHAT WE'VE LEARNT TO IMPROVE SUSTAINABLE SUBSTITUTION

ECHA took lessons learnt from its substitution strategy in 2018-19 and will use them to continue to boost the replacement of harmful substances with safer alternatives. Based on the gained knowledge, ECHA is **refining its substitution strategy for 2020-21**, building on the substitution achieved through implementation of its regulatory tasks and with activities building the capacity of companies and Member States to carry out analyses of alternatives and enhancing networking opportunities.

ECHA organised the second EU-wide substitution network meeting in May 2019 to take stock of different substitution activities undertaken by ECHA and stakeholders and to identify where it would add value to boost substitution. As part of ECHA's substitution strategy several substitution-related workshops were held on specific topics, such as the use of **alternative flame retardants and repellents in textiles** (in Belgium), **alternatives to the use of hexavalent chromium** (in Finland and Germany), **sustainable alternatives to bisphenol A in thermal paper** (in Belgium) and **challenges in biocidal preservation of paints and detergents** (in Belgium).

An online introductory training on analysis of alternatives was prepared in 2019 by the Lowell Center for Sustainable Production (UMass Lowell). The training is intended for a range of analysis of alternatives practitioners working in authorities, industry and NGO organisations and focuses on the essential topics for assessment of alternatives to support informed substitution. It has been made available to stakeholders in January 2020. A webinar on the GreenScreen hazard comparison method was also organised in 2019[21].

21 https://echa.europa.eu/-/greenscreen-an-effective-tool-and-methodology-to-compare-chemical-hazards-and-identify-safer-alternatives

infobox

SOCIO-ECONOMIC ANALYSIS – THE PROS AND CONS OF ACTIONS FOR SOCIETY

Socio-economic analysis plays a vital role in the restriction and authorisation processes under REACH as it provides information on the costs and benefits of action (or inaction) for society as a whole, or some part of it (for example, companies applying for authorisation). In response to earlier criticism, ECHA has worked on refining its methodologies for a more realistic understanding of the socio-economic impacts of restrictions and authorisations. For this, it has also worked with the OECD to establish **society's values for reducing the risks of certain detrimental outcomes of chemical exposure such as infertility**.

In May 2019, ECHA organised an inter-disciplinary workshop together with the **University of Gothenburg's Centre for Future Chemical Risk Assessment and Management Strategies** (FRAM). Toxicologists and economists discussed if and how it was possible to define numerical values for environmental impacts of chemicals. The findings suggested that this is a challenging undertaking and the collaboration between ecologists, ecosystem experts and economists is vital to designing valuation surveys that reliably estimate people's preferences for avoiding negative impacts of chemicals on the environment.

ECHA is working with the **Network of REACH, SEA and Analysis of Alternative Practitioners** (NeRSAP) to improve the knowledge about and use of methodologies for more impactful regulatory assessments. The network was set up as a joint effort between experts in Member States, the Commission, industry, academia, NGOs and consulting companies to exchange on methods, advances and experiences on practical concepts for socio-economic analysis and analysis of alternatives.

Biocides – proactively re-accelerating the Review Programme

In February 2019, ECHA organised a workshop with Member States, the Commission and stakeholders to identify the causes for the slowdown of the Review Programme of biocidal active substances and to agree on how to improve.

To **make more progress towards the deadline for the Review Programme at the end of 2024**, ECHA enhanced communication with Member States and is directly supporting them to prepare their assessment reports and streamline the process.

In 2019, ECHA developed an **action plan** that will be agreed by the biocides competent authorities in February 2020. The plan proposes to prioritise some substances, provide support to the Member States and streamline assessments and peer reviews.

During 2019, ECHA gave direct support to Member States for the evaluation of 16 active substances and for the endocrine disruptor assessment of 18 dossiers. Further advice was provided on 11 substances by the Endocrine Disruptor Expert Group.

The Biocidal Products Committee (BPC) opinions of 2019 include 10 opinions supporting Union authorisations that allow companies to place their products on the EU market without the need for specific national authorisations. This amount was less than initially anticipated and ECHA is working together with the Member States submitting product assessment reports as the basis for the opinions to understand the root cause for the delays and how to address them. The BPC adopted opinions on the assessment of the endocrine properties of six active substances that had been evaluated before this assessment was legally required. The committee also adopted opinions for the non-approval of two active substances: **DBNPA for product-type 4** (food and feed) as it had endocrine-disrupting properties and **carbendazim for product-type 9** (fibre, leather, rubber and polymerised materials preservatives) due to the risks it posed to the environment.

ECHA supported the Commission and Member States in revising the information requirements (Annexes II and III) of the Biocidal Products Regulation, as well as preparations for a number of guidance documents including one on the renewal of the approval of active substances.

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ONE COMMON TOOL FOR BIOCIDES AND REACH RISK ASSESSMENTS

Based on a feasibility study conducted in the first half of 2019, ECHA decided to redevelop the **European Union System for the Evaluation of Substances** (EUSES) for both biocides and REACH, combining it with Chesar.

This integrative tool will incorporate all the functionalities of EUSES into workflows that are already established in Chesar and adds another component for environmental risk assessment workflows for biocides. It will form a workable basis for further development, enabling more standardised formats, workflows and methodologies to be used throughout the EU for both REACH and biocides.

The first version will take at least two years to develop, but will help companies and authorities assess the exposure to workers and consumers under REACH and the environmental impact of substances covered under both pieces of legislation.

Successful onboarding of new and crosslinking tasks

The Agency has shown that it has the expertise to provide consistent scientific and technical advice across many different pieces of chemicals legislation. Bringing new regulatory tasks together under one roof, leads to greater effectiveness and saves resources while reinforcing our work on improving the safe use of chemicals. New responsibilities in the Agency's portfolio include proposing new persistent organic pollutants and making drinking water safer. We continued efforts on areas like poison centres, nanomaterials[22], occupational exposure limits, and establishing a chemicals legislation finder[23].

ECHA Submission portal – EU market access with one notification

In April 2019, the Agency launched the ECHA Submission portal that can be used by companies to securely prepare and submit information on hazardous mixtures and to send only one submission to notify several Member States where they intend to market their products. By the end of 2019, 4 560 notifications had been received from companies.

ECHA made this online gateway available free of charge to lower the administrative burden for companies. Nevertheless, some Member States may still charge a fee to cover their own costs. The portal incrementally provided capabilities that support efficient system-to-system integration, secure notification delivery to Member States.

Since its launch, two updates took place to improve the way users submit their notifications online and to introduce a system-to-system service. With this service, companies can prepare notifications in their own IT systems and then automate their submissions in the portal.

22 The EU Observatory for Nanomaterial is a task delegated to the Agency by the Commission.

23 The EU Chemicals Legislation Finder is a task delegated to the Agency by the Commission.

Poison centre notifications – making information available for emergency health responses

An updated version of the poison centre notification format was also published in April 2019, addressing minor issues mostly related to accompanying documents that were identified after the release of the first version in 2018.

The Commission gave mixture producers more time to comply with their obligations by postponing the first applicability date for harmonised reporting on mixtures intended for consumer use, from 1 January 2020 to 1 January 2021. Nevertheless, ECHA delivered its **poison centre notification database** in November 2019, providing controlled access for appointed bodies and poison centres to search and retrieve information included in the notifications received through the ECHA Submission Portal.

This early release gives authorities an opportunity to familiarise themselves with the security requirements to access the database and provide feedback to ECHA.

ECHA has provided support both to companies and authorities through information sessions, hands-on trainings and dedicated webinars throughout 2019.

EUON – adding value to the debate on nanomaterials

The European Union Observatory for Nanomaterials (EUON)[24] provides information about existing nanomaterials on the EU market integrating information from national registries, studies and other databases including ECHA's chemicals database. It also generates new data through market studies and surveys and presents it in a user-friendly way to business users, workers, consumers, scientists and policy makers. EUON is a task delegated to the Agency.

In 2019, EUON went through a review which concluded, on the one hand, that it is fulfilling its initial objectives, adding value to the debate on nanomaterials and giving reliable information on their safety. On the other hand, it was highlighted that more frequent and up-to-date information could strengthen and complete the data of the observatory further.

One of the biggest milestones in 2019 was the launch of a dedicated search function for nanomaterials that enables users to **find information on more than 300 nanomaterials found in the EU** and to link them to hazard data.

In September 2019, the results of a study commissioned by the EUON showed that the current available EU regulatory framework is capable of identifying the majority of "next generation" nanomaterials. While the results showed we are well-equipped to handle these new materials in the short term, they also indicated that companies would benefit from further guidance on registering nanomaterials under REACH.

In October 2019, we published a comprehensive list of test guidelines that are relevant for the safety testing of nanomaterials under REACH.

EUCLEF – broadening access to information on chemicals

*ECHA has spent 2019 preparing to set up the **European Union Chemicals Legislation Finder (EUCLEF)**[25] – an easy-to-use online service that gives companies an overview of legislation that is relevant to their substances. The service is due to be launched in March 2020 and is a task delegated to the Agency.*

EUCLEF brings more regulatory clarity to companies, particularly for SMEs, enabling them to search for information on how their substances are being regulated across the EU in one place for free. They can use this data to help them make informed business decisions.

Directly linked to the information stored in our chemicals database, the first version adds further data on 35 other pieces of EU chemicals legislation, including those dealing with pesticides, food contact materials,

24 Based on a delegation agreement between the European Commission and ECHA.

25 Based on a delegation agreement between the European Commission and ECHA.

cosmetic products and toy safety. The service enhances ECHA's chemicals database and establishes it as the place to go for information on chemicals. It will help companies easily navigate through the vast legislative framework for chemicals within the EU.

By 2021, the finder will be extended to cover 16 additional pieces of EU legislation.

Occupational exposure limits – reducing exposure at the workplace

In January 2019, ECHA signed an agreement with the Commission services of Directorate-General for Employment, Social Affairs and Inclusion to provide scientific opinions on the toxicological profiles of selected substance, when requested. These opinions may include proposals for ***occupational exposure limits*** *(OELs) to be set under the legal framework of the Chemical Agents Directive (CAD) and the Carcinogens and Mutagens Directive (CMD).*

These directives protect workers from the risks related to exposure to chemical agents and to carcinogenic and mutagenic substances found in their workplace environments. ECHA launched a new web section[26] explaining these tasks and the steps of the OEL process in February 2019.

The Commission identified two substance groups under CAD: **lead and its compounds** and **diisocyanates** for ECHA to evaluate and a public consultation was launched on the ECHA scientific report that ran from mid-October until mid-December 2019.

To improve the interface between REACH and occupational health and safety legislation, ECHA published a guidance for preparing scientific reports for health-based exposure limits and OELs at the workplace in August 2019. It addresses one of the actions of the REACH review to align REACH and occupational health and safety legislation methodologies to establish safe levels of exposure to chemicals at the workplace, taking into account findings from the joint task force of ECHA's Committee for Risk Assessment (RAC) and the Scientific Committee for Occupation Exposure Limits (SCOEL).

Persistent organic pollutants – identifying substances that stay in the environment

Persistent organic pollutants (POPs) *are organic substances that persist in the environment, accumulate in living organisms and pose a risk to our health and the environment. POPs are regulated worldwide under the Stockholm Convention and the Aarhus Protocol, which are implemented within the EU by the POPs Regulation.*

Under the recast of the POPs Regulation, which entered into force in July 2019, ECHA was tasked with supporting the Commission and the Member States under the Stockholm Convention for the identification of new POPs and the reporting on regulatory actions. ECHA has set up the new process: A web section was created fulfilling its role in communication, introducing the process including new EU consultations, a draft format for Union reporting and the architecture needed for IT support. ECHA has been also tasked with supporting the identification of methoxychlor as a persistent organic pollutant under the Stockholm Convention.

ECHA has also supported the search for new potential candidates to be proposed to the Convention. The implementation of the POPs Regulation will benefit from the synergies to ECHA's core activities under REACH and CLP.

Making drinking water safer

In 2019, ECHA prepared to take on a role in making drinking water safer for consumers under the ***Drinking Water Directive****.*

With the recast of the Drinking Water Directive, ECHA has been given a task to compile and manage an EU positive list of chemicals that can be safely used in materials that come into contact with drinking water. The aim is to improve consumer protection and ensure equal safety standards for industry. The first list is expected to cover around 1 500 chemicals and to be adopted by the Commission in 2024.

26 https://echa.europa.eu/understanding-cad-and-cmd

Management

With valuable input from the second REACH Review[27], we focused our priorities on where they matter most for protecting human health and preventing damage to the environment, and outlined the three strategic priorities in our new strategic plan for 2019-2023. Our reorganisation took effect in 2019 bringing processes closer together, capitalising on efficiency gains, and enabling ECHA to be more impactful[28]. With this, ECHA has proven to be agile and capable of undertaking major significant organisational changes.

The reorganisation translated the findings and recommendations of the REACH Review into an organisational setup, enabling ECHA to implement its new strategy towards a more impact-oriented way of working aligned with the political priorities of the EU and the United Nations' sustainable development goals. We added value to Europe's citizens, by refocusing our priorities where they matter most for protecting human health and the environment.

Our new performance management model now contains the approach for measuring the three strategic priorities, in pursuit of defining more outcome and impact-oriented indicators. This allows the intermediate and long-term impacts of the Agency's actions to protect human health and the environment to be measured.

As a result of the reorganisation, ECHA adjusted its governance, delegation and process structures to ensure staff and middle level management are sufficiently empowered, flexible and able to grow in their roles and take decisions, in particular, in lower risk areas.

The overall positive results of the 2019 staff survey indicate success of the reorganisation in areas such as working culture, commitment to ECHA, responsibility and initiative, as well as authority where satisfaction with staff empowerment and freedom to act autonomously has increased. Furthermore, ECHA refined its integrated management system and framework, assessing it, identifying and implementing improvements (see Sections 3.4. and 4.7. for more details on the assessment).

In 2019, in preparation for ECHA's chairing of the Network of EU Agencies (EUAN) and the Performance Development Network (PDN) in 2020, we were actively involved, as part of the Troika[29], to prepare the upcoming EUAN work programme. Coordinating the peer review exercise among environmental agencies, participating in working sessions to exchange good practices for performance and lean management, and providing short-term support to the European Centre for Decease Prevention and Control in the area of internal control are some examples where interagency cooperation has been intensified.

Further to this, ECHA continued its strategic cooperation with EFSA on IUCLID-as-as service, shared 13 % of the services of its Internal Audit Capability (IAC) with the Global Navigation Satellite Systems Agency and provided short-term support to the Consumers, Health, Agriculture and Food Executive Agency for data protection services.

ECHA developed a new communications strategy[30] to support its strategic goals, increase the transparency of its work and to adapt to ongoing changes in the Agency's operating environment and a modern communication landscape.

By reaching out to external stakeholders and partners, the Executive Director maintained and continued to improve relations with the Member States, EU Institutions and other external stakeholders and partners resulting in acknowledgement of ECHA's competences and appreciation for the work, the synergies and the improved consistency created.

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27 Commission General Report on the operation of REACH and review of certain elements, COM(2018) 116 final.

28 See further: Workload drivers and performance indicators of ECHA's performance management model (Appendix I).

29 The Troika consists of the chairing agency in 2019 (European Centre for Disease Prevention and Control - ECDC), the incoming chairing agency (ECHA) and the one chairing thereafter (European Environmental Agency - EEA).

30 https://echa.europa.eu/documents/10162/13609/echa_comms_strategy_2019-2023_en.pdf

Management Board

The Management Board provides strategic direction and strong governance to enable the Agency to fulfil its mandate and meet its stakeholders' expectations. To this end, in 2019, the Board finalised the review of its working methods, which resulted in the adoption of a new Code of Governance, revised Rules of Procedure, its Operating Framework and a Code of Conduct for Board members[31].

This has increased clarity on the Management Board's role, tasks, principles and ways of working. In this context, the Board **optimised the composition of and distribution of competences between its subgroups**, which now all benefit from clear and explicit terms of reference.

Throughout 2019, the Management Board welcomed the **synergies and consistency for chemicals safety stemming from ECHA taking on new tasks**, such as those under the Waste Framework Directive and dealing with occupational exposure limits. The Board paid specific attention to potential risks resulting from the allocation of such new tasks without adequate resources being provided. In this context, the Management Board highlighted the need to start a conversation about the **long-term sustainability of ECHA's financing model**.

The Management Board adopted all statutorily required documents, respecting the applicable rules and regulations. In addition, it adopted ECHA's new Financial Regulation based on the overarching EU Framework Financial Regulation and adopted ECHA's revised policy for the prevention and management of potential Conflicts of Interest.

2019

YEAR IN NUMBERS

5
plenary meetings

26
meetings of Management Board working groups

12
newly appointed members

Furthermore, the Management Board:

- Appointed Antoine Buchet as the new Chair of the Board of Appeal in April 2019. He took office in August.
- Elected Paul Krajnik from Austria as the Management Board's new Deputy Chair in June 2019.
- Continually monitored the actions taken in response to audits and evaluations as well as the Commission's second REACH Review, including the second evaluation of ECHA.
- Carried out the annual appraisal exercise of the Executive Director and the members of the Board of Appeal.

The Secretariat provided the Board with regular reports on ECHA's activities and gave monthly updates on progress in key operational areas. This concerned, in particular, the **Joint Action Plan on evaluation**[32] and improvements to opinion making on applications for authorisation, in response to stakeholder input.

31 These documents and the subgroup terms of reference are available at: https://echa.europa.eu/about-us/who-we-are/management-board

32 https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en

Financial management

In 2019, ECHA successfully managed its finances ensuring that the 2018 accounts were correctly closed and maintaining rigorous budget and liquidity management to counter the high uncertainty on fee income. The Agency met its budget implementation targets reaching 99 % commitment rate and 86 % payment rate (targets were 95 % and 80 % respectively).

The **combination of uncertain fee income and EU balancing subsidy** to finance the Agency's operations again proved challenging. Since the final registration deadline in 2018, ECHA's fee income has significantly reduced compelling the Agency to increasingly rely on the EU to finance its operations.

The split between fee income and subsidies in 2019 was around 40 % and 60 %, respectively. This is in stark contrast to the long-term average which has seen 72 % coming from fees and 28 % from EU subsidy.

ECHA's financial stability has been identified as an important issue by the European Parliament[33] and the European Court of Auditors[34], while the European Commission has also recognised the **challenges in ECHA's current financing model**.

The second REACH Review called on ECHA "to assess all possible options for financing in the context of projected reduced fee income..." The Agency has made proposals using the 2019 fee forecasting studies as reference points to support a review of ECHA's financing model.

The initial total budgetary payment appropriations for expenditure in 2019 amounted to EUR 117 million. However, the final total figure concluded in the third amending budget in December 2019 was EUR 112 million. There were two main reasons for the reduced budget. Firstly, following the reorganisation of the Agency and the related transition phase, ECHA's overall vacancy rate was, on average, higher than in previous years. The staff turnover rate in 2019 was also higher than expected, resulting in lower salary costs. Secondly, towards the end of 2019, it became apparent that the fee income was not developing as planned and the Agency had to find further savings to balance the budget.

Details on ECHA's budget information and budget management in 2019 can be found in Appendix II.

Human Resources management

With its Human Resource Strategy for 2019-2023, ECHA set the foundation for achieving its overall strategic priorities. The strategy ensures a work environment that promotes a culture of high performance and enables flexibility. While 97 % of establishment plan posts were filled, the turnover of temporary agents remained low at 3.9 %.

In 2019, we focused on providing high-quality services for ECHA's staff aiming to increase their well-being and satisfaction. To fulfil the priorities of the **HR strategy**, we kicked off activities on developing staff competencies, encouraging learning experiences and increasing motivation. For example, we began a **competency mapping** exercise for the Agency that allows resources to be used more flexibly and we invested in building up relevant skills for the organisation. In addition to prioritising a more flexible work environment, ECHA also invested in developing management actions to ensure a high level of people management and maintain a healthy working culture throughout the Agency.

We managed a high number of internal mobility calls during the year, offering staff members opportunities for career growth and the possibility to broaden their competencies. We also entered a new era of close **cooperation with the European Food Safety Authority (EFSA)** using the links between the agencies in assessing risk and

33 European Parliament, Discharge 2017, European Chemicals Agency, adopted 26 March 2019

34 European Court of Auditors, Annual report on EU agencies for the financial year 2017 (2018/C 434/01 on 30 November 2018)

providing scientific opinions to policy makers to launch a successful joint selection procedure for a scientific officer profile that is relevant for both organisations. We shared time and resources, and created a joint reserve list that can be used by both agencies.

In addition, EFSA and ECHA agreed to use EFSA's budget for staff working in ECHA on the pilot using **IUCLID for plant protection products** (see IT Resources management). This maximises the impact of the resources we have using already existing and sophisticated tools in an efficient way, allowing knowledge to be shared and saving taxpayers' money.

As part of a wider inter-agency benchmarking exercise initiated by the Commission, ECHA has 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. Reaching out and maintaining positive relations with ECHA's Staff Committee, the European School of Helsinki and other major stakeholders at EU and national level is another area of responsibilities for HR that requires attention.

Corporate Resources management

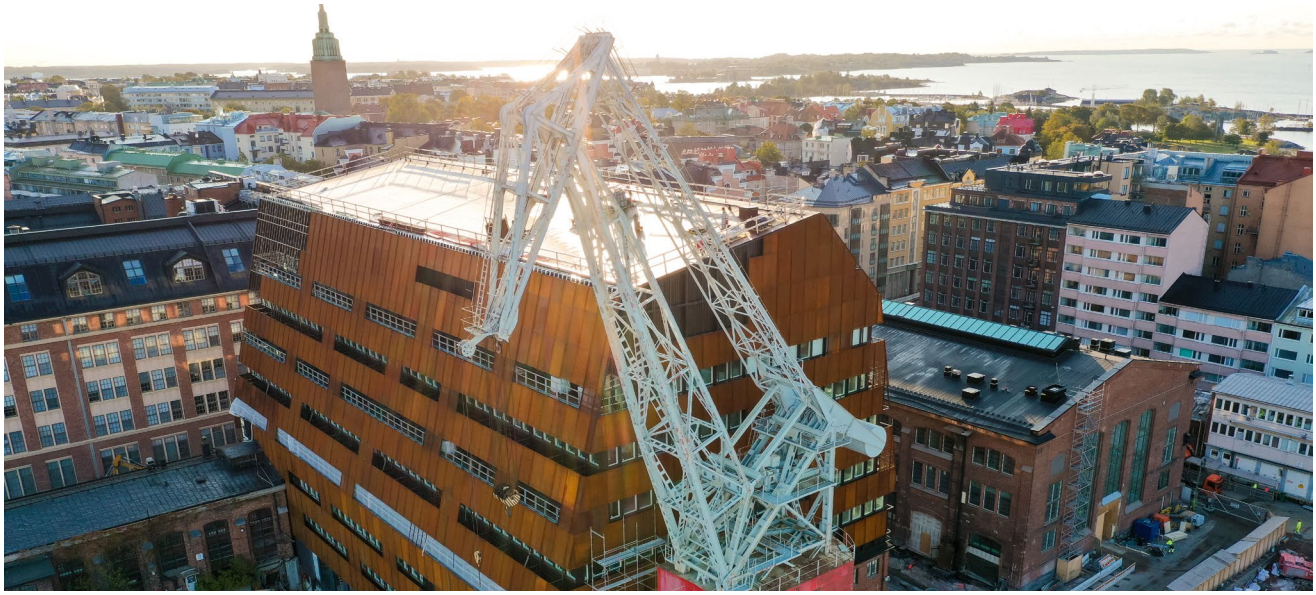
The project team for ECHA's new premises ensured business continuity and a smooth removal to new state-of-the-art and environmentally-friendly premises in the heart of Helsinki's historic shipyard area. The removal at the beginning of 2020 concluded four years of preparations for relocating staff.

Throughout 2019, we continually monitored the progress of the construction work, ensuring that the building meets the performance, functionalities and quality levels needed. By May 2019, most of the external construction had been completed and the focus turned to the building's interior where creative and collaborative workspaces have been formed.

"Team spirit is the key to achieving positive results. And this has never been more exemplified than in the professionalism and commitment shown by all those involved in the move to our new, state-of-the-art premises.

Shay O'MALLEY

Director of Resources



2019

YEAR IN NUMBERS

11 940
day visits from external participants
(**+29 %** compared to 2018)

15 600
remote Webex connections for virtual meetings

4 845
participants followed major webinars
(**+22 %** virtual connections compared to 2018)

A **network of "champions"** from each of ECHA's directorates was set up in June 2019, to help bring relevant information to staff. The network provided information to staff to help them prepare for the relocation and took part in several workshops during the second half of the year on practical aspects for the move, including:

- instructions about removal;
- disposal of waste, paper and inventory at the Annankatu location;
- finalisation of individual directorates' workplace allocations; and
- relevant information for staff at the new premises.

The new building is a **flexible and modern space** where cooperation can flourish and staff can work more efficiently and effectively to better protect the health of European citizens and the environment. It facilitates more modern ways of working and collaboration between different operational units, and will also foster staff wellbeing and support the work that already began at the start of 2019 during the reorganisation to help the Agency continue to thrive as **"One ECHA"**.

The physical removal process to ECHA's new premises began on 21 December 2019 and the new building was open and operational for ECHA staff as planned at the beginning of January 2020.

Environmental management

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

ECHA has been certified to **ISO 14001:2015** since 2016. Our environmental performance is linked to the consumption of natural resources, and the generation of waste and emissions, including CO2.

Preparations for the move to ECHA's new premises further raised awareness of the need for **environmentally-conscious actions**. A substantial review of the environmental aspects and objectives, including recalibration of some objectives due to the move to new premises, will be conducted during 2020 and green procurement continues to be applied in the Agency's daily work.

TABLE 2: ECHA environmental performance 2019

Environmental objective for 2019 (compared to level of 2017)	Result in 2019 (compared to level of 2017)	Achieved?
Reduce electricity consumption by 5 %	4 %	In 2019, ECHA reduced its electricity consumption by 4 % compared to 2017. ECHA also procured hydroelectricity to offset 2 500 MWH of electricity carbon emissions (equivalent to ECHA's annual electricity consumption)
Reduce paper consumption by 5%	27 % decrease in paper consumption	Exceeded
Reduce colour printing by 5%	27 % decrease of colour printing	Exceeded

We aim to steadily decrease our consumption, meeting or exceeding the set objectives. In 2019, the environmental programme followed the actions defined for 2016-2018. In 2019 ECHA measured the results vs the baseline set in the environmental programme of 2017.

IT Resources management

*We launched the **ECHA Interacts Portal** – a one-stop platform for national authorities, ECHA committee members and expert groups. It gives them access to search for information they need – displayed in a meaningful and targeted way – and allows them to collaborate to prepare documents. Authorities and experts can now work more efficiently and securely, relying on easy access to information, in pursuit of their respective regulatory tasks.*

IUCLID is becoming a fully featured web application offering multiple templates to submit information. Supported formats now include notification templates for poison centres and adaptations for nanomaterials. The data structures are now more flexible and the interest for adopting IUCLID has increased on an international level. We witnessed a significant increase in users, confirming the value of IUCLID formats and the tool itself as a global platform for handling chemicals safety data.

Member State authorities were given access to a text-based search functionality, the **Text Analytics tool**, originally a IUCLID extension, the tool is now self-standing. This has improved possibilities to analyse data.

IUCLID-as-a-Service, delivered from the ECHA Cloud Services, has seen a steady increase in use. It is the engine for notifying to poison centres and has since been considered for adoption by the European Food Safety Authority (EFSA) under the Plant Protection Products Regulation. We are cooperating with them to pilot a viable IUCLID-based solution delivered from the ECHA Cloud Services. The pilot has the potential to show how ECHA's IT competence can be used by other regulatory agencies and support them to manage data and carry out regulatory tasks that are similar to ours.

After seven years of continuity, ECHA successfully migrated its externally hosted server and storage systems to a new, state-of-the-art IT-infrastructure, saving significant costs. Critical servers and data continue to be replicated between two outsourced data centres, and can be made available out of both. As a means of ensuring business continuity, we carried out the yearly disaster-recovery testing.

IT security is a constant concern because of ever more sophisticated cyber threats and the release of IT-based services dealing with highly confidential business information (such as poison centre notifications). In 2019, thanks to the transition to new infrastructure services, we enabled better security measures, robust monitoring and response capabilities.

2019

YEAR IN NUMBERS

253 926
registered industry users
(49 users per entity on average)

2 825
registered authority users
(29 users per entity on average)

ECHA has delivered a central searchable database of poison centre notification for national appointed bodies and poison centres. Highly confidential data are accessible and secured thanks to ECHA's secure access measures for authorities.

Luisa CONSOLINI
Director of Information Systems

2019

YEAR IN NUMBERS

13
decisions of the European Court of Justice

17
decisions of the Board of Appeal concerning REACH
(5 dismissed, 5 upheld, 7 withdrawn)

3
decisions of the Board of Appeal concerning the BPR
(1 dismissed, 2 upheld)

11
external complaints

Litigation, appeals and complaints

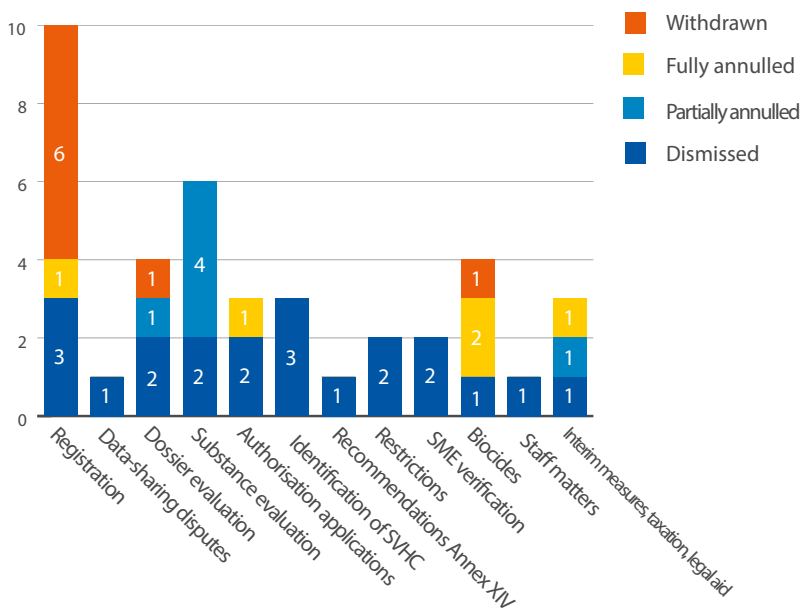
The EU Court ruled in favour of ECHA on endocrine disrupters. It also ruled for the first time on the scope and intensity of the power of review of ECHA's Board of Appeal on appeals against ECHA decisions.

ECHA's competence to identify substances of very high concern on the basis of their **endocrine disrupting properties** was confirmed in the *DEHP*[35] and *Bisphenol A*[36] cases. ECHA has this competence even where harmonised criteria are absent.

Two General Court judgments on substance evaluation rejected the arguments of BASF[37] and Germany[38] and confirmed that the **Board of Appeal is empowered to review** not only legal aspects, but also **scientific and technical aspects** of ECHA's decisions, and that it is not limited to verifying manifest errors. The judgments ruled that the Board of Appeal:

- is not required to conduct a completely new evaluation;
- is to confine itself to examining the pleas and arguments of appellants; and that
- the procedure before the Board of Appeal has an adversarial nature.

FIGURE 8: Number of Court and Board of Appeal cases per activity



35 Judgment C-419/17 P, Deza a.s. v ECHA.
36 Judgment T185/17, PlasticsEurope v ECHA.
37 Judgment T-125/17, BASF Grenzach v ECHA.
38 Judgment T-755/17, Germany v ECHA.

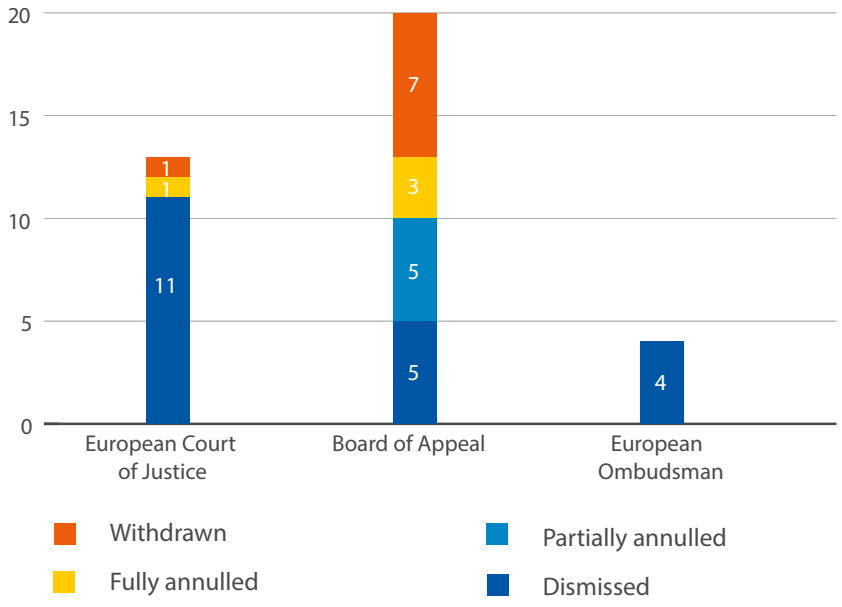
In a further case, the Court confirmed **ECHA's wide margin of discretion on the use of prioritisation criteria** when it prioritises substances for the Authorisation List (Annex XIV)[39]. The Court also reminded that registrants are responsible for keeping their dossiers up to date to allow ECHA to use the latest information.

In 2019, **13 cases were closed by the Court**.

The Board of Appeal adopted **20 decisions in appeal cases** brought against ECHA decisions. Most importantly, the Board of Appeal clarified the requirements for sharing data and costs between companies under REACH and the Biocidal Products Regulation. The Board of Appeal also clarified several aspects of the compliance check and substance evaluation procedures.

The Agency received **11 external administrative complaints** in 2019. Five complaints were related to the registration and dossier submission activity, three were on biocides and the rest were on processes such as identifying substances of very high concern, requests for use of an alternative chemical name according to Article 24 of CLP, and ECHA's Helpdesk. Within the integrated management system of the Agency all complaints are analysed and followed up resulting in corrective actions where appropriate.

FIGURE 9: Cases per litigation body



39 Judgment T-610/17, ICL-IP Terneuzen v ECHA.

Audits and evaluations

Internal Audit Service

The Internal Audit Service (IAS) of the Commission conducted an assurance audit on E**CHA's performance management**, resulting in:

- One *very important* recommendation to review the use of the four performance categories to ensure that each jobholder is appraised without being compared with the performance of other staff members, and to define a legal and regular approach on how to treat individuals who are included in the list of staff proposed for reclassification in a given year but who cannot be reclassified in that year as they are ineligible due to not having a third language.
- One *important* recommendation to update the planning, monitoring and reporting procedure.

The Agency is following up on the first recommendations and has already implemented the latter, while there are no pending issues from earlier IAS audits.

Internal Audit Capability

The Internal Audit Capability (IAC) conducted an assurance audit on Union authorisations under the Biocidal Products Regulation (BPR), resulting in:

- One *very important* recommendation to continue the work to clarify the causes for delays in Union authorisation evaluations together with evaluating competent authorities and develop actions to address these.
- Two *important* recommendations to (i) develop the peer review with evaluating competent authorities, the Commission and industry representatives; and (ii) to ensure that the IT tools serve the planning and monitoring needs of evaluating competent authorities and the Commission.

Another IAC assurance audit looked at the activities of the **Forum**, resulting in:

- Six *important* recommendations to (i) increase effectiveness of enforcement projects for REACH and biocides as well as pilot projects; (ii) improve communication on Forum activities; (iii) improve Forum working methods and activate members; (iv) improve cooperation with accredited stakeholder organisations; (v) promote the use and regularly review access rights to the Interact tool; and (vi) simplify the Forum Secretariat working methods with new IT tools and plan how to utilise efficiency gains.

The Agency follows up these IAC recommendations with corresponding actions. On earlier audits, the IAC conducted three follow-up audits to verify the implementation of the action plans concluding that no very important issues are currently pending.

European Court of Auditors

The European Court of Auditors (ECA) considered in its statement of assurance as part of the Annual Report on EU Agencies for the financial year 2018, published on 15 October 2019[40]: the 2018 accounts of the Agency present fairly, in all material respects, the financial position of the Agency on 31 December 2018, 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.

Furthermore, according to ECA's opinion, revenue and payments underlying the accounts for the year ending 31

40 The full report, including the follow up on actions from previous years, is available on the ECA website at: https://www.eca.europa.eu/Lists/ECADocuments/AGENCIES_2018/AGENCIES_2018_EN.pdf

December 2018 are legal in all material aspects.

The Court emphasised that ECHA is partly self-financed by the fees it collects. With regard to checking the status of companies as small and medium-sized enterprises (SMEs), the Agency carries out ex-post verifications resulting in considerable fee corrections. According to the Court, this is the result and limitation of a system that relies excessively on self-declarations made by registrants/applicants. To address this issue, ECHA has revised its approach to verifying SME status by maintaining the current verification rate and gradually reducing the time taken between dossier submission and verification. The Agency is aiming to complete verifications of the 2018 registration deadline-related SME registrants by the end of 2023, to perform the verification of 60 % of all SME registrants with registrations above 10 tonnes, and to increase the effectiveness with a better targeted selection of checked registrants.

In 2019, ECHA collected a total amount of EUR 1.01 million from administrative charges, out of which EUR 274 799 relate to overdue administrative charges collected through contracts signed in previous years with external law firms, covering ECHA's claims in 24 Member States. Initially, the Agency identified overdue administrative charges of EUR 2.85 million out of which a total of EUR 1.16 million was collected up to 31 December 2019 with a total of EUR 932 090 still outstanding.

Four of the actions following the ECA's audits from previous years (2014-2017) are ongoing with regards to (i) covering a larger percentage of biocides activities with application fees; (ii) speeding up and finalising ex-post verifications; (iii) collecting the outstanding administrative charges; and (iv) publishing vacancy notices on the European Personnel Selection Office (EPSO) website in addition to its own website and social media.

Two actions are considered to be outstanding and recognised as outside of the Agency's control. These are (i) ECHA's founding regulation not explicitly requiring periodic external evaluation of its activities; and (ii) the fact that two-thirds of companies do not update the registered information on the volumes of chemicals since Member States are responsible for verifying this.

ECA has recognised that the action on improving the carry-over rate is complete.

Ex-ante and ex-post evaluations

In 2019, the Agency performed two ex-post evaluations[41]. The evaluations were presented to the Management Board in June and December 2019, respectively.

The objective of the **ISO 9001:2015** assessment was to analyse the costs and benefits of the ISO 9001:2015 certification and to judge the extent to which the certification and the overall Integrated Management System has been efficient, effective, coherent, relevant, proportional, sustainable as well as how much value has been added.

In addition, the relevance of the Integrated Management System with ECHA's new Strategic Plan was also in the scope of the assessment.

The evaluation gave the following key recommendations:

- To improve efficiency and transparency, ensure that the scope and purpose of all audits are coordinated with the operational units and clearly communicated in advance. Ensure there is a performance-based focus in all audits, following ECHA's new strategy to pursue better performance and not only compliance.
- To improve efficiency and maintain the system as a day-to-day business, remove all quality (IMS) audits from the annual plan and foresee the possibility to perform audits requested by the business.

41 The legal basis of the ex-ante and ex-post evaluations is stipulated in ECHA's Financial Regulation and implementing rules. ECHA's evaluation framework and approach, established in 2015, is based on the Better Regulation guidelines of the Commission, as well as on benchmarking performed with other agencies.

- To improve efficiency, fundamentally question the documentation organisation and workflows to remove as many duplicate controls as possible. For example, consider whether ECHA's intranet (ECHAnet) and some visual workflows could replace some of the existing procedures and working instructions. If reviewing all documents before deciding, consider whether it is possible to remove obsolete documents that have not been opened for more than a year.
- From top to bottom and by setting examples, promote a new culture where staff is confident and empowered to take decisions autonomously either based on delegations or trust, where trial and error are seen as part of learning.
- As the number of documents has decreased, consider further decreasing the involvement of Quality Assurance Officers in reviewing documents. Instead, consider using the network for driving incremental process improvements to gain further efficiency.
- Consider focusing on managing only non-conformities that relate to external requirements and stakeholders and not those that refer to compliance with self-generated documents such as procedures and working instructions.

As a follow up, there was a successful surveillance audit in 2019, which confirmed the well-established management system of ECHA, and didn't find any non-conformities. ECHA's new Integrated Management System and Framework were developed following this evaluation, responding to the requirements of the Financial Regulation and providing the Agency with better agility and flexibility of its management system after the reorganisation. An **Integrated Management System Streamlining project** was launched to respond to the recommendations of the evaluation.

The objective of the ex-post evaluation of the **EU Observatory for Nanomaterials (EUON)** was to assess the observatory against the criteria of effectiveness, efficiency, coherence, added value and utility. Besides analysing the added value to stakeholders, the evaluation also aimed to support ECHA to identify areas where more information is needed and to set priorities for developing the EUON in the future.

The key recommendations made by the external and internal evaluators are:

- Increase the effectiveness and relevance of the information on EUON by providing additional information and increasing the frequency of publishing new information.
- Increase the effectiveness and relevance of the information on EUON by providing additional information and increasing the frequency of publishing new information.
- Increase the effectiveness of the EUON by increasing its user-friendliness for non-expert audiences.
- Increase stakeholder awareness of the EUON, as a secondary priority to improving and consolidating the website content.
- Develop measurable indicators and targets to track the progress of the project. Consider developing and monitoring indicators relating to cost, speed and the quality of the relevant milestones to facilitate the assessment of its effectiveness and efficiency.

As a follow up, there was an increase in the frequency of news (now on a weekly basis as opposed to a monthly basis in the past) and the EUON website[42] was updated with a link to consumer content: an interactive nano section for consumers and a new "nanomaterials in our lives"[43] were created to provide more content for non-expert audiences. EUON news are now also published in ECHA's other communication channels and an information campaign began in November 2019 to promote recent nano studies.

The last follow up on the evaluations performed in previous years was provided to the Management Board on 11

42 https://euon.echa.europa.eu

43 https://chemicalsinourlife.echa.europa.eu/nanomaterials-in-our-life

December 2019. A summary of the follow-up status is presented below for each evaluation.

The follow up of the **ex-post evaluation on the Cloud services** (performed in 2018) indicated that actions have been taken on all recommendations, with the main improvements as follows:

- Information was consolidated in the Cloud services, user support and simplified language was provided to first-time users.
- All available IUCLID features were implemented into the Cloud services.
- The Cloud services platform was used for the poison centres to save costs by using the existing platform and not developing the tool from scratch. Following the same principle, Cloud services could also be used in the SCIP database under the Waste Framework Directive.
- No overlaps exist anymore, there is only one IUCLID product and the aim is to phase out the old interface.
- An analysis of industry needs versus the value of a more restrictive security policy is planned.

The main improvements from the recommendations on the **ex-post evaluation on the Portal Dashboard for national enforcement authorities (PD-NEA) and Portal Dashboard for Member State competent authorities (PD-MSCA)** performed in 2018 are:

- Both PD-NEA and PD-MSCA were consolidated into the new Interact Portal where data is updated each day.
- The Interact Portal has improved the search functionality and fostered visibility on substance-specific activities for both the NEA and MSCA user groups.
- For MSCAs, associated process list views make data and documents under 11 REACH and CLP processes, as well as on BPR processes more visible for users. BPR processes will be included for NEA users in 2020.
- The translation of the tool into other languages will not be implemented due to several limitations.

Most of the recommendations under the **ex-post evaluation of the efficiency programme** (performed in 2017) have been tackled through the Agency's reorganisation, and subsequent projects and activities. As an example, there is now a better end-to-end reflection on processes, and processes are brought closer together, which provides opportunities for improvement projects (for example, in the MSC secretariat and dossier evaluation) where there is better coordination and improved handling of high peaks of work.

Internal control – system effectiveness

Risk management

As part the internal control routine, ECHA conducted an assessment exercise for 2019 to identify, assess and manage risks that might jeopardise the achievement of the objectives defined in the respective Work Programme. For the 2019 Work Programme, the Agency evaluated the possibly risks in 2018[44].

Based on this assessment, ECHA's management identified **five main risks** which were included in the corporate risk register. Throughout 2019, our senior management monitored and reviewed the risks to see whether their likelihood and impact have increased or decreased. Furthermore, they checked the effectiveness of the risk mitigation measures. They concluded that three of these risks could be reduced through specific actions described in the risk register action plan, one risk should be accepted provided it is due to external factors for which ECHA has no or limited influence, and one risk should be avoided by changing the objectives of the Work Programme.

At the time of the initial risk assessment, ECHA's management considered that the highest risk stems from insufficient fee income both in REACH and the Biocidal Products Regulation due to uncertain predictions for incoming dossiers, lower than foreseen biocides applications for active substances and Union authorisation and the rigid systems in place to adjust the EU balancing subsidy.

At the end of November 2019, a deficit for both the REACH/CLP and BPR fee income was projected. Therefore, in the third amending budget adopted by the Management Board at its meeting on 12 December 2019, the fee income estimates for REACH/CLP were decreased by EUR 3.1 million and for BPR by EUR 230 000. An external fee forecasting study conducted in 2019 also confirmed the challenges in making exact projections due to the random nature of the income.

Another risk with a high impact, which partially materialised at the end of 2019 was related to taking on new tasks. For the new tasks related to poison centres, the risk materialised and the implications for further development have been explained to the Commission. Funding of the work on poison centres was included in the 2019 budget, but due to the fee income reduction, funds could not be fully committed impacting the development for 2020. ECHA is preparing a letter to the Commission requesting for a funding solution to be provided in the first half of 2020.

For the work on persistent organic pollutants, the recast of the POPs Regulation was adopted and subsidy and staff resource was confirmed. For occupational exposure limits, EUR 240 000 has been received from the Commission allowing the two cases to be handled.

The remaining risks did not impact the execution of Work Programme 2019, although some of them continue to be relevant for the future.

Following the risk of insufficient controls in the conflicts of interest process identified in 2018, the policy was revised in 2019, including ex-post controls, and adopted by the Management Board on 25 February 2019. The signing of a memorandum of understanding with Member States on managing conflicts of interest is ongoing. Ex-post checks were performed in early 2020.

The change management risks related to the reorganisation did not materialise. ECHA's staff survey conducted in September 2019 showed good overall results, indicating that the Agency is dealing positively with the new organisational setup. As an example, the staff perception on whether ECHA facilitates high performance is at 56 % (49 % in 2017), and whether ECHA ensures a safe and healthy environment for staff is at 63 % (51 % in 2017). Also, there are more positive staff survey results with regards to empowerment (82 % of staff feel empowered

44 All risks are added to ECHA's risk register that forms part of the Programming Document 2019-2022 as Annex VIII available at: https://echa.europa.eu/documents/10162/13609/programming_document_2019-2022_en.pdf.

to take their decisions in 2019 compared to 75 % in 2017). Feedback from the higher and middle management also indicated that the "One-ECHA" mindset is improving and becoming mainstream.

In 2019, ECHA coordinated the peer risk review exercise among the agencies within the ENVI cluster[45]. The focus has been on identifying shared critical residual risks, for which controls exist in the different agencies and to share practices on how to treat such risks and identify alternative ways to increase the effectiveness of controls.

ECHA took the results of the peer review into account in the risk identification exercise for 2020.

Transparency, accountability and integrity

Throughout 2019, the Agency lived up to its values of transparency and independence. Both elements are key to gaining and keeping public and stakeholder trust in the impartiality and objectivity of ECHA's work.

Transparency efforts

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 full source data.

Changes to the database in 2019 have improved the usability by, for instance, giving users easier access to search by properties of concern and increasing the amount of multilingual information available. Steps were also taken to prepare for further extensions to the database in early 2020, including the first version of the EU Chemicals Legislation Finder (EUCLEF) that will let users see how their substances are regulated across 40 pieces of EU legislation and the new SCIP database with information about the presence of hazardous chemicals in articles and products.

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. In some of the processes, case owners are consulted during decision making.

Accredited stakeholder organisations[46] can 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. In most instances, they can intervene, distribute documents and have key points recorded in the minutes, at the discretion of the respective chairs.

Where consultations take place, the comments received are discussed and addressed. The reflections, minority opinions and conclusions of ECHA's scientific committees are reflected in opinions and minutes, and these are published online. When conclusions are drawn, the Agency communicates them clearly to affected parties. Substance-level conclusions are also widely communicated publicly, apart from those elements covered by business confidentiality.

Prevention of conflicts of interest

Policy update

The Commission's Internal Audit Service (IAS) carried out an audit on conflicts of interest and ethics in 2018.

45 Agencies under the remit of the European Parliament ENVI committee: European Centre for Disease Prevention and Control (ECDC), European Chemicals Agency (ECHA), European Environment Agency (EEA), European Food Safety Authority (EFSA), European Medicines Agency (EMA).

46 https://echa.europa.eu/about-us/partners-and-networks/stakeholders/cooperation-with-accredited-stakeholder-organisations

In its August 2018 audit report, the IAS made four recommendations. ECHA developed an action plan and had implemented all actions by mid-2019.

The main recommendations were implemented with the revision of ECHA's already robust Conflicts of Interest policy[47] (adopted by the Management Board on 25 February 2019). The main improvements include:

- The eligibility criteria applicable to key positions in ECHA were further strengthened:
  - The scope was extended to include all ECHA managers and the Chairs of committees.
  - The financial exclusion threshold was lowered.
  - Membership of permanent scientific advisory boards of chemical companies or interest groups also leads to exclusion.
- Existing restrictions were clarified and summarised in a clear overview of allowable and non-allowable interests (see Annex 1 of the policy);
- The template for annual declarations of interest has been revised, for example, the definition of "close family members" was extended to include other relatives under the care of the members of the household besides spouse/partner and dependent children.
- Different risk levels for the interests declared, with standard criteria and mitigating measures, were introduced as well as ex-post controls.

In addition, ECHA invited all the Member State competent authorities it collaborates with to sign a Memorandum of Understanding with the Agency on avoiding conflicts of interest.

Finally, revised procedures and practical arrangements for the appointment of the Chairman, two other members of the Board of Appeal, their alternates and additional members and their alternates aim to further clarify the roles and responsibilities of the different actors in the procedure.

Policy implementation

On the basis of its Procedure for Prevention and Management of potential Conflicts of Interest, ECHA has implemented an approach which involves systematically checking for potential conflicts before assigning tasks to staff members.

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 in 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 2019.

For the ECHA bodies, all members are assessed against the eligibility 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, specific declarations for items on the agenda are collected and documented in publicly available minutes together with the mitigating measures imposed. As the large majority of the members of ECHA's

47 https://echa.europa.eu/documents/10162/13608/pro_0067_04_coi_management_en.pdf

bodies are Member State public officials, most 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 not to be in a position to participate in the voting on such dossiers.

Post-employment

When leaving the service of the Agency, members of staff have to notify new occupational activities for the first two years. ECHA can forbid the new activity or impose conditions.

In 2019, 36 staff members left ECHA: 18 of them went to work for another EU institution, body or agency. Two staff members moved to a national public administration or international organisation. Seven staff members moved to the private sector or started self-employment and in six of these cases, the Agency saw it necessary to impose specific conditions.

In the remaining nine 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. None 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 the ECHA website, including their names, date of departure, positions, their foreseen new occupational activities and the outcomes of ECHA's assessments[48].

No breach of trust or disciplinary procedure was 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 2019. The Committee has 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 the Legal Affairs Unit of ECHA, as Chairperson.

On 12 June 2019, the CoIAC convened for its annual meeting at ECHA's premises in Helsinki. The members of the CoIAC discussed and agreed on changes to the the CoIAC Terms of Reference. The draft document was submitted and adopted by the ECHA Management Board (Management Board Decision 31/2019 of 20 June 2019)[49].

The main novelties to the Terms of Reference include changes following from the revised Procedure on Prevention and Management of potential Conflict of Interest adopted by the Management Board on 25 February 2019 (PRO-0067.04), based on learnings from the first seven years of the CoIAC.

In 2019, ECHA's Management Board decided to request an opinion of the CoIAC each time new members are appointed to the Board of Appeal or existing members are proposed for prolongation. This ensures the highest possible scrutiny of the independence of the Board of Appeal.

At the request of the Chair of the Management Board, the CoIAC has given advice on five cases relating to the Board of Appeal throughout 2019. 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 Chair (Head of the Legal Affairs Unit) who does not participate in matters relating to the Board of Appeal.

48 https://echa.europa.eu/documents/10162/13559/post-employment_senior_managers_en.pdf

49 https://echa.europa.eu/documents/10162/13608/echa_conflicts_terms_of_reference_en.pdf

Ex-post controls

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

A sample check on 40 annual declarations submitted by members of ECHA's bodies revealed that 100 % of them were in place, publicly available and sufficiently complete. A number of minor improvement recommendations were made to the respective Secretariats, for instance making use of the latest template or clarifying in one case that redacted personal data of a family member in the public version of the annual declaration was in any case available to the Secretariat for scrutiny.

In addition, ex-post reviews were carried out on four scientific dossiers to verify whether the required conflict of interest checks were performed. All dossiers contained the necessary records to document the conflict of interest checks performed for all staff working on the file. In one case, the check was pending at the time of review for a staff member indicated as a back-up.

Fraud prevention

The Agency's internal control systems are designed with fraud prevention embedded, with an emphasis on critical areas such as financial transactions, procurement and selections.

Some important actions implemented during 2019 include a mandatory online training on whistleblowing for all staff and a continued focus on awareness on important topics such as ethics, procurement and contract management and information security for newcomers and established staff.

ECHA's Code of Good Administrative Behaviour[50] 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.

The ECHA Anti-Fraud Strategy, 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

After the entry into force of a revised legal framework regarding personal data protection on 11 December 2018, several changes were made to ensure full compliance:

- The integration of a procedure for personal data breach notifications into the Integrated Management System (IMS).
- Changes to the terms and conditions of several ECHA IT systems.
- Revised privacy statements and data protection records for key processes published on ECHA's website.
- The adoption by the Management Board of internal rules concerning restrictions of certain rights of data subjects in duly justified, exceptional cases[51].

The Data Protection Officer advised the units on the occurrence of three personal data breaches and one complaint submitted to the European Data Protection Supervisor (the complaint was dismissed). He also supported colleagues from the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) by

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

51 https://echa.europa.eu/documents/10162/5551984/FINAL_MB_27_2019_%281%29_Restriction_data_protection_rights_MB54.pdf

performing a gap analysis for them with regard to the actions needed to comply with the new data protection regulation.

Security and business continuity

During 2019, we reviewed our business continuity plans based on a business impact analysis. In May 2019, ECHA faced a crisis with an outage of all of ECHA's IT systems during migration of servers to a new infrastructure. The crisis was resolved in 48 hours. On the positive side, it gave the Agency an opportunity to test the crisis management procedure and prove its effectiveness. More specifically:

- The incident occurred during the migration of IT services to a new but untested resilient solution, designed to withstand exactly this kind of incident. The business continuity testing ECHA carries out every year, subsequently validated the solution design.
- We confirmed that, in managing a crisis, separating the strategic decision making function from the communication function and the operation function (working to resolve the incident) is good practice.
- Independent systems for communication are key. We confirmed that having access to communication tools independent from the core IT, in this case mobile phones, was crucial to the management of the crisis.
- It was not a security incident. The immediate wrong assumption, both internally and externally, was that the crisis was due to a security incident. Significant communication efforts were required to dispel this notion. It is clear that stakeholders are sensitive to this matter. If it had been a security related crisis, our procedures would have been the same, possibly more careful to the interests at stake and therefore more collegial with our Security Officers' Network.
- ECHA's ongoing critical activities at the time were resilient, for instance, we managed to complete a Member State Committee meeting under crisis conditions.
- ECHA cannot rely only on outsourcers. Our IT staff and management was on the front line for 48 hours to coordinate the incident resolution and take quick decisions. After the end of the outage, further intensive work was necessary for full recovery and further risk mitigation back to normality, working closely with the operational processes to prioritise and validate service recovery.
- We confirmed the advised crisis approach to be open and communicated promptly. Use all the channels available, in ECHA's case, email, website, LinkedIn and Twitter, mobile phone chats and flip charts for staff, and mobile phone chats for the Crisis Coordination Group.

Security was also heavily involved in the work to relocate to ECHA's new premises. Fire safety training, first aid training and occupational safety certification for ECHA was organised.

In May 2019, we conducted ID badge checks and new guarding and reception services were implemented in December 2019.

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

In 2019, the Framework Financial Regulation brought new requirements to have an internal control strategy, organisational management strategy and efficiency strategy as part of ECHA's Programming Document.

ECHA developed on this basis its new **Integrated Management System Strategy and Framework**[52] in 2019, which was approved by the Management Board on 15 December 2019 and replaced the Integrated Management

52 https://echa.europa.eu/documents/10162/0/pol_0001_07_man_system_strategy.pdf

Standards. The document is aligned with the Internal Control Framework of the Commission and ECHA's previous standards. However, it integrates more elements besides quality and internal control in the framework, such as environmental management and sustainability. It is also aligned with the Agency's way of operating after the reorganisation in 2019 and the connected principles, such as flexibility, simplicity, transparency, and higher risk tolerance.

In 2019, a thorough assessment of ECHA's compliance and performance under the Integrated Management System Strategy and Framework was performed.

ECHA's Authorising Officer performed a comparative analysis based on audit results (including IAC, IAS and ECA audits, internal quality audits, ISO 9001:2015 and ISO 14001:2015 recertification audits), ex-ante and ex-post evaluations, non-conformities, complaints, risks, opportunities, performance measurements, staff, stakeholders and internal surveys, as well as other internal documentation. This analysis fed the assessment of the Integrated Management System Strategy and Framework. The purpose was to triangulate evidence from different sources, compare with the previous years' assessments and identify trends and areas for improvement. This assessment, together with the rest of the information from this report will be discussed as part of the 2020 Management Review.

Overall, ECHA is either fully or mostly compliant with the requirements of the Integrated Management System Framework and implementing well the Integrated Management System Strategy.

The main highlights from the assessment of the Framework are as follows:

Governance

Mission

- Clear, and up-to-date mission, linked to ECHA's strategy, representing a good framework for ECHA to develop its policies and actions.
- Improved communication to the policy stakeholders on the value and impact of ECHA's work is needed.
- ECHA to regularly check both with its staff and external partners their commitment to the mission/vision.

Ethical and organisational values

- ECHA's current values are apt for the new strategic priorities. Overall, ECHA is perceived as a transparent organisation.
- Inter Audit Service (IAS) of the Commission audit on conflicts of interest has been followed up well.
- Better results in the staff survey with regard to the trust in Senior Management compared to previous years.
- Management is promoting appropriate behaviour through good examples.

Management responsibility

- Good progress in adapting ECHA's governance, delegation and process structure to the new strategy.
- Good progress in empowering staff to find the right balance between cost, risk and benefit and to ensure decisions are taken at the level corresponding to the process risk.
- Senior Management needs to continue communicating on agreed principles and strategic priorities to be cascaded further down (including negative priorities), as well as addressing silos and ensuring clear staff/management roles in the new ECHA.

Human resources

- Skilled personnel, with high competence and an adequate work-life balance.
- Good progress in the implementation of the new HR strategy aligned to ECHA's strategic priorities, capturing the strengths and weaknesses of the HR processes well.
- Good results for the staff survey 2019.
- Focus to be put on long-term preparations for ECHA's competence and profiles (especially leadership and managerial), further promoting staff development, flexibility and agility.

Stakeholders' and partners' engagement

- ECHA is well committed to stakeholders and building good relations with them.
- ECHA's media coverage has been mostly neutral throughout 2019 (79.5 %), positive (18.5 %) and negative (2 %) on average, with good perception for ECHA's transparency value and its work with regulatory partners.
- Synergies, aiming for economies were found with EFSA. Cooperation on sustainability criteria and environmental indicators started with EEA. Positive feedback received by ECDC for the support on internal control.
- Even if ECHA is engaged and active with its stakeholders, there is a need to develop a more focused approach and ensure more user-friendly communication.

Strategy, planning and risk management

Objectives planning and resources allocation

- New strategic priorities are well aligned to ECHA's mission and vision and EU political priorities, with more focus on outcome and impact indicators. Impact on staff working on negative priorities not sufficiently considered.
- Prioritising in a stricter manner the on-boarding of new tasks in view of the resources allocated to those is needed.
- Clearer milestones, a more streamlined approach and increased awareness of middle managers is needed when setting priorities.

Risk management

- A sound, well-structured and integrated corporate risk management exercise.
- Flexibility, risk tolerance and simplicity are part of the ECHA's new strategy, whose first results are already visible in 2019.
- There is a need to make risk discussions more explicit while involving the Management Board, peer organisations and focus on the most significant risks.

Operations and operational structure

Activity management

- Processes have been brought closer together with the reorganisation, enabling ECHA to focus more on

outcome/impact.

- The 'One-ECHA' concept was welcomed, however there is a need for further work to embed it into the mentality of ECHA staff/managers.
- There is a need to better communicate the progress on the actions and impact of strategic priority 1, in particular how ECHA's data can help to better protect the citizens and environment.
- Even if suppliers' (sub-contractors') management functions well overall, suppliers' evaluation and suppliers' change management could be further improved.

Information and data management

- ECHA started to implement its data strategy by putting the IUCLID strategy at the centre of it.
- Synergies with EFSA and ECHA's own legislations were found and as a result economies of scale were achieved by re-using existing IT platforms.
- ECHA's IT cost-effectiveness and competencies needed to run the IT strategy were benchmarked against peer organisations with positive conclusions on both.
- There is a need for further consolidation/integration, in particular, for data collection and data management.

Change management

- With the reorganisation, ECHA has proven agile and capable of undertaking significant organisational changes without major disruptions in its operational activities.
- Staff and management are committed to improving the Agency's Integrated Management System.
- In alignment with its new strategy, ECHA undertook a cost-benefit analysis of its ISO 9001:2015 certification and Integrated Management System concluding to continue with the certification scheme, while further streamlining the system.
- ECHA needs to keep its agility in terms of financial sustainability, resource allocation and staff development in alignment to external/political priorities and the EU's Multi-annual Financial Framework (MFF).

Evaluation and improvement

Performance management

- The first measurements were undertaken on progress in allocating substances to the different categories under strategic priority 1.
- Positive external feedback was received on ECHA's monthly reporting on selected metrics.
- There is a need to further improve the performance management system, seeking simplifications, focusing on the needs of key stakeholders/partners and reviewing the existing IT tools.

Assessments, audits and evaluations

- ECHA staff members have the right expertise in evaluation, internal control, quality and audit.
- A fit for purpose and balanced approach in line with strategic and operational needs to be sought when selecting audit and evaluation topics.

Specific efforts to improve the efficiency and economy of financial and operational activities

In 2019, ECHA made progress towards implementing the commitments under ECHA's Integrated Management System Strategy in particular in the area of flexibility, risk tolerance and simplicity through reduced bureaucracy and efficiently executing its activities.

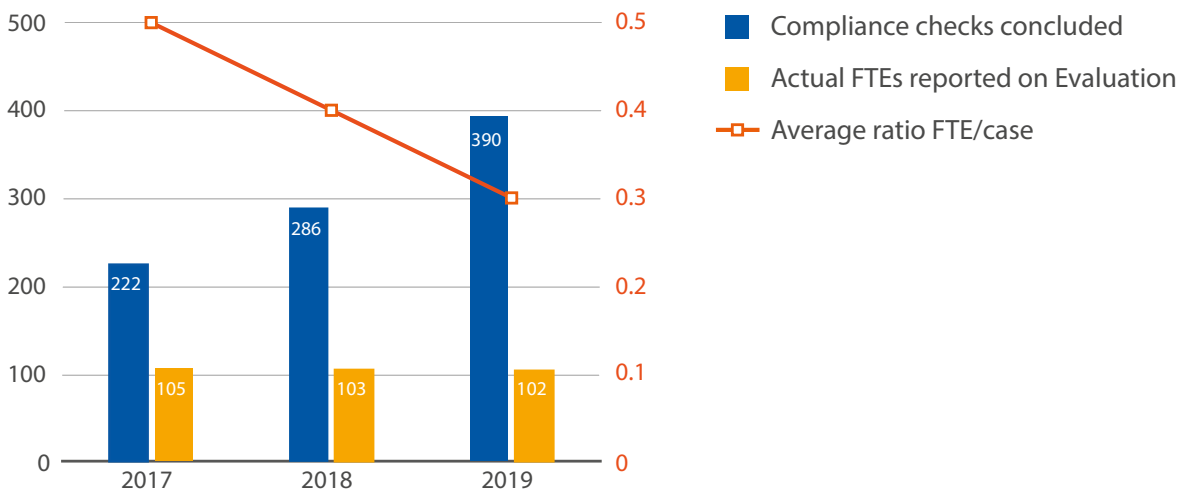
Efficiency gains have been also delivered in previous years through re-engineering and automation of operational and support processes. Several tasks have been entirely digitalised and become self-service, with workflows and controls built into the digital flow.

The 2019 report of the independent consultancy Gartner[53] compared ECHA's IT spend between 2011 and 2017 with other Agencies. The report found that ECHA's workload has increased by 86 %, while the total budget increased by only 25 % and staff numbers by only 16 %.

Efficiency gains have been possible due to ECHA's investment in automation while supporting the introduction of additional pieces of legislation. In addition, ECHA's total IT spend decreased by 13 % from 2015 to 2018, while ECHA has taken up tasks for a series of new pieces of legislation. At the same time, the quality of ECHA's software shows a very high level of conformity with best practice.

In 2019, further streamlining of processes, maintenance of the proportionality of controls to risks, and the delegation of decision making to lower management levels where risks are low continued. The staff survey results of 2019 show that 82 % of staff feel empowered to take their own decisions compared to 75 % in 2017. One example of this streamlining is the centralisation of authorising low value payments (below EUR 6 000) in the Finance Unit. An estimated five days each year are saved in terms of accessing systems. In addition, by combining the authorisation and verification steps, heads of unit and directors save around 30 days a year from reviewing and authorising the payments. These calculations are based on conservative averages and do not take into account the complexity of the individual transactions.

FIGURE 10: Trend on efficiencies gained in evaluation



53 https://echa.europa.eu/documents/10162/13612/gartner_echa_benchmark_en.pdf

Another example of a simplified workflow includes the removal of eight out of eleven steps in the standard documentations' workflow in ECHA's Integrated Management System tool. Delegations were also integrated in the tool, removing the need to keep paper files in different locations and duplicate registries of decisions and delegations.

Thanks to a combination of IT tool investments and streamlining operational workflows, the efficiency of operational activities has also increased. As an example, in the dossier evaluation process, the number of compliance checks concluded increased while maintaining the same resources. The main process improvements that have been introduced include standard texts that enable a higher level of automation and better integration of scientific and legal reasoning when drafting decisions, and more focused decision making in the Member State Committee.

Review of the elements supporting assurance - assessment by management

The Authorising Officer performed the required assessment of the effectiveness and efficiency of the internal control system, based on ECHA's Integrated Management Strategy and Framework.

A number of surveys, reports, audit results, non-conformities, complaints, risks, opportunities, ex-post evaluations and other sources of information were analysed to draw conclusions.

The assessment of the internal controls acknowledged their effectiveness but also reinforced the commitment of the Agency to pursue further improvements under some of the areas covered.

To fulfil the requirements of the quality management standard ISO 9001:2015, a management review meeting will be held in 2020. The internal controls assessment of the Authorising Officer will be used to reflect on the strengths, weaknesses, risks and opportunities of the management system. On the basis of this retrospective assessment, directors will collectively decide on the priorities and actions to take in 2020 in line with the Agency's new strategy.

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.

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[54] 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 9 March 2020

SIGNED

54 As regards the implementation of the European Union legislation and the fee regulations under the Agency's remit, this assurance has to be limited to the field of competences of the Agency. Since the mandate of the European Chemicals Agency does not include controls or inspections at national level, it cannot be confirmed that only registered or authorised substances and products, for which a fee has been paid to the Agency, are circulating on the European Union market.

APPENDICES

Appendix I – Actions, outputs and indicators

Actions and outputs

In its Work Programme 2019[55], the Agency established the actions and outputs for each of its activities. 222 actions have been carried out and all outputs have been achieved, except for 20 listed here:

1.1.1 Dossier preparation

Main actions and outputs specified in the Work Programme 2019	Achieved [Yes/No]	Additional information/ Explanation
Data availability and compliance		
Provide guidance on what parts of a registration needs to be reviewed and updated and on corresponding timelines, and provide input to the Commission on a possible implementing act on the update of registrations [2019] [REACH Review Action 1] [REACH Review Action 2] [REACH Review Action 14].	Partially	Substantial input to the Commission was provided. The update of the guidance on registration will continue in 2020, after the Implementing Regulation on the update of registrations is adopted.
Data sharing		
Review and update ECHA's Guidance and other support material to reflect the end of the phase-in period and other regulatory developments. [2019]	Partially	Support material was made available. The update of the guidance on registration has started after the adoption of the Implementing Regulation on the end of phase-in in October 2019, and is to continue in 2020.

1.1.2 Dossier submission

Main actions and outputs specified in the Work Programme 2019	Achieved [Yes/No]	Additional information/ Explanation
Carry out a new campaign of retrospective completeness checks. [2019, 2020]	No	In view of priorities, it was decided to replace this activity by the "integrated early support" initiative, which supports companies with upcoming regulatory deadlines for successful submission.

1.1.3 Screening and prioritisation

Main actions and outputs specified in the Work Programme 2019	Achieved [Yes/No]	Additional information/ Explanation
Develop in close cooperation with the Commission and Member States a regulatory approach to effectively address the growing societal concern of exposure to skin sensitising substances. [2019, 2020]	Partially	The work will continue in 2020.

55 As part of the Programming Document 2019-2022 available at: https://echa.europa.eu/documents/10162/13609/programming_document_2019-2022_en.pdf

1.1.4 Evaluation

Main actions and outputs specified in the Work Programme 2019	Achieved [Yes/No]	Additional information/ Explanation
Examine testing proposals within the set legal deadlines and in accordance with the plan set for testing proposals included in the registrations from the 2018 deadline, giving priority to non-phase-in testing proposals and to the resubmitted 2010 testing proposals for reproduction toxicity. [2019, 2020] [REACH Review Action 2]	Partially	All testing proposals examined within the legal deadlines. As compliance check was the main priority in 2019, testing proposals motivated by the 2018 deadline will start being addressed in 2020.
Continue verification of compliance with good laboratory practice requirements for (eco)toxicological tests analysis. This entails requesting audits of randomly selected studies, and targeted study audits in case a concern about compliance with principles of good laboratory practice is identified. [2019, 2020] [REACH Review Action 2]	Partially	The GLP verification has continued for the studies submitted as a result of compliance checks. Requests for study audits decreased due to other priorities in evaluation and a long-term absence.

1.2.1 Authorisation

Main actions and outputs specified in the Work Programme 2019	Achieved [Yes/No]	Additional information/ Explanation
In 2019, RAC and SEAC will have evaluated the first two Review Reports submitted by 'upstream' authorisation holders. In 2020, additional Review Reports, e.g. on the use of trichloroethylene, will have been evaluated. This experience will allow ECHA to establish how helpful the communication from downstream users to the upstream authorisation holders has been. Based on this experience, ECHA can act to reduce the uncertainties that were inherent in the original upstream application. [2019, 2020] [REACH Review Action 6]	No	No 'upstream' Review Reports were submitted because the authorisation holders substituted away from Trichloroethylene.

1.2.2 Restrictions

Main actions and outputs specified in the Work Programme 2019	Achieved [Yes/No]	Additional information/ Explanation
Develop methodologies for risk to impact assessment (including estimations related to human via environment) and work on improved guidance for Member States and Committees on analysis of alternatives and consequent successful substitution of hazardous substances. [2019, 2020] [REACH Review Action 5]	No	This work was postponed due to the operational restriction and applications for authorisation work. It will be taken up in 2021.
Additional capacity building for Member States, RAC and SEAC on regulatory impact assessment, in particular methods used in socio-economic analysis relevant for restrictions or in applications for authorisation. [2019, 2020] [REACH Review Actions 5, 9]	Partially	Workshops on valuation and on substitution as well as joint work with some Member States on restriction cases partly built this capacity. Due to ECHA's resource constraints this capacity building was limited.

1.2.5 Safe and sustainable use of chemicals

Main actions and outputs specified in the Work Programme 2019	Achieved [Yes/No]	Additional information/ Explanation
Concerning substances in articles, ECHA will:		
Develop and adopt a strategy to support a safer use of chemical substances in articles. [2019]	No	Work was not prioritised/resourced.

Main actions and outputs specified in the Work Programme 2019	Achieved [Yes/No]	Additional information/ Explanation
Based on the activities carried out in 2019, define the detailed work programme for 2020. [2019]	No	Work was not prioritised/resourced.
Upon request of the Commission, provide support in the review of Article 33 of REACH with a view whether to extend the scope of that provision to cover other dangerous substances. [2019]	No	No request received.
Concerning substitution, ECHA will:		
Further investigate how to facilitate access to REACH/CLP data relevant for substitution (e.g. information on alternatives from applications for authorisation and restrictions). [2019, 2020] [REACH Review Action 5]	Partially	Different options considered. Priority setting initiated based on available resources and ECHA's level plans for work on data and dissemination.
Facilitate access to and promote enhancement of financial and technical support for substitution. Based on the experience gained, continue, adapt or discontinue the facilitation. [2019, 2020] [REACH Review Action 5]	Partially	Due to resource constraints this was a rather small activity. Continued discussion with DG RTD, GROW and ENV on how Horizon Europe could support substitution/safe-by-design.
Monitor the emergence of new substances and innovation e.g. in PPORD notifications, inquiries and registrations of new substances, in particular with a view to substitution. [2019, 2020]	Partially	Feasibility checked. Analysis over 2019 ongoing.

1.3 Biocides

Main actions and outputs specified in the Work Programme 2019	Achieved [Yes/No]	Additional information/ Explanation
Support the Member State competent authorities in the preparation of BPC opinions on the early review of already approved active substances following the adoption of the endocrine-disrupting criteria. Such opinions are foreseen to be requested by the Commission for at least three active substances. [2019, 2020]	No	No request received.
Roll out the process for biocides confidentiality claim assessment with the Member States. [2019]	No	Process developed but not rolled out as the further work was not prioritised/resourced.

1.5 Data management and dissemination

Main actions and outputs specified in the Work Programme 2019	Achieved [Yes/No]	Additional information/ Explanation
Data management		
Implement other actions prioritised in the data strategy set in 2018, which includes facilitating the re-use of REACH, CLP, and BPR data, e.g. through data download and ability to link with the dissemination portal and making available data from external sources as relevant. [2019, 2020]	No	The work was not prioritised resourced. The prioritise actions in the data strategy have been focused on IUCLID; Data deficiencies and regulatory concerns and analysing initial support for grouping (implementations started towards the end of 2019 and will deliver in the first half of 2020).

Main actions and outputs specified in the Work Programme 2019	Achieved [Yes/No]	Additional information/ Explanation
Promote the usage of data by interested parties, in cooperation with other EU agencies, particularly EMA and EFSA. [2019, 2020]	Partially	This target is defined by the execution of a European study on the potential of a common data platform. The procurements steps helped clarifying the methodology and approach but were late and the study will actually start in 2020.

2.3.4 ICT

Main actions and outputs specified in the Work Programme 2019	Achieved [Yes/No]	Additional information/ Explanation [FWC=Framework Contract]
Align the IT business continuity service to the needs of new ICT infrastructure and new services such as the poison centres portal. [2019]	Partially	The new infrastructure has adequate resilience, but poison centre continuity and service level requirements remain to be analysed further and confirmed during 2020.

Workload drivers and performance indicators

ECHA achieved 34 out of the 53 workload driver and performance indicator estimates set in the Work Programme 2019. The 19 workload drivers and performance indicators estimates not met in 2019 relate mainly to input and output indicators. For input indicators it is difficult for ECHA to predict industry intentions and output related indicators are often dependent on respective external input.[56]

1.1.1 Dossier preparation

Work Programme 2019 workload drivers and performance indicators	Type	2019 estimate	2019 actual
Effective working time for processing inquiries	Performance	0.7 person day/ inquiry	0.4 person day/ inquiry[56]
Inquiries received and concluded	Output	3 000	4 172 received, 4 241 concluded

56 Due to the inquiry process redesign implemented in June 2019, we reduced the time of ECHA staff used per inquiry concluded.

1.1.2 Dossier submission

Work Programme 2019 workload drivers and performance indicators	Type	2019 estimate	2019 actual
Number of PPORD notifications	Input	320	338
Effective working time for processing a registration dossier (first submission)	Performance	0.55 – 0.60 person days	0.42 person days
Registration dossiers received (incl. updates)	Input	15 000	16 053
Registrations stopped for manual verification at technical completeness check	Input	4 500	4 784
Number of registrations failing first technical completeness check	Output	1 300	1 082
Share of registration dossiers over 100 tonnes in the database that has passed the enhanced technical completeness check	Outcome	40 %	40 %

1.1.3 Screening and prioritisation

Work Programme 2019 workload drivers and performance indicators	Type	2019 estimate	2019 actual
Share of dossier updates following the sector specific actions for metals and inorganics	Outcome	70 %	28 %[57]

1.1.4 Evaluation

Work Programme 2019 workload drivers and performance indicators	Type	2019 estimate	2019 actual
Number of substances for which a conclusion was reached in a dossier or substance evaluation	Outcome	180	186[58]
Effective working time for processing one conclusion in dossier evaluation	Performance	25-28 person days	26.85 person days
Number of substances for which additional information was requested through dossier or substance evaluation	Outcome	200	249[59]
Priority compliance checks concluded: draft decisions or no action	Output	175	301
Substance evaluation final decisions issued	Output	30	15
Priority compliance checks opened	Input	200	362[60]

57 28 % of the 327 substances in the context of the metals and inorganics sectorial approach were updated. MISA foresees to gradually resolve outstanding technical and scientific issues on how participating consortia can improve their dossiers. As only part of these issues have been addressed so far, the majority of the updates are expected after 2019.

58 Substances for which no further request was made or the request made has been fulfilled

59 Substances for which a request for information was made in any decision adopted under testing proposal, compliance check or substance evaluation.

60 Number of cases opened in 2019; a share of them will be concluded in 2020.

1.2.1 Authorisation

Work Programme 2019 workload drivers and performance indicators	Type	2019 estimate	2019 actual
Number of new entries in the Candidate List	Output	15	8
Recommendation for inclusion of substances in the authorisation list	Output	1	1
Cumulative number of downstream user notifications of authorised uses of SVHCs	Outcome	5 000	723
Number of RAC and SEAC opinions adopted on applications for authorisation (number of uses)	Output	50	14
Effective working time of ECHA staff per opinion	Performance	38-46 person days	34 person days
Applications for authorisation received (number of uses)	Input	60	95

1.2.2 Restrictions

Work Programme 2019 workload drivers and performance indicators	Type	2019 estimate	2019 actual
Number of RAC and SEAC opinions on restriction proposals	Output	2	3
Restriction proposals 69(1) or reports developed under Article 69(2)	Output	7	1
Effective working time of ECHA staff per opinion	Performance	200-255 person days	119 person days

1.2.3 Classification and labelling

Work Programme 2019 workload drivers and performance indicators	Type	2019 estimate	2019 actual
Number of RAC opinions on proposals for harmonised classification and labelling	Output	60	51
Decisions made on requests to use alternative (Article 24)	Output	45	37
Effective working time for processing RAC opinions	Performance	45-55 person days	31 person days
Proposals for harmonised classification and labelling	Input	70	60

1.3 Biocides

Work Programme 2019 workload drivers and performance indicators	Type	2019 estimate	2019 actual
Number of BPC opinions on active substances approval (under the Review Programme)	Output	5	3
Number of BPC opinions on the renewal of active substances approval	Output	3	0
Number of BPC opinions on endocrine-disrupting properties of active substances approval	Output	5	6
Number of BPC opinions on early review of approved active substances	Output	2	0
Number of applications for Union authorisation for biocidal products (received, fee paid)	Input	41	54
Number of applications for same biocidal product Union authorisation (received, fee paid)	Input	40	76
Number of BPC opinions on Union authorisations for biocidal products	Output	24	10
Number of ECHA opinions on same biocidal product Union authorisations	Output	15	0
Effective working time for processing BPC opinions	Performance	27 – 33 person days	33 person days

1.4 PIC

Work Programme 2019 workload drivers and performance indicators	Type	2019 estimate	2019 actual
Scientific and technical support provided to the Commission, EU and non-EU DNAs	Output	3 500	3 100
Export notifications processed (validated, rejected, resubmissions)	Output	11 400	10 522
Share of notifications validated/accepted by ECHA	Outcome	87 %	93 %
Effective working time for processing export notifications sent by email	Performance	8,5 min.	5,5 min.

1.5 Data management and dissemination

Work Programme 2019 workload drivers and performance indicators	Type	2019 estimate	2019 actual
Number of unique user page views for published information on chemicals	Outcome	44.0 M	45.0 M
Description and number of data requests	Outcome	Internal:60 External: 30	Internal:123 External: 45
Average time taken for publication (days)	Performance	3 days	3 days[61]

61 Excluding Oct–Nov 2019 when the dissemination platform was upgraded to handle the new IUCLID format.

1.6 Delegated tasks

Work Programme 2019 workload drivers and performance indicators	Type	2019 estimate	2019 actual
Number of views for EUON information	Input	22 000	42 955

2.2 Management

Work Programme 2019 workload drivers and performance indicators	Type	2019 estimate	2019 actual
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	3	4
Reputational survey - ECHA's activities overall - combined neutral and positive feedback monitored in media publications >90 %	Outcome	Increasing positive trend [baseline established in 2019]	Neutral: 79.5 % Positive: 18.5 %
Website unique visitors/traffic to the web content	Outcome	3.6 million	5.4 million
Number of enforcement trainers trained by the Forum	Output	80	78[62]

2.3.1 Financial resources

Work Programme 2019 workload drivers and performance indicators	Type	2019 estimate	2019 actual
Level of budget implementation: commitment rate and cancelled carry-over rate	Performance	Min. 95 %, max. 5 %	Commitment rate 99 %; cancelled carry-over rate 2 %
Timely processing of payments	Performance	99 %	99 %

2.3.2 Human resources

Work Programme 2019 workload drivers and performance indicators	Type	2019 estimate	2019 actual
Percentage of Establishment Plan posts filled	Performance	98 %	97 %

62 52 trainers on REACH and CLP; 78 for REACH, CLP and the BPR.

Appendix II - Budget implementation reports and statistics on financial management

Budget overview

The initial total budgetary payment appropriations for the expenditure of 2019, as concluded by the Management Board in December 2018, amounted to EUR 117 million, while the final total figure concluded in the third amending budget in December 2019, amounted to EUR 112 million.

Budget overview (amounts in EUR)

Revenue	Initial voted budget	Amending budgets	Final voted budged
Total revenue	117 093 971	(5 124 659)	111 969 312

Expenditure	Initial voted budget	Amending budgets	Final voted budged
Commitment appropriations	118 291 550	(5 457 260)	112 834 290
Payment appropriations	117 093 971	(5 124 659)	111 969 312

1.1 Revenue

The budget funding of ECHA in 2019 consisted of the following (amounts in EUR):

Description	Initial Budget 2019	Amending Budgets 2019	Final Budget 2019	Entitlements established 2019	Revenue received 2019
Fees and charges from Registrations	32 773 450	(4 700 000)	28 073 450	28 418 522	28 418 522
Fees and charges from Authorisations	3 600 000	1 500 000	5 100 000	5 047 530	5 047 530
Fees SME Administration	1 000 000	0	1 000 000	1 011 915	1 011 915
Fees and charges from CLP	168 000	43 000	211 000	215 000	215 000
Fees and charges from Appeals	0	47 641	47 641	47 641	47 641
Total REACH Fee & Charges Income (incl. Appeals)	**37 541 450**	**(3 109 359)**	**34 432 091**	**34 740 608**	**34 740 608**
Fees relating to Biocidal Active Substances	1 610 000	(928 738)	681 262	726 600	726 600
Fees for Union Authorisation of Biocidal products	4 117 559	3 379 801	7 497 360	7 290 960	7 290 960
Miscellaneous fees	1 520 000	110 724	1 630 724	1 624 588	1 624 588
Fees and charges from Appeals	0	0	0	2 500	2 500
Total BPR Fee & Charges Income (incl. Appeals)	**7 247 559**	**2 561 787**	**9 809 346**	**9 644 648**	**9 644 648**
REACH subsidy	62 879 520	(4 533 520)	58 346 000	58 346 000	58 346 000
BPR subsidy	5 122 104	(2 143 689)	2 978 415	2 978 415	2 978 415
PIC subsidy	1 564 000	0	1 564 000	1 564 000	1 564 000
EFTA Contribution - REACH	1 412 237	0	1 412 237	1 412 237	1 412 237

Description	Initial Budget 2019	Amending Budgets 2019	Final Budget 2019	Entitlements established 2019	Revenue received 2019
EFTA Contribution - BPR	97 425	0	97 425	97 425	97 425
Confederation of Switzerland Contribution - BPR	179 676	(74 306)	105 370	105 370	105 370
Total EU Contributions	**71 254 962**	**(6 751 515)**	**64 503 447**	**64 503 447**	**64 503 447**
Total Other income - miscellaneous	**0**	**0**	**0**	**277 194**	**228 318**
Total	**117 093 971**	**(5 124 659)**	**111 969 312**	**112 332 825**	**112 283 950**

REACH/CLP Revenue

A) REACH/CLP fees and charges

In accordance with the REACH Regulation (No 1907/2006), ECHA is financed through fees paid by industry and by an EU balancing subsidy. 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/charges in 2019 in terms of the cash received amounted to EUR 34.69 million (EUR 81.59 million in 2018). In addition, EUR 0.05 million (EUR 0.02 million in 2018) was recorded in relation to REACH appeal fees[63] giving a total of fees and charges of EUR 34.74 million (EUR 81.61 million in 2018).

During 2019, ECHA cashed in a total of 8 704 invoices, compared to 28 290 invoices cashed in 2018 (the year of the final registration deadline), representing a decrease of almost 70 %. This marks the start of a new era for registration fee income, as no further registration deadlines are defined in the REACH legislation that would generate peaks in registration fee income.

In 2019, the Agency received payments for 88 applications (6 in 2018) for REACH authorisation. The total REACH authorisation income collected in 2019 amounts to EUR 5.05 million (EUR 0.61 million in 2018). The Agency received payments for 68 applications under the CLP Regulation. The total receipts under CLP for 2019 amount to EUR 0.22 million (EUR 0.14 million in 2018).

The additional registration fee income generated through the SME size verification process (included in the REACH registration income) in 2019 amounted to EUR 0.70 million (EUR 1.13 million in 2018). A total of 333 enterprises (414 in 2018) were verified for their company size during the year. On top of the additional registration fees, the Agency generated EUR 1.01 million in administrative charges (EUR 1.73 million in 2018) levied on companies who were not eligible for the already received rebates.

B) REACH/CLP contributions:

During 2019, the Agency received an EU subsidy for REACH/CLP of EUR 58.35 million (EUR 24.37 million in 2018) and a European Free Trade Association (EFTA) contribution of EUR 1.41 million (EUR 0.61 million in 2018).

63 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.

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 subsidy. 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/charges for 2019, in terms of the cash received amounted to EUR 9.64 million (EUR 6.37 million in 2018).

B) BPR contributions

During 2019, the Agency received an EU subsidy of EUR 2.98 million (EUR 4.88 million in 2018) and an EFTA contribution of EUR 0.01 million (EUR 0.02 million in 2018). In addition, the Agency received a contribution from the Confederation of Switzerland of EUR 0.1 million (EUR 0.18 in 2018).

PIC and POPs revenue

In accordance with the Prior Informed Consent (PIC) Regulation (No 649/2012) and Persistent Organic Pollutants (POPs) Regulation (No 2019/2021), ECHA is fully financed by an EU subsidy. In 2019, the EU contribution amounted to a total of EUR 1.56 million for the regulations concerned (EUR 1.10 million in 2018 for PIC).

Contribution and Service Level Agreements

The Agency has signed contribution agreements with the Commission to implement the European Union Observatory for Nanomaterials (EUON) and the European Union Chemical 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 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 IUCLID software for plant protection products.

In 2019, ECHA received an amount of EUR 3.17 million in aggregate for these tasks.

The Agency also has a number of Service Level Agreements with the Commission services in the context of providing administrative support to the Agency.

Other miscellaneous income

The table below shows other miscellaneous income received by the Agency in 2019 (amounts in EUR).

Description	Entitlements established 2019	Revenue received 2019
Legal recoveries	134 250	85 374
Car parking recoveries	70 470	70 470
Sale of goods	5 600	5 600
Recoveries from other EU agencies	55 216	55 216
Other cost recoveries	11 658	11 658
Miscellaneous income	**277 194**	**228 318**

Expenditure

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) summarises the execution of appropriations per title and a more detailed breakdown is provided in Appendix I as well.

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

The initially adopted budget for the Agency in 2019 was EUR 117.2 million and the overall decrease during the year, including 10 transfers and three amending budgets, was EUR 7.6 million, to arrive at EUR 109.6 million as the final budget.

There were two main reasons for the reduction in the budget. Firstly, following the re-organisation of the Agency and the related transition phase, ECHA's overall vacancy rate was, on average, higher than in previous years. In addition, the overall staff turnover rate in 2019 was higher than expected. These factors resulted in lower salary costs. Secondly, towards the end of the year, it became apparent that the fee income is not developing as planned and thus the Agency was required to find further savings in order to balance the budget.

The final executed amount totalled EUR 108.3 million corresponding to an execution rate of

99 % for the appropriations.

Carry over of appropriations to 2020

The commitments and payment appropriations carried over to 2020 totalled EUR 14.1 million, corresponding to 13 % of the committed amount.

The carryover of staff related expenditure budgeted, in Title 1, was limited and mainly relates to the commitments for trainings and interim services.

In Title 2, covering the Agency's infrastructure, the carry over totalled EUR 4.4 million, stemming mainly from commitments related to ECHA's new building and to 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 PIC and POPs. The carry over in operational titles totalled EUR 9.3 million and was mostly related to IT projects.

The 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 2018 totalled EUR 15.1 million and the finally executed amount was EUR 14.8 million, corresponding to 98 %. The cancelled 2 % relates mostly to IT projects in Titles 2 and 3, to consultancy services on establishing and maintaining a database on substances of very high concern, as well as on operational missions.

Late interest payments

During 2019, ECHA did not pay late interest for commercial invoices.

Procurement procedures

In 2019, in implementing its budget, ECHA signed 558 contracts and purchase orders. Moreover, ECHA issued 346 catering orders and 596 travel orders through the electronic ordering tools of the relevant framework contracts.

Out of the 558 signed contracts, 458 were specific contracts and orders under framework contracts, 77 were contracts resulting from tendering procedures, 13 were renewals. A total of 10 contracts were signed following negotiated procedures without prior publication based on the relevant rules of the Financial Regulation (Annexes 1–11.1), eight of which refer to legal services and the remaining to subscription and direct purchase of services for technical reasons.

In 2019, the performance of the suppliers of the Agency was satisfactory overall and in accordance with the terms of the contracts, with no relevant exceptions.

Green procurement continued to be a priority and an integral part of the Agency's management system. It is noted that in the context of the relocation of the Agency to new premises as of January 2020, for all relevant services to be set up such as catering, cleaning, furniture supply, removal, sales of assets etc. specific environmental requirements have been considered as part of the respective procurement procedures. Furthermore, to promote and ensure "Green computing", the IT equipment to be provided by the contractor under the new framework contract for Managed IT Workplace Services should be compliant with current industry standards regarding sustainability and energy efficiency, such as TCO, EPEAT, the ECO Declaration, Energy Star, or other similar ecolabels and environmental certificates.

The annual list of contractors is published by ECHA by 30 June of each year for the previous year to ECHA website[1].

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.

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 2019: Breakdown and changes in commitment appropriations and implementation of the appropriations for the current year (C1) per Title* (EUR)

Title	Description	Budget 2019 (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	75 889 886	-5 050 756	70 839 130	70 453 710	99.5%	70 839 130	70 106 452	99.0 %	342 477	0.5 %	390 201
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	18 428 240	-1 044 749	17 383 491	17 180 600	98.8%	17 383 491	12 743 715	73.3 %	4 436 884	25.8 %	202 891
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	20 060 833	-3 102 779	16 958 054	16 376 586	96.6%	16 093 076	9 502 882	59.0 %	6 276 607	38.3 %	581 468
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	2 392 717	1 457 510	3 850 227	3 697 185	96.0%	3 850 227	1 122 479	29.2 %	2 574 706	69.6 %	153 042
B0-5	OPERATIONAL EXPENDITURE - PIC & POPs	469 874	109 086	578 960	572 056	98.8%	578 960	138 534	23.9 %	433 522	75.8 %	6 904
	Total	**117 241 550**	**-7 631 688**	**109 609 862**	**108 280 136**	**98.8%**	**108 744 884**	**93 614 063**	**86.1 %**	**14 064 196**	**13.0 %**	**1 334 507**

** 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 2019: 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 2019 (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	66832408	-3884462	62947946	62624112	99.5%	62947946	62320248	99.0%	299083	0.5%	328615
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	16137545	-988239	15149306	15029985	99.2%	15149306	11149150	73.6%	3880835	25.8%	119321
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	20060833	-3102779	16958054	16376586	96.6%	16093076	9502882	59.0%	6276607	38.3%	581468
	Total	103 030 786	-7 975 480	95 055 306	94 030 683	98.9%	94 190 328	82 972 280	88.1 %	10 456 525	11.1 %	1 029 404

BIOCIDES

Title	Description	Budget 2019 (1)	Transfers / amendments (2)	Final Available Commitment Appropriations (3)	Executed Commitment Amount (4)	% Committed (4)/(3)	Final Available Payment Appropriations (5)	Executed Payment Amount (6)	% Paid (6)/(5)	Carried over RAL (C8) (7)	Carried over % (7)/(4)	Cancelled (3)-(4)
A-1	STAFF	8 219 816	-1 070 608	7 149 208	7 102 324	99.3%	7 149 208	7 070 970	98.9 %	31 354	0.4 %	46 884
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	2 034 231	-43 110	1 991 121	1 909 868	95.9%	1 991 121	1 416 016	71.1 %	493 852	25.9 %	81 253
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	2 392 717	1 457 510	3 850 227	3 697 185	96.0%	3 850 227	1 122 479	29.2 %	2 574 706	69.6 %	153 042
	Total	12 646 764	343 792	12 990 556	12 709 376	97.8%	12 990 556	9 609 464	74.0 %	3 099 912	24.4 %	281 180

PIC & POPs

Title	Description	Budget 2019 (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	837 662	-95 686	741 976	727 274	98.0%	741 976	715 235	96.4 %	12 039	1.7 %	14 702
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	256 464	-13 400	243 064	240 747	99.0%	243 064	178 550	73.5 %	62 197	25.8 %	2 317
B0-5	OPERATIONAL EXPENDITURE - PIC & POPs	469 874	109 086	578 960	572 056	98.8%	578 960	138 534	23.9 %	433 522	75.8 %	6 904
	Total	**1 564 000**	**0**	**1 564 000**	**1 540 077**	**98.5%**	**1 564 000**	**1 032 319**	**66.0 %**	**507 758**	**33.0 %**	**23 923**

Budget 2019: Breakdown and changes in commitment appropriations and implementation of the appropriations for the year (C1) per Chapter (EUR)

Chapter	Description	Budget 2019 (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-11	STAFF IN ACTIVE EMPLOYMENT	69 235 200	-5 094 584	64 140 616	64 069 860	100 %	64 140 616	64 065 080	100 %	0	0 %	75 536
A-12	MISCELL EXPEND ON STAFF RECRUITMENT AND TRANSFER	581 321	167 363	748 684	718 867	96 %	748 684	713 538	95 %	5 330	1 %	29 817
A-13	MISSIONS AND DUTY TRAVEL	44 000	-3 000	41 000	38 013	93 %	41 000	37 002	90 %	1 011	3 %	2 987
A-14	SOCIO-MEDICAL INFRASTRUCTURE AND SOCIAL WELFARE	1 883 478	-18 535	1 864 943	1 821 733	98 %	1 864 943	1 762 417	95 %	59 316	3 %	43 210
A-15	TRAINING	951 801	-212 072	739 729	647 877	88 %	739 729	569 491	77 %	78 386	12 %	91 852
A-16	EXTERNAL SERVICES	3 194 086	110 072	3 304 158	3 157 359	96 %	3 304 158	2 958 925	90 %	198 434	6 %	146 799
	Total	**75 889 886**	**-5 050 756**	**70 839 130**	**70 453 710**	**99 %**	**70 839 130**	**70 106 452**	**99 %**	**342 477**	**0 %**	**390 201**

Chapter	Description	Budget 2019 (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-20	RENTAL OF BUILDINGS AND ASSOCIATED COSTS	8 335 861	-1 030 081	7 305 780	7 297 639	100 %	7 305 780	7 132 611	98 %	165 028	2 %	8 141
A-21	INFORMATION AND COMMUNICATION TECHNOLOGY	7 683 629	-586 560	7 097 069	6 993 292	99 %	7 097 069	5 022 637	71 %	1 970 655	28 %	103 777
A-22	MOVABLE PROPERTY AND ASSOCIATED COSTS	1 789 443	660 729	2 450 172	2 410 033	98 %	2 450 172	492 162	20 %	1 917 871	80 %	40 139
A-23	CURRENT ADMINISTRATIVE EXPENDITURE	607 307	-87 838	519 469	472 702	91 %	519 469	91 383	18 %	381 318	81 %	46 767
A-25	MEETINGS EXPENDITURE	12 000	-999	11 001	6 934	63 %	11 001	4 922	45 %	2 012	29 %	4 067
	Total	**18 428 240**	**-1 044 749**	**17 383 491**	**17 180 600**	**99 %**	**17 383 491**	**12 743 715**	**73 %**	**4 436 884**	**26 %**	**202 891**

Chapter	Description	Budget 2019 (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)
B3-0	REACH	17 338 833	-2 232 334	15 106 499	14 822 095	98 %	15 106 499	8 545 488	57 %	6 276 607	42 %	284 404
B3-1	MULTIANNUAL ACTIVITIES	2 122 000	-670 445	1 451 555	1 354 510	93 %	551 577	525 259	95 %	0	0 %	97 045
B3-8	INTERNATIONAL ACTIVITIES	600 000	-200 000	400 000	199 980	50 %	435 000	432 135	99 %	0	0 %	200 020
	Total	**20 060 833**	**-3 102 779**	**16 958 054**	**16 376 586**	**97 %**	**16 093 076**	**9 502 882**	**59 %**	**6 276 607**	**38 %**	**581 468**

Chapter	Description	Budget 2019 (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)
B4-0	BIOCIDES	2 392 717	1 457 510	3 850 227	3 697 185	96 %	3 850 227	1 122 479	29 %	2 574 706	70 %	153 042
	Total	**2 392 717**	**1 457 510**	**3 850 227**	**3 697 185**	**96 %**	**3 850 227**	**1 122 479**	**29 %**	**2 574 706**	**70 %**	**153 042**

Chapter	Description	Budget 2019 (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)
B5-0	PIC & POPs	469 874	109 086	578 960	572 056	99 %	578 960	138 534	24 %	433 522	76 %	6 904
	Total	**469 874**	**109 086**	**578 960**	**572 056**	**99 %**	**578 960**	**138 534**	**24 %**	**433 522**	**76 %**	**6 904**

Total ECHA	Budget 2019 (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)
	117 241 550	-7 631 688	109 609 862	108 280 136	99 %	108 744 884	93 614 063	86 %	14 064 196	13 %	1 334 507

Budget 2019: Implementation of differentiated appropriations (EUR)

Budget line		Available commitment appropriations	Commitments made	%	Available payment appropriations	Payments made	%
B3-111	Substance evaluation and Rapporteurs (Multiannual)	2 086 870	1 842 329	88 %	551 577	525 259	95 %
B3-801	Cooperation with international organisations for IT programs	1 054 788	848 931	80 %	435 000	432 135	99 %
	Total	**3 141 658**	**2 691 260**	**86 %**	**986 577**	**957 394**	**97 %**

Out of the total available commitment appropriations, EUR 1 290 103 was stemming from commitments made in earlier financial years. The available commitment appropriations for 2019 totalled EUR 1 851 555 out of which EUR 1 554 490 (84 %) were committed. The amount of commitments carried forward to 2020 totals EUR 1 733 866.

Budget 2019: Implementation of assigned revenue (C4, C5, R0)

Title	Desciption	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	55 216	3 687	7 %	55 216	3 626	7 %	51 530	51 590
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	CND	C4	77 152	56 430	73 %	77 152	0	0 %	20 722	77 152
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	CND	C4	76 421	9 569	13 %	76 421	9 524	12 %	66 852	66 898
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	CND	C4	18 776	0	0 %	18 776	0	0 %	18 776	18 776
			C4	**227 565**	**69 686**	**31 %**	**227 565**	**13 150**	**6 %**	**157 879**	**214 415**

Title	Desciption	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	15 352	15 352	100 %	15 352	15 352	100 %	0	0
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	CND	C5	118 291	118 215	100 %	118 291	78 660	66 %	0	39 631
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	CND	C5	62 144	62 144	100 %	62 144	14 071	23 %	0	48 073
			C5	**195 787**	**195 711**	**100 %**	**195 787**	**108 083**	**55 %**	**0**	**87 704**

Title	Desciption	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	558 390	358 508	64 %	558 390	132 759	24 %	199 882	425 631
B6-010	EUON	CND	R0	1 669 926	930 512	56 %	1 676 107	657 955	39 %	739 414	1 018 153
B6-011	EUCLEF	CND	R0	2 098 682	967 680	46 %	2 092 500	536 993	26 %	1 131 001	1 555 507
B6-020	Occupational exposure limits	CND	R0	240 000	199 236	83 %	240 000	106 388	44 %	40 764	133 612
B6-021	Further development of IUCLID (w/ third parties)	CND	R0	784 428	784 428	100 %	784 428	187 175	24 %	0	597 253
			R0	**5 351 425**	**3 240 365**	**61 %**	**5 351 425**	**1 621 270**	**30 %**	**2 111 061**	**3 730 155**

Budget 2019: Implementation of the appropriations carried forward from previous year (C8) Per Title

Title	Description	Carried Forward from 2018	Paid	Cancelled	% cancelled
A-1	STAFF	256 142	242 204	13 938	5 %
A-2	BUILDING. EQUIPMENT AND MISCELL. OPER EXPEND	3 829 837	3 748 524	81 313	2 %
B0-3	OPERATIONAL EXPENDITURE - REACH/CLP	10 428 202	10 229 283	198 919	2 %
B0-4	OPERATIONAL EXPENDITURE - BIOCIDES	426 251	413 369	12 882	3 %
B0-5	OPERATIONAL EXPENDITURE - PIC & POPs	131 282	131 131	151	0 %
		15 071 714	**14 764 511**	**307 203**	**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 2019				Posts filled 31 December 2019*			
	TA				TA			
	REACH/CLP	Biocides	PIC	TOTAL	REACH/CLP	Biocides	PIC	TOTAL
AD 15	0	0	0	0				0
AD 14	8	0	0	8	5			5
AD 13	16	0	0	16	9			9
AD 12	18	2	0	20	6	2		8
AD 11	31	3	0	34	21			21
AD 10	39	5	0	44	32	3		35
AD 9	53	10	0	63	45	2		47
AD 8	53	10	1	64	49	5	1	55
AD 7	63	4	0	67	72	13		85
AD 6	20	6	0	26	54	12		66
AD 5	9	1	0	10	12			12
Total AD	310	41	1	352	305	37	1	343
AST 11	0	0	0	0				0
AST 10	0	0	0	0				0
AST 9	3	0	0	3	2			2
AST 8	6	0	0	6	3			3
AST 7	8	1	2	11	6			6
AST 6	18	1	0	19	12			12
AST 5	28	3	0	31	20	1		21
AST 4	18	3	2	23	23	3	1	27
AST 3	12	1	2	15	11	2	2	15
AST 2	1	0	0	1	12	2	3	17
AST 1	0	0	0	0				0
Total AST	94	9	6	109	89	8	6	103
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	50	7	461	394	45	7	446

	CA estimated need of FTEs 2019					CA posts filled 31 December 2019*				
	REACH/ CLP	Biocides	PIC	Other tasks	TOTAL	REACH/ CLP	Biocides	PIC	Other tasks	TOTAL
CA FG IV	20	7	2	5	34	21	4	1	4	30
CA FG III	64	6		1	71	53	4		1	57
CA FG II	18	2			20	32	6	1		39
CA FG I					0					0
TOTAL CAs in place						106	14	2	5	127
Total CA (FTE)	102	15	2	6	125	103.4	14.5	1.4	3.1	122.40

Percentage of posts filled on 31 December 2019

	REACH/CLP/PIC	Biocides
TA posts	98%	90%
CA posts	100%	97%

Geographical and gender balance (as per 31 December 2019)

		TA			CA			OVERALL	
Nationality		Male	Female	Total	Male	Female	Total	Sum	%
FI	Finnish	57	88	145	11	25	36	181	32.26 %
IT	Italian	19	20	39	7	4	11	50	8.91 %
DE	German	23	11	34	2	0	2	36	6.42 %
FR	French	19	12	31	2	3	5	36	6.42 %
UK	British	7	4	11	2	0	2	13	2.32 %
ES	Spanish	11	9	20	6	7	13	33	5.88 %
GR	Greek	14	6	20	5	6	11	31	5.53 %
BE	Belgian	8	6	14	3	0	3	17	3.03 %
PL	Polish	6	9	15	1	2	3	18	3.21 %
RO	Romanian	1	4	5	3	9	12	17	3.03 %
IE	Irish	11	4	15	0	1	1	16	2.85 %
BG	Bulgarian	0	8	8	2	4	6	14	2.50 %
PT	Portuguese	5	4	9	0	3	3	12	2.14 %
SE	Swedish	4	4	8	1	0	1	9	1.60 %
NL	Dutch	13	2	15	1	1	2	17	3.03 %
HU	Hungarian	2	5	7	0	3	3	10	1.78 %
LT	Lithuanian	1	4	5	0	1	1	6	1.07 %
EE	Estonian	0	6	6	1	2	3	9	1.60 %
SK	Slovakian	1	3	4	0	2	2	6	1.07 %
SI	Slovenian	3	3	6	1	0	1	7	1.25 %
CZ	Czech	0	3	3	1	0	1	4	0.71 %

		TA			CA			OVERALL	
Nationality		Male	Female	Total	Male	Female	Total	Sum	%
LV	Latvian	1	3	4	0	1	1	5	0.89 %
AT	Austrian	2	3	5	0	0	0	5	0.89 %
DK	Danish	2	1	3	0	0	0	3	0.53 %
MT	Maltese	0	3	3	0	0	0	3	0.53 %
IS	Iceland	1	0	1	0	0	0	1	0.18 %
CY	Cypriot	0	0	0	0	0	0	0	0.00 %
LU	Luxembourger	0	0	0	0	0	0	0	0.00 %
NO	Norwegian	0	0	0	0	1	1	1	0.18 %
LI	Liechtenstein	1	0	1	0	0	0	1	0.18 %
Other	Other	0	0	0	0	0	0	0	0.00 %
	TOTAL	212	225	437	49	75	124	561	100 %

2.1 Middle and senior management – gender and nationality overview

NATIONALITY		MALE	FEMALE	TOTAL	%
FI	Finnish	4	4	8	25.0 %
NL	Dutch	4	0	4	12.5 %
BE	Belgian	3	0	3	9.4 %
FR	French	2	1	3	9.4 %
UK	British	2	1	3	9.4 %
IE	Irish	2	0	2	6.3 %
IT	Italian	1	1	2	6.3 %
DE	German	1	0	1	3.1 %
DK	Danish	1	0	1	3.1 %
ES	Spanish	0	1	1	3.1 %
PT	Portuguese	1	0	1	3.1 %
RO	Romanian	0	1	1	3.1 %
SI	Slovenian	1	0	1	3.1 %
TOTAL	OVERALL	22 (72 %)	9 (28%)	31	100 %

Results of the screening / benchmarking exercise

Key functions	Type of contract (official, TA or CA)	Function group, grade of recruitment (or bottom of the brackets if published in brackets)	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
Deputy Executive Director	TA - 5 + 5 years + indefinite	AD 14	Management
Director (Head of Directorate) (Level 2)	TA - 5 + 5 years + indefinite	AD 13	Policy (operational)/
Administration			
Head of Unit			
(Level 3)	TA - 5 + 5 years + indefinite	AD 9 – AD 12	Operations/ Administration
Administrator	TA - 5 + 5 years + indefinite	AD 5 – AD 9	Operations/Administration
Support functions			
Head of Administration (Head of Directorate)			
(Level 2)	TA - 5 + 5 years + indefinite	AD 13	Administration
Head of Human Resources (Level 3)	TA - 5 + 5 years + indefinite	AD 9 – AD 11	Administration
Head of Finance (Level 3)	TA - 5 + 5 years + indefinite	AD 9 – AD 11	Administration
Head of Communication (Level 3)	TA – 5 + 5 years + indefinite	AD 10	Administration
Head of IT Unit	TA - 5 + 5 years + indefinite	AD 10	Administration
Senior Assistant	TA - 5 + 5 years + indefinite	AST 10 – AST 11	Operations/Administration
Assistant	TA - 5 + 5 years + indefinite	AST 1 – AST 5	Operations/Administration
Special functions			
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 exercise in 2019, in accordance with the Commission's requirements.

Last year's results indicate an increase of 3.8 % in the percentage of the operational staff in comparison to 2018. This is explained by the reorganisation that has taken effect at the beginning of 2019 where efforts and staff were shifted towards the agreed priority areas. This is in contrast with the decrease in the percentage of administrative support and coordination staff, which has dropped by 2.8 % in comparison to 2018.

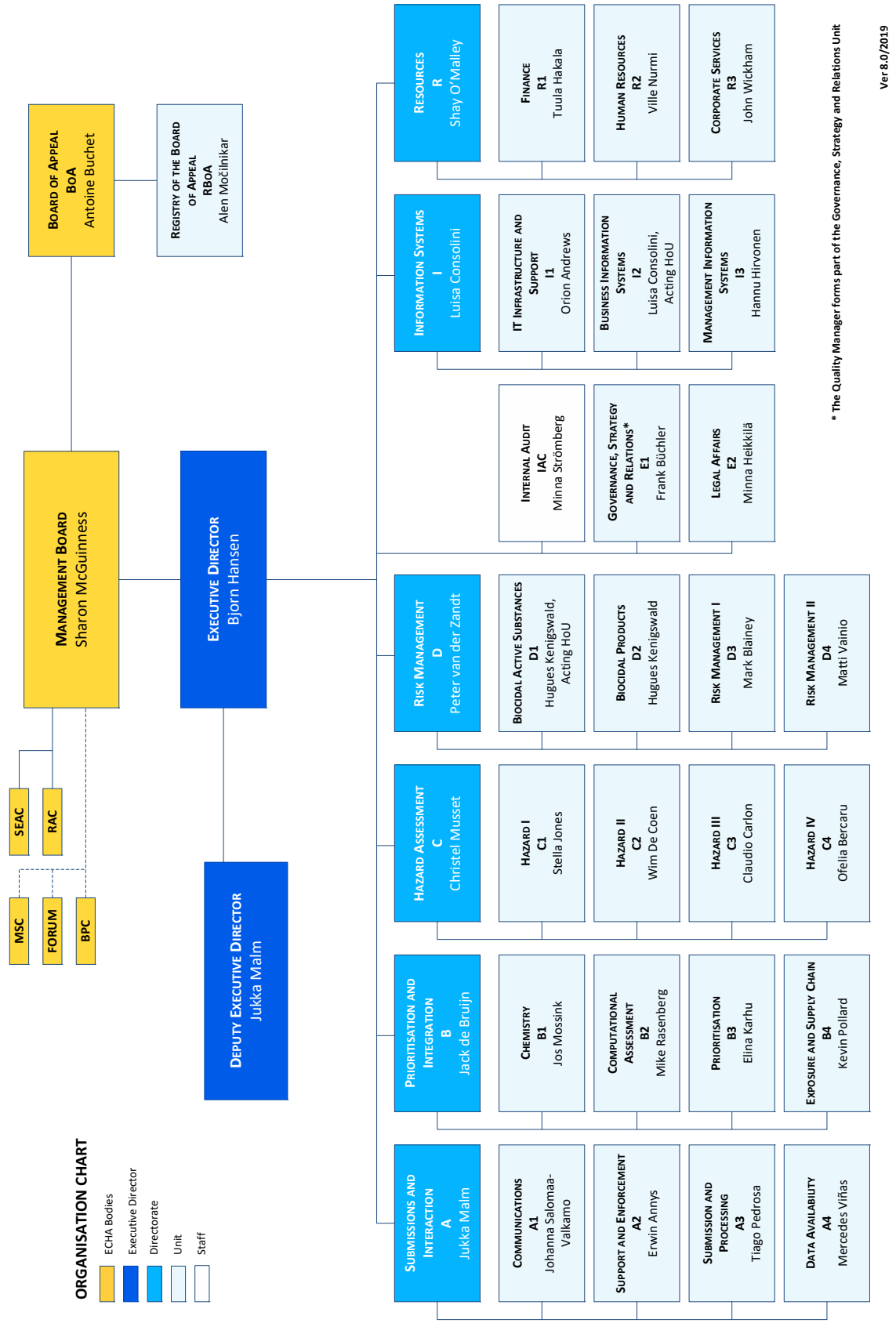
Job type (sub) category	2017 (%)	2018 (%)	2019 (%)
Administrative support and coordination	17	18.4	15.6
Administrative support	14	15.1	12.8
Coordination	3	3.3	2.8
Operational	77.7	75.9	79.7
General operational	22.7	25.2	20.9
Programme management	48.2	44.3	52.6
Top level operational coordination	3.5	3.1	2.7
Evaluation and impact assessment	3.3	3.3	3.5
Neutral	5.3	5.7	4.7
Finance	5.0	5.4	4.6
Control	0.3	0.2	0.1

Appendix IV - Human and financial resources by activity

WP 2019 Activity	Final estimate 2019 (FTEs)	Actuals 2019 (FTEs) for GR (TA, CA, SNE)*	Initial Budget 2019	Budget 2019 - actuals
1.1.1 Dossier preparation	45	40	10 912 458	9 945 995
1.1.2 Registration and dossier submission	43	36	8 577 865	7 987 299
1.1.3 Screening and prioritisation	19	23	4 496 432	4 004 744
1.1.4 Evaluation	112	102	19 685 839	18 179 296
1.2.1 Authorisation	31	34	6 530 125	5 940 277
1.2.2 Restrictions	18	19	4 024 353	3 552 078
1.2.3 Classification and Labelling	28	24	4 737 939	4 301 171
1.2.4 Support to other legislations	3	3	512 160	479 317
1.2.5 Safe and sustainable use of chemicals	18	20	3 728 378	3 466 631
1.3 Biocides	67	61	12 646 764	12 709 376
1.4 Prior Informed Consent and Persistent Organic Pollutants	9	9	1 564 000	1 540 077
1.5 Data management and dissemination	41	37	10 662 521	10 109 822
1.6 Delegated tasks	3	4	600 000	3 240 365
2.1.1 Committees	16	11	2 917 920	2 493 817
2.1.2 Forum	7	5	1 308 600	1 121 002
2.1.3 HelpNet and Security Officers Network	2	1	185 580	166 713
2.1.4 Board of Appeal	11	9	1 626 297	1 482 315
2.2 Management	32	39	7 623 296	6 836 402
2.3.1 Financial resources	26	27	4 678 709	4 363 554
2.3.2 Human resources	24	20	3 437 557	3 213 137
2.3.3 Corporate services	20	16	2 751 074	2 571 120
2.3.4 ICT	23	20	3 436 106	3 214 115
TOTAL	**598**	**560**	**116 643 971**	**110 918 623**

* SNEs are also included as the Commission is considering together with the CA posts

Appendix V – Organisational chart



Appendix VI – Management Board Assessment of the Annual Report for 2019

In assessing the Annual Report of the Authorising Officer for the year 2019, the Management Board makes the following observations[64]:

The Report provides a detailed account of the activities carried out by ECHA in 2019, a comprehensive overview of achievements, financial information, results of audits, ex-post evaluations and assessment of the internal control systems, the risks related to its activities and the measures taken to address them.

In the view of the Management Board, the overall performance and quality of the outputs was high. Despite the risks, constraints and unexpected developments in some areas, ECHA achieved 34 out of the 53 performance estimates set in the Work Programme 2019. The 19 estimates not met relate mainly to input and output indicators. For input indicators it is difficult for ECHA to predict industry intentions and output related indicators are often dependent on respective external input.

The Management Board welcomes the steps that ECHA has taken to implement the eleven recommendations of last year's Management Board assessment, noting that some of these recommendations are of ongoing nature and still relevant.

The Management Board welcomes in particular the following achievements:

1. As a follow up of REACH Refit actions, the Secretariat's reorganisation took effect focusing its efforts on where they matter the most for protecting human health and the environment, enabling to bring processes closer together, enhancing scientific and technical expertise related to the safety of chemicals and enabling operational effectiveness and efficiency.

2. The Secretariat revised ECHA's Integrated Management System Strategy and Framework to deliver on its strategic priorities in a more coherent way. The strategy sets high-level commitments that will guide the Agency in the coming years, as well as consolidating and integrating the different elements of ECHA's management system.

3. The efforts in the screening and prioritisation activity, which covered over 21 000 substances, shows good progress towards acceleration of data generation, identification of and regulatory action on chemicals of concern for human health or the environment despite the challenges due to the high number of substances and the limited information for many of them.

4. The Management Board welcomes the Secretariat's readiness to address non-compliant information on chemicals and the significant progress in generating needed hazard information, by speeding up the dossier evaluation process, putting further measures in place to raise the percentage of the checked dossiers and increasing the efficiency of decision making both in dossier and substance evaluation. ECHA invested in sectorial approaches with key sectors to improve the quality and completeness of registration files. The program provided in 2019 a positive momentum on the sectors awareness and preparedness.

5. The Management Board recognises the increasing workload of RAC and SEAC Committees due to the increased complexity of cases requiring broader expertise, notwithstanding the limited number of members. It also notes, that ECHA has taken steps to clarify how companies apply for authorisation to continue marketing and using their substances once they are listed in the Authorisation List. This includes explaining to applicants when they need to provide substitution plans and developing more consistent and concise opinions that define the boundaries of the scientific opinion making of ECHA's committees. ECHA started to put these opinion formats into practice and adapted its working practices, reflecting the conclusions of the "Report from the Management Board ad hoc group on the European Parliament Resolution on sodium dichromate" of 12 June 2019, to allow a high number of authorisation applications to be processed, while

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

ensuring proper control of risks to human health and the environment, and that substances of very high concern are substituted with safer alternatives.

6. The Secretariat worked on four restriction proposals in 2019, addressing risks to human health and the environment, including one for intentionally added microplastics thus providing valuable input to the European Commission's Strategy for Plastics in a Circular Economy. ECHA also worked on refining its methodologies for a more realistic understanding of the socio-economic impacts of restrictions and authorisations.

7. ECHA made data more accessible to all users (European governmental institutions, industries and stakeholders), by giving them enhanced possibilities to identify the stage their substances are at under different regulatory processes, whether they had properties of concern or whether they were present in nanoforms on the market. Still, it has to be noted that tonnage bands and exposure information are not yet available.

8. In response to Action 3 of the REACH General Report and under strategic priority 2, ECHA carried out a gap analysis to find out what are the main obstacles blocking the successful communication of exposure scenario-related information accompanying safety data sheets in supply chains.

9. ECHA worked with Member State enforcement authorities through the Enforcement Forum on REACH, CLP, PIC, POPs and the Biocidal Products Regulation, urging them to prioritise and tighten cooperation in enforcing evaluation decisions to help tackle insufficient information in registrations.

10. With the constrained resources, ECHA managed to show progress under strategic priority 3, by integrating new tasks into its portfolio, such as the SCIP database or preparations for assessing substances used in materials that may come into contact with drinking water.

11. ECHA showed that it has the competence and expertise to leverage the experience achieved through working with REACH, CLP, BPR, PIC and POPs and to achieve coherence and synergies in implementing various additional pieces of chemicals legislation.

12. ECHA developed a framework for on-boarding new tasks. This framework takes into consideration existing capabilities, structures and how well new tasks can be integrated into ECHA's activities to support a more holistic approach for safer chemicals.

13. In view of the delays at the level of evaluating Competent Authorities of the Member States on the implementation of the review programme for biocides active substances, ECHA developed an action plan aiming to increase the number of dossiers submitted for peer review by the Member States. As part of this action plan, ECHA has increased the collaboration with Member States and provides them with concrete support to finalise their dossiers for decision-making.

14. ECHA developed an extensive communication package to support companies and minimise disruptions to the EU market during the preparation for the UK withdrawal from the EU and the transition period.

15. ECHA contributed to the worldwide development of standards and tools for risk assessment of chemicals, provided capacity building for third countries under the instrument for pre-accession and support to the Commission and the EU agenda for international chemical management.

16. The Agency achieved a high degree of budget execution with a commitment and timely payment rate of 99%, average payment rate of 86%, low degree of vacancies with 97% of its Establishment plan filled in. The Management Board also notes that ECHA collected 33% higher than the initially estimated volumes of fees and charges in the Biocides regulation. This higher than estimated volumes of fees and charges demonstrates the challenge to estimate correctly the fee income for the Agency.

17. The Agency followed up as high priority recommendations from external and internal audits and ex-post evaluations, effectively managed the risks related to its activities, ensured the effectiveness of its internal control systems and made further efforts to improve the economy and efficiency in its operations.

18. ECHA closely followed up that the ECHA building project progresses as planned and ensured the smooth removal of the Agency's staff from the current to the new building without operational disruptions.

The Management Board recommends for 2020 to:

1. Contribute with scientific-technical input to the Green Deal objectives of the European Commission, in particular the expected Chemical Strategy for Sustainability, in order to support the delivery of a toxic-free environment and the zero pollution ambition.

2. Support the Commission in the implementation and further development of its Strategy for Plastics and also more general in a Circular Economy by developing the substances of concern in products (SCIP) database, as well as with scientific opinions and proposals, including the restriction proposals on microplastics.

3. Monitor and report regularly to the Management Board about the progress of the Committees to implement the recommendations of the 54th meeting of the Management Board and of the Management Board ad hoc working group on applications for authorisations. This is to recognise the high level of political and public scrutiny and follows the judgements of the General Court, the European Parliament's objection to the restriction of lead and its resolutions on draft implementing authorisation decisions. In view of the increasing workload for RAC and SEAC members, analyse the Committees' setup and investigate how to obtain complementary expertise and to increase the workload capacity.

4. Follow the implementation of the new organisational structure in support of the implementation of ECHA strategic plan for 2019-2023, ensure that it delivers the expected outcomes, taking into account lessons learned, and take any action, as appropriate, in order to meet these expectations.

5. Further investigate the chemical universe of REACH registered substances to support achieving the aim of the integrated regulatory strategy and increase transparency on how authorities address all substances on the EU market in a proportionate manner in view of demonstrating to ECHA's stakeholders and partners the impact of ECHA's activities.

6. Progress further in the implementation of the REACH Joint Evaluation Action Plan to tackle the challenge of non-compliance of registration dossiers and in making efficient use of the resources allocated for this task in the 2020 Work Programme.

7. On the basis of the Active Substances Action Plan (ASAP), undertake activities to improve the outcome of the Biocide Review Programme, ensure that relevant actions are taken in cooperation with the Commission and Member States in order to accelerate the programme. Improve the Union authorisation evaluation process in particular as regards the respect of legal deadlines and the quality of BPC opinions including the Summary of Product Characteristics (SPC) and the translations of the SPC.

8. In light of the uncertainty of the revenue of fees and charges, analyse together with the Commission options with a view to create a more predictable and stable financial environment for the Agency.

9. Prepare in a timely manner for new tasks arising from the Drinking Water Directive and related initiatives, present an evaluation and monitoring strategy, and seek adequate resources. Present regularly, and for the first time for the 58th Meeting of the Management Board, an interim analysis of how the new tasks could be implemented in the work of ECHA and its Committees and of how the implementation of the new tasks could affect ECHA's resources.

10. Ensure a high level of transparency towards and engagement with the Management Board for any new task with a view of enabling the Board to provide strategic steer in analysing the match between the capability of ECHA for carrying out the new task and a sustainable resource allocation for it.

11. Avoid conflicts of interests, and if conflicts of interests arise, manage these in a transparent manner in accordance with the revised ECHA Policy on prevention and management of potential conflicts of interest.

12. Implement the necessary measures, as far as possible, to minimise disruption to ECHA's activities, the EU Internal Market and environmental and human health protection due to the United Kingdom ´s withdrawal from the Union.
13. Accelerate work on the dissemination strategy to increase public access to exposure relevant information.
14. Continue providing support to industry by further developing the guidance on the new nano registration requirements, including webinars to help them overcome technical and administrative hurdles.
15. Following the implementation of the new organisational structure, ensure that it delivers the expected outcomes, propose efficiency targets and take any action, as appropriate, in order to meet these expectations. Carry out an interim assessment of the results of the re-organisation by the end of 2021.
16. Continue cooperating with other Agencies to ensure consistency of scientific opinions and guidance and to provide mutual support, aim for synergies where possible.
17. Keep monitoring the income from fees and charges and alert the Commission and the Management Board on any shortfall in a timely manner.

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