ECHA
EUROPEAN CHEMICALS AGENCY

General Report 2018

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Foreword

2018 was a remarkable year for ECHA. The main developments covered in this general report will impact our work on the safe use of chemicals – today and for years to come.

As ECHA's new Executive Director Bjorn took charge of the Agency at the beginning of the year. The handover and transition went smoothly, allowing a quick induction into the complex system of ECHA's processes and structures. This was crucial ahead of the third REACH registration deadline in May, which completed the transitional regime for substances on the EU market. We now open a next chapter on the protection of human health and the environment against harmful chemicals. ECHA holds a wealth of information on chemicals. At the same time, we know that we still lack important safety information and we will need to work on this.

The Commission published the second review of the REACH Regulation in 2018. The Agency analysed all findings from the review and added the actions incumbent on it into its Work Programme 2019, as well as into its new five-year strategic plan, following a public consultation. The Management Board has provided valuable input for the drafting of this strategic plan, since the beginning of the process in 2016. The new strategic plan is based on ECHA's competences in scientific-regulatory work and IT. With its three strategic priorities, it focuses on ECHA's core regulatory tasks under REACH, CLP, BPR and PIC, as well as on its new tasks, such as the occupational exposure limits and the EU chemicals legislation finder. We are confident that it will be a compass for ECHA in the future. It will help us to navigate past the uncertainties today and overcome the challenges of the future – the new multiannual financial framework or the UK withdrawal from the EU, to name two.

"I found a mature and agile organisation that allowed me very rapidly to add my contribution to achieving the common goal of sustainable chemicals regulation."

Bjorn Hansen
Executive Director

We want the Agency to be prepared for the upcoming challenges, both externally, towards stakeholders' expectations, and internally. With this consideration, the Agency invested significant effort to analyse its structure and see how it can be improved to serve the new strategic plan best. The work and all the processes are now grouped around competences. We believe that this re-organisation will allow us to be more efficient in our work and take up new tasks in a more coherent way.

There are many more encouraging achievements in 2018 that the present report addresses, and we invite you to read it. The report also shows the direction of our further work – and we are very enthusiastic to address these challenges together with ECHA's staff and stakeholders.

Bjorn Hansen
Executive Director

Sharon McGuinness
Chair of ECHA's Management Board

ECHA's legal mandate

The European Chemicals Agency (ECHA) is a European Union (EU) body established on 1 June 2007 by Regulation (EC) No 1907/2006 of the European Parliament and the Council concerning the 'Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)'.

ECHA was established for the purposes of managing and, in some cases, carrying out the technical, scientific and administrative aspects of the REACH Regulation and to ensure consistency at EU level. It was also established to manage tasks related to the classification and labelling of chemical substances which, since 2009, have been governed by the Regulation on 'Classification, Labelling and Packaging of substances and mixtures' (CLP Regulation (EC) No 1272/2008 of the European Parliament and the Council).

In 2012, ECHA's mandate was expanded by Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products – the 'Biocidal Products Regulation' (BPR).

The recast of the Prior Informed Consent (PIC) Regulation (Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals) also entered into force in 2012. In 2014, certain tasks related to PIC were transferred from the European Commission's Joint Research Centre (JRC) to ECHA. These legislative acts are applicable in all EU Member States (MSs) without the need for transposition into national law.

ECHA's mission, vision and values

ECHA's mission[1]

We, together with our partners, work for the safe use of chemicals.

ECHA's 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.

ECHA's values

Transparent
We actively inolve our regulatory partners and stakeholders in our activities and are transparent in our decision-making. We are easy to understand and to approach.

Independent
We are independent from all external interests and impartial in our decision-making. We consult members of the public openly before taking many of our decisions.

Trustworthy
Our decisions are science based and consistent. Accountability and the security of confidential information are cornerstones of all our actions.

Efficient
We are goal-oriented, committed and we always seek to use resources wisely. We apply high-quality standards and respect deadlines.

Committed to well-being
We stimulate the safe and sustainable use of chemicals to improve the quality of human life in Europe and to protect and improve the quality of the environment.

1 ECHA's mission and vision were renewed during 2018. The new mission and vision are effective as of January 2019.

Executive summary

Following the 10-year registration period, the end of which was marked by the successfully managed last REACH deadline in 2018, ECHA now has data on all registered substances on the EU market. Together with Member States, ECHA can now use it's unique source of information on chemicals to determine which substances can be considered safe and which require further regulatory action. While the situation is significantly better than it was before REACH, it is still clear that the quality of information does not allow immediate conclusions to be made for many substances.

As such, ECHA will need to intensify its work on improving the level of compliance of the information submitted by industry. The valuable input from the European Commission's REACH Review[2] helped to focus ECHA's priorities where the Agency's work can have the greatest impact on protecting human health and the environment.

In developing and finalising a new strategic plan for 2019-2023, the Agency prepared for future challenges and to efficiently and effectively carry out tasks under REACH, CLP, the BPR and PIC together with work in new key areas including tasks related to poison centres, occupational exposure limits, the Waste Framework Directive, the EU Chemicals Legislation Finder and persistent organic pollutants.

Key achievements in 2018

OPERATIONS

- The **registration phase of REACH was completed** without causing market disruption. Companies received support for registering 28 357 dossiers and benefitted from enhanced support to prepare their registration dossiers. ECHA will look at ways to improve the level of compliance.
- Companies were able to submit their registrations by the **2018 deadline** using IT tools and support. ECHA now holds data on the most used chemicals on the EU market and can assess it together with the Member States.
- **Key data on chemicals was published**, including all the registration information submitted for the 2018 deadline, and the biocidal product assessment reports and summaries of product characteristics of authorised products. ECHA is taking steps to make further use of the data it has collected over the years.
- ECHA developed an approach to map the chemical space of substances registered under REACH to support achieving the aims of the **integrated regulatory strategy** and to increase transparency on how authorities address all substances on the EU market in a proportionate manner. This will help to achieve the World Summit on Sustainable Development 2020 goals.
- ECHA continued to focus on generating information required to clarify the long-term **effects of substances on human health and the environment**, and increased the efficiency of evaluation by addressing groups of substances. Single draft decisions are now addressed to all lead registrants of the substances in a given group. The Agency is preparing to address the lack of compliance as well as the concerns raised in the public discussions on this issue.
- ECHA was fully **transparent** to operators and stakeholders about the status of evaluation decisions through relevant updates published on the Agency's website.
- In close collaboration with Member States, chemically-related **substances registered above 100 tonnes per year were grouped** – contributing to forming a better understanding of the chemical universe and the implementation of effective and coherent regulatory action where needed.

2 Commission General Report on the operation of REACH and review of certain elements, COM(2018) 116 final available at: https://ec.europa.eu/growth/sectors/chemicals/reach/review_en.

- 16 new substances were added to the **Candidate List**. Seven substances were recommended to be added to the **Authorisation List** due to the threat they pose to health and the environment. Preparations were made to take in the next wave of applications for authorisations.
- ECHA developed a record number of **restriction proposals**, some of which broke new ground, such as the proposal on microplastics.
- ECHA accelerated meaningful, informed and innovative **substitution** by improving access to its public database on chemicals, increasing the capacity of Member States and stakeholder to analyse alternatives, and enhancing networking opportunities.
- The trend for submitting **harmonised classification and labelling** dossiers has increased by approximately 50 %, mainly driven by submissions related to active substances in plant protection and biocidal products.
- The first set of tools for the harmonised notification of information on hazardous mixtures for **poison centres** were provided to industry and work progressed on the central notification portal for authorities.
- To speed up the **Biocides Review Programme**, ECHA started to provide earlier and increased support to Member States. The first Union authorisations were granted allowing companies to have their biocidal products authorised for the entire EU market with one application.
- Improved quality of regulatory information in export notifications made under PIC enabled non-EU authorities to make better-informed decisions.
- ECHA decided to proceed with building an **EU Chemicals Legislation Finder**, following the conclusions of the feasibility study conducted in the first phase of the project.
- The **EU Observatory for Nanomaterials** was further expanded with information on research and innovation.

GOVERNANCE

- A **new strategic plan** adopted by the Management Board and the **review of the organisational structure** helped the Agency prepare for future challenges. The new priorities, along with the new communications strategy under preparation, link ECHA's work closely to the UN sustainable development goals.
- ECHA's **new Executive Director** continued the solid communication streams and relationship with institutions, Member States and stakeholders of the departing Executive Director.
- **Committee's work** is successfully managed thanks to a continued high level of commitment and dedication of the members and Member State experts.
- Key enforcement projects coordinated by the **Forum** focused on obligations aimed at protecting consumers and workers, revealing that hazard information is mostly missing for chemicals sold online and that there are shortcomings in the safety information passed to workers.
- The **HelpNet** offered support so that companies could live up to their 2018 REACH registration obligations and submit their registration dossiers in time.
- The **Security Officers' Network** extended the security model for accessing ECHA's databases to individual experts involved in ECHA's committees.
- **Finance**: The mixed financing regime, a combination of fee income and EU balancing subsidy, proved particularly challenging in 2018. This was due to the unpredictability of the registration volumes stemming from the REACH registration deadline. It resulted in divergent outcomes – more fee income under REACH and less under the BPR than expected.
- A new **human resources strategy** was put in place to guide the direction of the Agency's HR development in the long term.
- The implementation of initiatives related to ECHA's **future building** progressed.

OPERATIONS

Integrated Regulatory Strategy

Increased transparency on how substances are regulated

ECHA has developed an approach for mapping the universe of registered substances. Under REACH and CLP, a common approach to screening, which includes the grouping of substances, will support authorities in defining what further hazard information is needed to confirm a concern or initiate regulatory action. One of the main aims of the Integrated Regulatory Strategy is to have this understanding for all substances registered at or above 100 tonnes per year by 2020 and thereby contribute to achieving the World Summit on Sustainable Development 2020 goals.

"The first report of the Integrated Regulatory Strategy provides further insight into the different processes and activities ongoing on substances which support clarifying the chemical universe"

Jack de Bruijn
Director of Risk Management

Main achievements

The Integrated Regulatory Strategy helps authorities use the most appropriate combination of REACH and CLP processes to address substances of concern as soon as possible. Companies and industry sectors can support this approach by making sure that their registration dossiers as well as other REACH/CLP dossiers are up to date, and by providing any further information requested by ECHA on time.

The strategy takes on board the experience gained in implementing the SVHC Roadmap to 2020, and further integrates the REACH and CLP regulatory processes. Bybringing a greater coherence to these processes, the strategy will also contribute to meeting the 2020 goals of the World Summit on Sustainable Development[3].

With the Member States, ECHA implements a common screening process under REACH and CLP for identifying substances with the highest potential for adverse impacts on human health and the environment. This screening process helps to categorise:

- the registration dossiers for which further information needs to be generated to be compliant with the respective requirements;
- the substances which need further information to be generated through substance evaluation; and
- the substances that can be directly earmarked for confirmation of hazard properties through harmonised classification, for inclusion in the Candidate List or for EU-level regulatory risk management.

In 2018, ECHA developed an approach to map the universe of registered substances. ECHA's ambition is to know by 2020 how all substances registered at or above 100 tonnes will be addressed. The intention is to reduce the pool of substances of potential concern and to conclude, for as many substances as possible, whether they require specific action or that they are currently of low priority for further work.

To speed up the process and ensure consistency in how substances are dealt with, ECHA started working systematically to enhance the grouping of structurally-related substances. This work is carried out together

3 https://www.who.int/wssd/en/

with Member States. Companies from different industries and sectors can also proactively contribute by keeping their dossiers up to date and providing better use and exposure information.

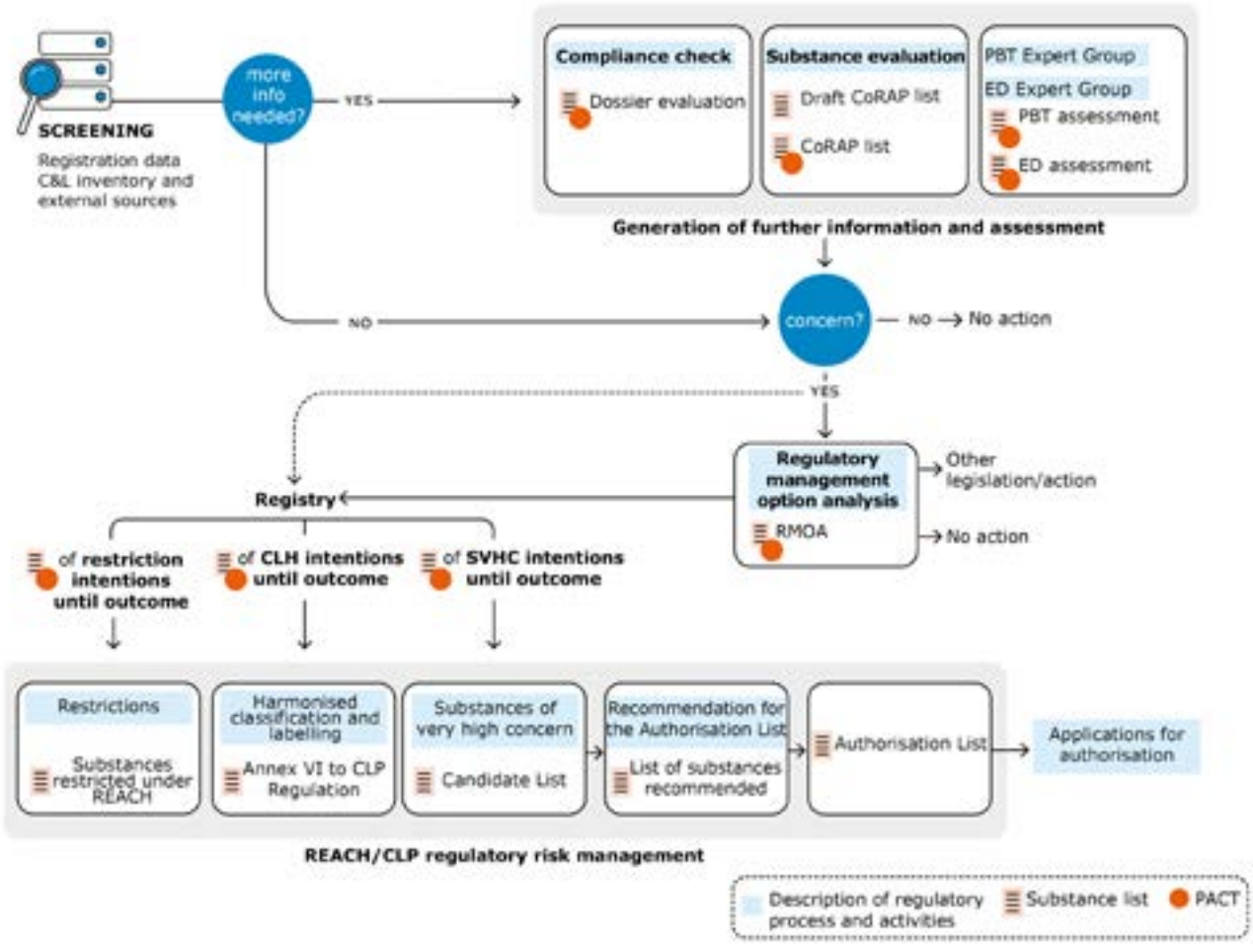
infobox

MAIN GOALS OF THE INTEGRATED REGULATORY STRATEGY

The strategy aims to:

1. Provide confidence among stakeholders and the public that registrants meet REACH information requirements, followed up by improved communication on safe use in the supply chain.
2. Efficiently select substances that raise potential concern, generating the necessary information for assessing their safety so that any remaining concerns can be addressed through the most suitable regulatory risk management instrument.
3. Enable appropriate and timely intervention from all actors (industry, ECHA, Member States, and the European Commission) within the different REACH and CLP processes so that chemicals of concern are properly addressed as soon as possible.

FIGURE 1: Integrated Regulatory Strategy



REACH dossier management and assessment

Registration dossier preparation and submission

The registration phase of REACH now complete with all registered substances on the EU market known

The 10-year registration period for existing chemicals is now over following the last REACH registration deadline on 31 May 2018. During this time, 93 376 dossiers covering 22 059 substances were submitted. 26 081 of these dossiers covering 4 449 substances, were for the 2018 deadline. With information inthe world's largest public regulatory database on chemicals at their disposal, ECHA and Member States can now look at how best to assess them.

Main achievements

The last REACH registration deadline on 31 May 2018 was successfully managed with extensive amounts of information on chemicals on the European market now publicly available. Over the 10-year lifespan of the registration phase, 13 000 companies submitted registrations to ECHA, creating the largest database of regulatory information on chemicals in the world.

Registration numbers have been granted to a large majority of dossiers submitted by the final deadline. The vast majority of companies submitted complete dossiers.

For the dossiers deemed incomplete, ECHA is waiting to receive further information from companies. These include 477 cases where companies faced exceptional circumstances as defined by the Directors' Contact Group (DCG). Here, the companies submitted their dossiers with a DCG solution and were granted an extension for submitting the missing information. The Agency expects to conclude on all pending cases by May 2019. At the time of publication of this report, around 1 % of REACH 2018 dossiers have been rejected.

ECHA has continued to receive registration dossiers after 31 May 2018, including for substances in the tonnage band of 1 to 100 tonnes per year.

In 2018, a total of 26 081 registrations were received – 92 % new and 8 % updates, and 23 % were submitted by SMEs.

The figure was smaller than anticipated, equivalent to 47 % of the Agency's initial forecast. Overall, however, the numbers for the 10-year registration period are closer to expectations. Also, no market disruptions have been reported to ECHA to date.

Check also:

- Evaluation
- Infobox: Full transparency of dossier evaluations
- Infobox: Progress in examination of testing proposals for reproductive toxicity
- Communication of risk management advice through the supply chain

Year in numbers

28 357
registration dossiers received (including updates) in 2018

92 %
new and **8 %** updates

4 449
substances registered for the first time

23 %
of registrations from SMEs

313
data-sharing disputes handled

6 143
inquiries concluded

Table 1

Number of registration dossiers and substances submitted in 2018 compared to the total number received by ECHA

	All time data	Submitted in 2018
Registration dossiers	93 376	26 081
Substances registered	22 059	4 449
Registration dossiers updated	57 019	2 276
Substances for which an update was received	13 778	2 325

"With this last registration deadline, we have reached an important milestone for the safe use of chemicals in Europe"

Christel Musset
Director of Registration

For the 2018 deadline, there was a clear trend of registrations coming from outside the EU including a high number of submissions of high-volume chemicals. Two-thirds of all registrations were from countries outside Europe – 43 % from importers and 29 % from only representatives on behalf of non-EU entities.

This trend was also observed in the inquiries submitted to ECHA. In 2018, the Agency received over 6 000 inquiries, including on high-volume chemicals, the majority of which were from non-EU countries. This is three times more than the Agency's initial forecasts.

In 2018, companies – especially SMEs – could benefit from enhanced IT tools and support provided by the Agency. This included putting novel ways of interaction into practice, including online chat, live Q&As, and video tutorials.

The cloud version of the chemical data management tool IUCLID, built with special features to support SMEs, was made available to companies of all sizes. The cloud service was designed to ease the preparation of small-volume REACH registrations, with functionalities prioritised according to the needs of SMEs, to help them manage their data and prepare their IUCLID dossiers directly online on a platform hosted and support by ECHA.

The Agency continued coordinating communication activities through various networks, using multiple communication channels to remind chemical companies of their REACH obligations and orient latecomers towards relevant support. Numerous training initiatives were held throughout Europe, often in collaboration with national or regional entities to ensure that SMEs have access to hands-on training and practical information sessions.

Additionally, ECHA's network of national helpdesks (HelpNet) shared the most appropriate approaches to supporting SMEs, making information available to companies in their own languages. These activities were followed by the publication of the final phase of ECHA's communication campaign on the 2018 deadline, which reminds all companies of their legal obligations to keep their registration dossiers up-to-date.

ECHA also provided a significant level of support when registrants could not reach an agreement on data sharing and access to the joint submission. This proved to be beneficial – especially to SMEs – when facing difficulties in data-sharing negotiations due to a lack of knowledge on cost elements and negotiation skills.

4 Substances not previously registered under REACH. Total number of substances covered by 2018 deadline registrations is 10 700.

Evaluation

Generating information that matters on (groups of) chemicals of potential concern

In 2018, ECHA made further progress in closing important data gaps by requesting missing information through compliance check decisions. ECHA will continue to look at ways of increasing compliance, and focus on increasing efficiency by addressing substances in groups rather than one by one. The status and outcomes of these evaluations are now available in a dedicated section on ECHA's website.

Main achievements

Progress on dossier evaluation

Out of 286 new compliance checks performed in 2018, almost 200 checks were done on substances of potential concern, in line with the Integrated Regulatory Strategy. In more than three quarters of these checks, gaps were found in the data required to clarify the long-term effects of substances on human health and the environment.[5]

These gaps need to be filled to ensure substances are used safely. An increasing number of substances were addressed in groups, applying a read-across approach.

The evaluation of testing proposals also made significant progress, with nearly 200 cases examined. A quarter of these were testing proposals for extended one-generation reproductive toxicity studies (EOGRTSs) re-submitted after the European Commission's decision in late 2017. The complexity of the EOGRTS tests and the discussions they inspire during the decision-making procedure makes this number a true achievement and proof of an effective and efficient process.

The majority of registrants (70 % in 2018) complied with ECHA's decisions and provided the information requested. In the still significant number of remaining cases, registrants had either submitted inadequate or insufficient information, or no information at all. In such cases, ECHA either began a new decision-making process or invited the Member State authorities to consider enforcement actions by issuing a simple statement of non-compliance. Enforcement actions show effect in ensuring compliance with the decisions and have – so far – resulted in registrants submitting the requested data in 74 % of the cases where enforcement authorities were invited to act.

In May 2018, the General Court of the EU clarified the legal status of statements of non-compliance, and the existing procedure had to be revised.

5 The 286 compliance checks resulted in either a draft decision initiating the decision-making procedure or a conclusion where no further data was deemed necessary. The Agency took 144 compliance check decisions in 2018 following the respective decision-making process.

Year in numbers

286
new compliance checks

198
testing proposals examined

229
follow-up evaluations concluded

21
new substance evaluations performed

21
substance evaluations finalised

"Dossier evaluation is now more efficient and focuses on grouping as basis to our further work in closing knowledge gaps"

Ofelia Bercaru
Head of Unit Evaluation

Pending cases were kept on hold for the majority of 2018 and beyond, as the legal proceedings are still awaiting a decision by the Court of Justice.

The impact of dossier evaluation can be seen in the follow-up evaluation process, where ECHA examines whether registrants provided the requested information and assesses whether that information raises concerns and prompts additional regulatory risk management measures.

As a result of the 2018 follow-up evaluations, 33 substances were flagged as candidates for further regulatory processes, such as harmonised classification and labelling, substance evaluation or a new compliance check.

Progress on substance evaluation

Substance evaluation plays an important role in the Integrated Regulatory Strategy as it generates information that can clarify concerns that may require EU-wide risk management measures to be implemented.

The evaluation follows the rolling nature of the Community rolling action plan (CoRAP). In 2018, evaluating Member States concluded evaluations of 22 substances that started in 2017, 16 of which required decision making to be started to request further information. Under the updated CoRAP for 2018-2020, adopted in March 2018, evaluating Member States began evaluating 21 new substances. Since then, evaluating Member States have also received information requested in previous evaluations and, in some cases, they had to request additional information.

As a result of earlier annual rounds of evaluation, ECHA adopted 21 substance evaluation decisions asking registrants to clarify suspected concerns, which were mostly related to persistent, bioaccumulative and toxic (PBT) and very persistent, very bioaccumulative (vPvB) or endocrine disrupting properties. In 2018, evaluating Member States also prepared 21 substance evaluation conclusion documents, indicating the need for EU-wide risk management measures in 15 of them.

Additionally, the pilot projects on a collaborative approach were finalised as planned with the publication of a final project report[6]. The approach involved ECHA, Member States and registrants, and aimed to improve the information used to decide on the needs for further regulatory risk management, in particular, by inviting industry to proactively improve their dossiers. As a result of the pilot projects, collaborative approaches will not become default but may be considered under specific circumstances in the future.

infobox

FULL TRANSPARENCY OF DOSSIER EVALUATION

Registrants can now consult a single table to follow the progress of a dossier for a given substance through the evaluation process. The table is part of the public activities coordination tool (PACT) on ECHA's website and replaces both the previous page hosting the non-confidential versions of adopted decisions and the list of substances potentially subject for compliance checks.

The new web page brings together information on the type, scope and status of the assessment undertaken for a given dossier. It is searchable by substance identifiers and shows whether ECHA has opened a compliance check or is examining a testing proposal for a given substance. Registrants can also track the progress from the draft to the adopted decision through to when the evaluation is eventually closed after the follow-up evaluation.

Shortly after the evaluation decision is adopted, a non-confidential version of the decision is also made available. The date on which the decision is adopted and sent to registrants is then published as well.

6 https://echa.europa.eu/documents/10162/13628/colla_pilot_project_report_en.pdf/0ba58a2e-675f-387e-4827-05aba076a0e0

infobox

PROGRESS IN THE EXAMINATION OF TESTING PROPOSALS ON REPRODUCTIVE TOXICITY

In 2017, the European Commission prepared decisions on 216 testing proposals and compliance check cases addressing reproductive toxicity that were referred to it following a stalemate in the Member State Committee coinciding with the change of the legal requirement for that information requirement in the REACH annexes.

For those dossiers not already updated with a testing proposal for an extended one-generation reproductive toxicity study, the Commission decisions requested registrants to update their dossiers by providing such a testing proposal or a valid adaptation. Except those who ceased manufacture, nearly all registrants complied with the Commission decisions and submitted a dossier update.

In 2018, ECHA started evaluating the newly submitted testing proposals, focusing first on dossiers for individual substances and small categories, and sending almost 50 draft decisions for registrants' commenting during the year.

This work will continue in 2019 by addressing testing proposals for substances belonging to larger categories.

Communication of risk management advice through the supply chain

Clear and accessible safe use information at every step along the supply chain remains the goal

2018 saw renewed commitment by ECHA and its stakeholders to invest in improving two-way supply chain communication, in terms of both the information content and the implementation mechanisms. Foremost in this were the 24 collaborative actions set out in a three-year programme under the Exchange Network on Exposure Scenarios (ENES). Furthermore, the Agency launched a major scoping exercise for the update of the EU tool for environmental exposure assessment.

Main achievements

Exposure scenarios have started to flow down the supply chain. However, there is strong evidence that recipients of extended safety data sheets are not (yet) satisfied with the content and format of exposure scenarios, a finding which is reinforeced by thr results of market studies carried out in Finland, Italy and labour inspectors in 20 EU countries. Furthermore, many companies at the bottom of the supply chain – the companies that would benefit the most from well-prepared risk management– are not yet aware of the new information and their duties related to it.

To address such isses, ECHA published a programme of 24 actions under the Exchange Network on Exposure Scenarios (ENES) Work Programme to 2020[7]. The ENES programme focuses on the supply chain's main actors – registrants, formulators, distributors and end users – and the tasks each ones carries out to generate and process exposure scenarios.

7 https://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios

A number of pilots were run throughout 2018 to collect feedback on the added value and on difficulties encountered when main actors carry out their tasks, such as when a registrant performs a chemical safety assessment based on use maps in various situations defined by the test cases.

One new feature in the governance of ENES is the involvement of five industry sectors[8] representing downstream (end) user industries, providing experience and perspectives from a diverse range of industries that use chemicals in their processes and in producing articles at the end of the chemical's supply chain.

In 2018, ECHA focused on sector use maps, taking forward the joint statement[9] signed in October 2016 by Cefic, the Downstream Users of Chemicals Co-ordination Group (DUCC) and ECHA on the crucial role these play in generating accurate and clear information on the safe use of chemicals and its communication down the supply chain.

Specifically, ECHA supported eight sectors in updating or publishing new use maps in a format that registrants can download directly into their chemical safety assessments using Chesar[10]. Chesar files have been published by five sectors[11]. Chesar 3.4 was released with improved functionalities for integrating updated use map information into existing chemical safety assessments, thereby facilitating the update of registration dossiers.

ECHA set up a network of 13 use map developers, facilitating regular exchange of experience and discussion on harmonisation across sectors. In cooperation with ECHA, Cefic launched a testing exercise for use maps. Its aim was to gain experience that could be used to enable registrants updating their safety assessments or registration dossiers to take advantage of sector use maps and 'real-life' downstream information when generating the exposure scenarios needed for the safety data sheets for their substances.

12 registrants carried out chemical safety assessments based on use map information and reported back on their experiences. When surveyed, the companies reported that use maps are efficient tools for preparing registrations – although not perfect.

Market studies were carried out on downstream end user needs, intensified contact with occupational safety and health inspectors, and involvement in the Forum's work, for example, the REF-5 harmonised enforcement project and an initiative with ECHA's accredited stakeholder organisations on improving safety data sheet quality. These efforts served to increase understanding of how to improve the way in which safe use information travels down the supply chain, and to develop proposals for a system to monitor progress in the flow of exposure scenarios and regarding their influence at the end of the supply chain.

In 2018, ECHA also collaborated with the European Agency for Safety and Health at Work (EU-OSHA) on its Healthy Workplaces Campaign on dangerous substances. The collaboration comprised joint promotion of information aimed at small and medium-sized enterprises on the benefits that REACH and CLP bring to their business, as well as promotion by EU-OSHA of information on, for example, ECHA's guide on safety data sheets and exposure scenarios and the European Union Observatory for Nanomaterials (EUON) to its 76 000 contacts.

8 ACEA, CheMI, Orgalime, FIEC, SMEUnited.
9 https://echa.europa.eu/documents/10162/13563/Joint+statement+on+use+maps/d76045c3-a4ad-40db-a617-e8c429130071
10 Fertilizers Europe, A.I.S.E., EFCC, Imaging & Printing, ESIG, ECPA, FEICA, Concawe.
11 A.I.S.E., EFCC, FEICA, ESIG, Imaging & Printing.

Risk management

Identifying needs for regulatory risk management

Addressing groups of high-tonnage substances

To increase the effectiveness and coherence of managing the risks of substances registered at or above 100 tonnes in close collaboration with Member States, chemically related substances were grouped on the way to forming a better understanding of the chemical universe.

Main achievements

Together with the Member States and the Commission, ECHA has set up a common screening process to identify substances of potential concern and guide them towards appropriate REACH and CLP processes.

As of 2017, the focus of ECHA's substance identification has shifted from an approach based on single substances towards one based on groups of related substances. Substances are grouped together based on read-across or category arguments proposed by registrants in their dossiers and on structural similarity. This means that when a substance of potential concern is shortlisted, related substances are included and assessed together with that substance. This ensures consistency when scrutinising related substances and helps to avoid regrettable substitution by industry.

The use of grouping, along with the work done to map the universe of registered substances, will ensure that all substances registered at or above 100 tonnes per year are addressed and recommended for further regulatory action (or considered of low priority for the time being). The grouping also helps to address already low-tonnage substances and non-registered ones.

The expert groups continued to provide support to Member States for concluding on the persistent, bioaccumulative and toxic and endocrine-disrupting properties of substances under assessment or for identifying the need for further information before concluding on these properties. Currently, evaluating Member States bring the majority of the substances they consider under REACH substance evaluation and SVHC identification to the expert groups.

New guidance was finalised to provide advice on how to identify endocrine disruptors in line with the endocrine disruptor criteria set out for pesticides and biocides. It describes how to gather and evaluate all relevant information for the assessment, conduct a mode-of-action (MoA) analysis, and apply a weight-of-evidence (WoE) approach in the evaluation. So far, the ED Expert Group has discussed the first five Member State evaluations of biocidal active substances using the guidance, and the number is expected to increase substantially.

Risk management option analysis (RMOA) is a voluntary step that aims to enable early exchange among authorities on the selection of the most appropriate regulatory action to address identified concerns for a given substance. In 2018, the number of new substances increased compared to the previous year, with 13 new intentions published on ECHA's website. The number of concluded cases rose to 21 substances.

The Integrated Regulatory Strategy Implementation Report 2018 provides further insight into the common screening approach and how it serves the different evaluation and regulatory risk management steps.

Check also:

- Authorisation
- Infobox: Strategy for supporting substitution
- Restrictions
- Infobox: Socio-economic analysis supports risk management of chemicals
- Classification and labelling
- Infobox: First set of tools for the harmonised notification of information for poison centres provided
- Biocides
- Prior Informed Consent (PIC)

Authorisation

Authorisation promoting substitution

ECHA included 16 substances of very high concern (SVHCs) in the Candidate List for authorisation and recommended seven substances for inclusion in the Authorisation List. These lists provide companies with advance notice of the need for substitution. While ECHA's scientific committees finalised the work on the first peak of authorisation applications, the Agency prepared for the next wave of applications, due in 2019 and 2020. ECHA also started implementing its substitution strategy.

Main achievements

In 2018, 16 substances of very high concern (SVHCs) were added to the Candidate List in 2018 on the basis of proposals submitted by Member States. Two substances were included because of their identified endocrine-disrupting properties, two due to their respiratory sensitising properties, and nine because they are persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB). The Candidate List now contains 197 SVHCs.

ECHA continued to prioritise substances from the Candidate List for inclusion in the Authorisation List. The eighth draft recommendation, which comprised seven substances, was submitted by ECHA on 5 February 2018. ECHA also prepared the draft ninth recommendation – its list of 18 substances contains substances with endocrine-disrupting and respiratory sensitising properties, as well as one vPvB substance. The substances were prioritised either because of their high volume and widespread use, which 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.

ECHA and its scientific committees finalised the peak of applications related to chromium compounds, 1,2-dichloroethane and diglyme by concluding on 26 opinions on applications for authorisation. One application was proposed not to be granted an authorisation. The efficiency gains achieved since the Agency started processing opinions were maintained.

With the help of the Task Force on the Workability of Applications for Authorisation, the Agency and the Commission overhauled the formats used for documenting the opinions and for applying for authorisations. The purpose is to increase the clarity of the opinions underpinning the Commission's decision making. The revisions also aim to help stakeholders better contribute to the assessment of the alternatives.

The second REACH Review concluded that the authorisation system delivers on its objectives on substitution and risk reduction. However, improvements are still needed, in particular in relation to cases where companies high up in the supply chain apply for authorisation. ECHA and the Commission services have discussed how to make these improvements, involving also stakeholders in the discussion.

Year in numbers

16
new SVHCs added to the Candidate List

7
SVHCs prioritised for the Authorisation List

24
pre-submission information sessions for authorisation applicants

22
combined RAC and SEAC opinions on applications for authorisation

6
applications for authorisation (**5** initial, **1** review report)

1
meeting of the Authorisation Task Force

Table 2

Status of received applications for authorisation per year					
	Received applications (applicants)	Number of uses	RAC-SEAC opinions per use	RAC-SEAC opinions per use and per applicant	Commission decisions per use and per applicant
2012	0 (0)	0	0	0	0
2013	8 (10)	17	1	1	0
2014	19 (33)	38	30	34	2
2015	7 (20)	13	25	51	10
2016	77 (132)	112	63	180	52
2017	10 (13)	16	58	74	47
2018	5 (7)	5	24	28	61
Total	**126 (215)**	**201**	**201**	**365**	**172**

Table 3

Status of received review reports per year					
	Received review reports (authorisation holders)	Number of uses	RAC-SEAC opinions per use	RAC-SEAC opinions per use and per applicant	Commission decisions per use and per applicant
2017	2 (2)	4	-	-	-
2018	1 (1)	1	4	4	-
Total	**4**	**5**	**4**	**4**	**-**

infobox

STRATEGY FOR SUPPORTING SUBSTITUTION

ECHA implemented its strategy for encouraging business-friendly substitution:

1. ECHA participated, supported or co-organised around 10 capacity-building workshops on substitution, and is already supporting similar events planned for 2019.
2. ECHA has held several discussions with the European Commission services, especially with the Directorate General for Research and Innovation, on how to enhance the support given to research activities that aim to directly or indirectly promote substitution away from harmful chemicals. These discussions are held in the context of the forthcoming Horizon Europe, the ambitious EUR 100 billion research and innovation programme that will succeed Horizon 2020.
3. Facilitating the use of registration, classification and risk management data for sustainable substitution, ECHA held two webinars on how to make use of its public database.
4. ECHA presented its substitution strategy at different stakeholder meetings – including 2018 SETAC, OECD and NeRSAP meetings – calling for the active support and contribution of stakeholders to substitution initiatives. The Agency has also established a LinkedIn group on substitution, a substitution contact list, and revamped web pages on the topic.

ECHA plans to hold the second European substitution network meeting in May 2019.

Restriction

Finding new ways to tackle microplastics

ECHA worked intensively on restrictions throughout 2018. Five restriction proposals were developed – more than in any year since the entry into force of REACH – including a politically important proposal on intentionally added microplastics. ECHA's scientific committees discussed eight proposals and adopted four opinions. Four new restrictions hit the statutes, and work to enhance the restriction process intensified.

Main achievements

The restriction proposal on intentionally added microplastics was one of the concrete actions delivered by ECHA to support the EU's plastics strategy, complementing the Commission's proposal on single-use plastics. ECHA also prepared restriction dossiers for:

- five soluble cobalt salts used in industrial metal treatment industries (submitted in October 2018);
- formaldehyde used in consumer articles (submitted in January 2019);
- cyclo-siloxanes D4, D5 and D6 used in consumer and professional mixtures (submitted in January 2019); and
- calcium cyanamide used as a fertiliser (submitted in January 2019).

ECHA also worked on a dossier on substances other than polycyclic aromatic hydrocarbons (PAHs) in rubber granules and on a dossier on oxo-(bio)degradable plastics.

The Commission's 2018 REACH Review proposed a number of actions to improve the restriction process and encourage Member States to submit more restriction proposals, with particular attention given to easier identification of candidates for restriction and to developing the capacity of Member States to prepare new restriction proposals. The Commission, Member States, ECHA, and the Agency's committees met to discuss these issues as the Restriction Task Force in December 2018, with further meetings planned for 2019.

ECHA's scientific committees discussed a proposal made by ECHA and four Member States in 2017 for the first EU-wide restriction of certain harmful substances in tattoo inks and permanent make-up. The Committee for Risk Assessment (RAC) adopted its opinion supporting the need for the restriction in November 2018. The Committee for Socio-economic Analysis (SEAC) agreed on a draft opinion supporting the restriction in November 2018. SEAC will adopt its final opinion in early 2019, after the two-month consultation on the draft opinion.

The Committees also discussed a number of ECHA and Member State dossiers during the year, adopting opinions on restrictions for:

- lead used as a stabiliser in PVC (proposed by ECHA);
- di-isocyanates (proposed by Germany);

Year in numbers

5
opinions adopted for restrictions

3
proposals for restriction under scientific evaluation

12
dossiers under preparation

2
meetings of the Restriction Task Force

"2018 was striking, as ECHA prepared several restrictions, some of which broke new ground."

Matti Vainio
Head of Risk Management Implementation Unit

- lead in shot used over wetlands (proposed by ECHA);
- C9-C14 perfluoralkylcarboxilic acids (PFCAs) (proposed by Germany and Sweden).

Restriction proposals on PAHs in rubber granules (Netherlands), DMF (Italy) and cobalt (ECHA) are still under discussion in the committees, and the opinions on the proposals will be finalised in 2019.

ECHA also prepared a report on the use of lead ammunition to supplement its restriction proposal for lead in shot in wetlands.

Table 4

Status of received restriction dossiers per year

	Received intentions	Annex XV PCs	SEAC DO PCs	Dossiers by MSs	Restrictions by ECHA	RAC-SEAC opinions	Commission decisions
2009	4	-	-	-	-	-	-
2010	1	4	-	3	1	-	-
2011	3	1	4	1	-	4	
2012	2	2	2	2	1	1	4
2013	8	4	2	3	1	2	-
2014	5	6	5	5	2	4	3
2015	4	2	5	3	-	6	2
2016	2	2	1	3	2	2	5
2017	4	5	4	1	2	2	2
2018	-	3	3	2	1	3	3
Total	**33**	**29**	**26**	**23**	**10**	**24**	**19**

infobox

SOCIO-ECONOMIC ANALYSIS SUPPORTS RISK MANAGEMENT OF CHEMICALS

ECHA continued to work with the Commission, the OECD and Member States to improve the understanding of how socio-economic analysis (SEA) is used in regulatory decision making, especially in relation to restrictions and to applications for authorisation.

In July, ECHA participated in the World Congress of Environmental and Resource Economists in Gothenburg, Sweden. ECHA representatives presented in sessions on chemicals management and participated in a pre-conference workshop 'The knowns and the unknowns in valuation of hazardous chemicals', organised by the FRAM Centre for Future Chemical Risk Assessment and Management Strategies of the University of Gothenburg. As a result, ECHA and FRAM will hold a workshop in the margins of the 2019 SETAC Meeting. Its focus will be on the valuing of environmental harms linked to chemicals exposure.

In February and November, ECHA organised and participated in the 7th and 8th meetings of the Network of REACH SEA and Analysis of Alternatives Practitioners (NeRSAP), which took place in Bilbao and Antwerp, respectively. The focus of these meetings was on improving assessments of how chemicals impact humans through the environment, and on analysing alternatives and the possibilities and costs of substitution.

ECHA also collaborated with the OECD in setting up and getting the funding for a joint OECD-wide valuation exercise which will be rolled out in the coming years. In 2018, the foundation for this work was established and five health-related endpoints were selected for valuation work.

Classification and labelling

A turnaround and upward trend in the number of CLH dossiers

The earlier trend in the submission of dossiers from harmonised classification turned around in 2018, with the number of dossiers increasing by approximately 50 %, driven mainly by submissions on active substances in plant protection products and biocidal products. Manufacturers of these products are now better able to inform professional users and consumers of any health and environmental hazards that they should consider when using these products.

Main achievements

ECHA's Committee for Risk Assessment (RAC) provided opinions on 62 proposals for harmonised classification and labelling (CLH) in 2018. This was almost double the number for the previous year, and is the highest number of opinions provided in one year since ECHA was established.

Year in numbers

62
opinions on proposals for harmonised classification and labelling

19
dossiers for active substances in plant protection products

14
dossiers for active substances in biocidal products

146 000
substances notified to the Classification and Labelling Inventory

Of these proposals, more than half were for active substances used in plant protection products and biocidal products – an upward trend for these chemicals which, until this year, had been falling. The increase in the number of dossiers for these active substances is welcome, and will provide more information for the manufacturers of plant protection products and biocidal products, which will in turn translate into professional users and consumers also being made more aware of any health and environmental hazards and how to use these products safely.

The number of CLH dossiers for industrial chemicals also increased reaching 29 in total. The Integrated Regulatory Strategy focuses on substances that matter for safe use, and the identification of candidates for harmonised classification and labelling is part of the common screening approach for identifying substances of potential concern.

The CLP Regulation implements the Globally Harmonised System (GHS) in the EU, and ECHA actively contributes to GHS activities and is involved in the UN's scientific and technical work to refine and complement the criteria used for classification. In 2018, ECHA continued to contribute to the review of human health hazard criteria regarding non-animal testing methods, for example, in vitro and in silico methods, focusing on skin corrosion or irritation. The Agency also contributed to the discussion on the potential of developing a global list of harmonised classifications.

ECHA's Classification and Labelling (C&L) Inventory is a comprehensive source of information on all self-classifications and harmonised classifications. Industry is obliged to self-classify substances for hazards that do not have harmonised classification under CLP and to notify ECHA accordingly. In 2018, over 10 000 new substances were notified to the C&L Inventory – the total number of substances in the inventory now stands at over 146 000.

At the same time, the inventory was complemented with additions or updates concerning 37 harmonised substances based on the 10th Adaptation to Technical Progress (ATP). Work also progressed on integrating the 11th ATP into the inventory. This ATP covers the translations in all EU languages for substances up to the sixth ATP, totalling over 4 000 substances. This work is expected to be concluded by the middle of 2019.

The information contained in the C&L Inventory has also been shared with Member States, who have requested its use for their own internal systems, contributing to the dissemination and use of C&L information in the EU.

infobox

FIRST SET OF TOOLS FOR THE HARMONISED NOTIFICATION OF INFORMATION FOR POISON CENTRES PROVIDED

In 2018, the first set of tools for the harmonised notification of information on hazardous mixtures for poison centres were provided to industry, and the work on the central submission portal started.

The Agency published the harmonised notification format, the European product categorisation system (PCS), and the Unique Formula Identifier (UFI) Generator.

As requested by the European Commission, the Agency has been working on the development of a central notification portal to support the notification process, as well as the development of a searchable database to be used by the national appointed bodies. The launch of the first version of the portal is expected in the beginning of 2019.

Substantial effort was placed in collaborating with stakeholders, to obtain input for the development of tools and support material, as well as to increase their awareness.

New webpages were also available with new support material on how to prepare and submit information on hazardous mixtures.

Biocides

Increased support to Member States to speed up the Review Programme

Having observed a marked reduction in the number of assessment reports for active substances finalised by Member States, ECHA has increased its support to Member State competent authorities to re-accelerate the Review Programme. Help was provided to Member States and industry for assessing endocrine disruptors, including through the publication in June of the joint EFSA–ECHA guidance on endocrine disruptors.

Main achievements

Following the marked reduction in the number of assessment reports finalised by Member States since mid-2017, only 24 opinions on active substances were adopted by the Biocidal Products Committee in 2018.

In addition, 11 opinions were agreed by the committee but could not be adopted because the assessment of the endocrine-disrupting properties according to the new criteria was not available.

This situation increases the risk that the Review Programme would not be finalised by 2024, thus further postponing the regularisation of the biocidal products already on the market since 2000. To finalise the Review Programme in time, the number of opinions would need to increase to approximately 80 per year until 2024. With the objective of re-accelerating the Review Programme, ECHA started to develop its support to competent authorities, especially that provided for the evaluation phase.

Year in numbers

24
BPC opinions on active substances

4
opinions on Union authorisations

2
other opinions addressing European Commission requests

1
new and **6** revised guidance documents

26
working group meetings

In June 2018, EFSA and ECHA's published the guidance for the identification of endocrine disruptors in the context of the biocides and pesticides regulations. It was welcomed by industry and Member States as a key tool for achieving an effective and harmonised assessment of endocrine-disrupting properties. The guidance provides a strategy for the assessment, a step-by-step approach and an overview of the information sources.

ECHA has also actively supported the coordination group with the mutual recognition referrals and the clarification of important technical and policy issues for product authorisations. The dedicated working party made significant progress to define rules for biocidal product families.

Companies, competent authorities and the European Commission benefited from the improvements brought to the R4BP 3 submission tool and the SPC Editor by two version updates. The most positively received functionalities included the improved R4BP communications, and the enhancements tothe SPC Editor for comparing summaries of product chracteristics (SPCs), and for exporting SPC content directly to Microsoft Word.

Prior Informed Consent (PIC)

Improving information available to non-EU countries

ECHA has taken actions to improve the quality of the information provided in export notifications, building on feedback received from the authorities in importing countries. Better notifications increase efficiency, as resubmission requests are less likely. In 2018, ECHA improved the section in export notifications explaining EU regulatory action on PIC chemicals and published guidelines to help EU exporters improve their notifications, in particular regarding prohibited and allowed uses. These guidelines give non-EU authorities a clearer picture of how these chemicals are used in the EU.

Year in numbers

9 634
export notifications processed in 2018

234
helpdesk questions from companies answered

2 600
scientific/technical questions answered

Main achievements

Information provided in export notifications by EU companies is particularly important to authorities in developing countries which receive imports, and the EU is considered a trustworthy source for information they can rely on for their decision making.

Revisions carried out throughout 2018 focused on Section 6 of the export notifications, which provides a summary of information on the final regulatory action taken by exporting countries.

The update of Section 6.1, which contains the summary, reasons and date of entry into force for the final regulatory action, was started for the most exported chemicals, and covered almost half of the entries. In addition, guidelines were provided to industry for filling in Section 6.2 on prohibited and allowed uses. This is expected to improve the information quality of notifications and reduce the number of re-submission requests, which are an administrative burden for all actors involved – exporters, designated national authorities and ECHA. Following the publication of the guidelines, the number of re-submissions decreased from 17 % to 10 %.

The impact of the UK's withdrawal from the EU on the IT tool ePIC was analysed. With the available budget, ECHA started to implement changes that enable exporters in the 27 EU Member States to smoothly notify their exports to the UK in light of the withdrawal.

ECHA also followed up on the proposals for improving Article 22 implementation raised in the 2017 report on the first three years of operation of the PIC Regulation. The Agency began discussions with the European Commission on how to address these proposals and improve collaboration and working practices effectively.

On reporting obligations, ECHA published the second report on information exchange under Article 20 of the PIC Regulation in November 2018.

The Article 10 report on the actual exports and imports of PIC chemicals that tookaking place in 2017 was published in December 2018. In 2017, the EU exported almost 830 000 tonnes of PIC chemicals. As in 2016, the most exported substance was ethylene dichloride, with more than 340 000 tonnes exported. Benzene was the most imported substance, with more than 230 000 tonnes entering the EU.

Check also:

- Data management and dissemination
- EU Chemicals Legislation Finder
- Nanomaterials

Cross-linking work

Circular economy

Moving towards a circular economy

The revised Waste Framework Directive entered into force in July 2018 as part of the implementation of the EU's action plan for the circular economy. The revision gave ECHA the new task of developing a database with information on articles containing REACH Candidate List substances of very high concern (SVHCs). At a time of growing public awareness on the possible negative health and environmental impact of universal use of plastic products, ECHA took immediate actions to address concerns, developing restriction proposals for intentionally added microplastics and for oxo-degradable plastics.

Main achievements

Revised Waste Framework Directive

The amended Waste Framework Directive requires ECHA to establish a new database containing information on articles – which contain Candidate List substances. EU suppliers will be provided this information, and it will cover both articles produced in the EU and articles imported from non-EU countries. The database will help waste operators sort and recycle such articles, and support consumers in making informed choices, considering how to best use and dispose of them. Taken as a whole, the aim is to contribute to the progressive replacement of substances of concern in articles and to the development of safer alternatives.

When taking on the new task in 2018, ECHA directed its first efforts to consulting the key stakeholders on their needs and constraints. In October, a workshop was organised to present and discuss an initial proposal for the database. Representatives from all stakeholder groups – industry, environmental and consumer NGOs, Member State competent authorities for waste and for REACH, and the European Commission – attended the workshop.

The discussion and feedback provided solid material on which to base the design of the database and related submission and dissemination tools, and in particular the information requirements for article suppliers. In 2019, work will focus on developing a first prototype of the database, awaiting the realisation by the Commission of a sustainable financing mechanism for all the activities needed under this waste legislation – all the preparatory work in 2018 was carried out without such a mechanism.

Plastic products

In 2018, the European Commission adopted its circular economy package. The EU strategy for plastics in the circular economy is a key part of this. The universal use of plastic products and its effects – in particular in the

context of marine litter – has grabbed the spotlight in recent years, but the presence of substances of potential concern in plastics has also raised some concerns. As part of the implementation of the EU plastics strategy, ECHA developed two restriction proposals: one on intentionally added microplastics (submitted in January 2019), and one on oxo-degradable plastics in various consumer and professional use products (expected to be submitted in July 2019).

In December 2018, ECHA completed the sector approach for plastic additives, a project initiated in 2016 and carried out together with manufacturers of plastic additives (Cefic's sector groups, Eurocolour, Eurometaux and BSEF) and plastics compounders and converters (EuPC and PlasticsEurope). Using registration information available on ECHA's website and industry sector knowledge, the collaboration generated an overview of the known high-volume chemicals widely used as additives in different types of plastic articles for certain functions (pigments, flame retardants, plasticisers, stabilisers, antioxidants, antistatic agents and nucleating agents).

The overview includes information on the types of polymers in which the additives can be found and the typical concentration ranges. The project also provides a method to compare the release potential of plastic additives. The method can support authorities in identifying substances in plastics for which a more in-depth assessment through a suitable REACH process is needed. It should also help industry identify what use and exposure information is relevant to determine safe use of substances in articles, including for registration and supply chain communication purposes. Comparing the release potential of additives with the same technical function can also help in substituting hazardous substances by non-hazardous alternatives. The project results were made available in February 2019.

Data management and dissemination

All 2018 registration deadline data and additional information on biocidal products and active substances is now available

Additional key data on chemicals was published including all the registration information submitted for the 2018 deadline, biocidal product assessment reports and summaries of product characteristics of authorised products. Additional ways for searching for information on biocidal products were also made available. ECHA will continue to explore how to further utilise the data it has collected through the years.

Main achievements

Disseminating information to the public

ECHA's Info Cards and Brief Profile pages have been enriched with more information on the risks posed by the use of biocidal products. They became available to the public in November and cover summaries of product characteristics (SPCs), product assessment reports and authorisation documents.

At the same time, additional functionalities were provided, including extended search possibilities and a tool for comparing information on biocidal products, which aimed to enable users to make informed

"We've proven yet again our business and IT capabilities to standardise, collect, integrate, publish, and secure data on the safe use of chemicals and apply advanced analytics to the data."

Luisa Consolini
Director of Information Systems

choices about the products they use and, for example, to select products containing an active substance that is less hazardous for health or the environment. For REACH information, over 99 % of the registration dossiers for the 2018 deadline have been published. For the remaining dossiers, the assessment of the confidentiality requests has started.

Further measures to ensure transparency were taken. From the Info Card and Brief Profiles, users can now find out whether a dossier evaluation for a particular substance is ongoing, follow the progress and even relate with the companies concerned by the evaluation.

Efforts were made to improve the readability of the information published on the dissemination web pages, the documents explaining the Info Card and Brief Profile were extensively re-written and a document explaining the types of data that can be found in the registration dossiers, What is a Registered substance Factsheet?[12] was released.

"After the 2018 REACH deadline, 10 years of REACH and CLP, five years of BPR and four years of PIC, we now have the richest database and state-of-the-art data management practices to boost the impact of our regulatory work."

Luisa Consolini
Director of Information Systems

More information made available

ECHA increased the information available to Member State competent authorities through the activities coordination tool (ACT). The ACT is a one-stop shop for substance activity coordination which allows users at competent authorities to search for substance-specific activities planned, ongoing or completed under the REACH and CLP regulations. The ACT is accessible through the portal dashboard for competent authorities.

ECHA has also created the online public activities coordination tool (PACT) for stakeholders on ECHA's website.

Data analytics further support regulatory work

The pilot for the Scientific Data Analysis Platform (SDAP) has proven successful. The platform is the backbone for screening and data analysis activities and for supporting regulatory actions by ECHA and Member States. In 2018, ECHA decided to enhance the pilot platform by making it more robust and maintainable.

A major revamp of the Business Intelligence and Data Integration platform was also initiated, with the aim of replacing the end-of-life technology, delivering improvements in managing substance identifiers for the regulatory master list, and providing an extensible platform for future developments.

Progress was also made in developing a reporting system for deficiencies and concerns. It will be used to map the chemical universe and categorise substances according to whether they are of potential concern, have a regulatory action ongoing or planned, or can be considered of low priority for further regulatory work.

ECHA's information has been increasingly used to support other regulatory activities both at authority and industry level. As part of the activities for promoting the use of the data collected by the Agency, a project was put in place to share information with regulatory bodies in the United States to support their regulatory actions.

12 https://echa.europa.eu/documents/10162/22177693/registered_substance_factsheet_en.pdf/4ce42d65-58bb-d829-2cee-f803579b13d5

EU Chemicals Legislation Finder

Laying the groundwork for the legislation finder

Based on the results of a business and architectural analysis on the European Union Chemicals Legislation Finder (EUCLEF) carried out in 2018, the European Commission has tasked ECHA with building the portal and having its first version operational in the first quarter of 2020.

Main achievements

The European Union Chemicals Legislation Finder (EUCLEF)[13] is an online service that will provide companies with information on how the EU regulates a given substance. Hosted on ECHA's website, the service will cover regulations directly under ECHA's remit as well as other legislation related to chemicals, such as that on pesticides, food contact materials, cosmetic products and toy safety.

Regulatory compliance is a condition for selling and distributing chemicals in the EU. Companies – especially SMEs – will benefit significantly from being able to find all pieces of legislation that apply to a substance in one place. The legislation finder will also help the European Commission and national authorities identify any regulatory overlaps or gaps.

"Companies will be able to find all regulations that apply to a substance in one place."

Gabriele Christ
Senior Scientific Officer

In 2017, the Commission found ECHA to be the most suitable body to offer the EUCLEF service. In 2018, the Agency carried out additional studies on the scope, feasibility, and IT and resource needs of the project.

A detailed business analysis looked to specify which pieces of EU legislation would be covered by the first phase of the project. This was followed by a pre-market study to identify market operators that would be able to provide ready-to-use, processed data to be integrated into ECHA's dissemination website. Based on the results, ECHA decided to proceed with building the service. Implementation was set to start in 2019, with a view of having a first version covering 40 pieces of EU legislation ready by the beginning of 2020.

Nanomaterials

Improved information about nanomaterials

Building on feedback from stakeholders, ECHA developed content for the second phase of the European Union Observatory for Nanomaterials (EUON) covering a wide range of topics, including the benefits of nanomaterials, the different regulations concerning them, occupational exposure, and many others.

Main achievements

As well as creating new pages for the main EUON[14] site, the Agency published nanomaterial-related content in the dedicated sections of Chemicals in our Life[15] – ECHA's website aimed at consumers, launched in April 2018. New infographics were also produced that provide information in a user-friendly and understandable format about the presence of nanomaterials in different products in our daily lives.

13 The EU Chemicals Legislation Finder is a task delegated to ECHA.
14 The European Observatory for Nanomaterials is a task delegated to the Agency
15 ECHA's consumer website on chemicals (Chemicals in our Life): chemicalsinourlife.echa.europa.eu

During the first half of 2018, NanoData, a database on innovation related to nanomaterials, was finalised and published. A "light integration" of eNanoMapper, a database containing research data on the safety of nanomaterials, was also completed and ECHA created a custom interface for the tool on the EUON website. Both databases went live on 12 June 2018.

The results of the first two studies run with funding from the EUON were also published in 2018. The studies were:

- a literature study about the risks of using nanomaterials as pigments[16] ; and
- a critical review of the relevance and reliability of data sources, methods, parameters and determining factors for producing market studies on manufactured nanomaterials in the EU[17].

On the basis of the results of the pigments study, a list of nano pigments[18] available on the EU market was establised. The list was linked to information in ECHA's registration database, allowing the public to obtain information on these substances with one click, including information on hazards and on ECHA's regulatory activities concerning these substances.

The overall presence of the EUON on social media has been strengthened through regular news and content updates. The EUON LinkedIn group has grown to over 340 international members, withnews and event information relating to nanomaterials, being regularly posted by the EUON as well as stakeholders.

16 Literature study on the uses and risks of nanomaterials as pigments in the European Union: euon.echa.europa.eu/documents/23168237/24095696/070918_euon_nanopigments_literature_study_report_en.pdf/58977ab1-1059-4b41-f003-18ae9d7a157c

17 Critical review of the relevance and reliability of data sources, methods, parameters and determining factors to produce market studies on manufactured nanomaterials on the EU: euon.echa.europa.eu/documents/23168237/24095696/170718_critical_review_of_market_studies_nanomaterials_final_report_en.pdf/ec77f39e-0918-5984-d7b1-654e3b1f14da

18 EUON's list of nano-pigments on the EU market: euon.echa.europa.eu/nano-pigments-inventory

GOVERNANCE AND SUPPORT

ECHA's bodies and Networks

Committees

Essential work in ensuring chemicals safety

The four committees – the Member State Committee (MSC), the Committee for Risk Assessment (RAC), the Committee for Socio-economic Analysis (SEAC) and the Biocidal Products Committee (BPC) – continued to provide opinions and seek agreements to support decision making by ECHA and the European Commission. The commitment and dedication of committee members, Member State experts, and the Secretariat ensured that the workload of 2018 was successfully managed and that all processes were carried over smoothly and without any backlog into 2019.

Main achievements

In 2018, RAC and SEAC issued 92 and 27 opinions respectively, while the MSC reached 89 agreements and adopted one opinion, and the BPC adopted 30 opinions.

RAC's workload for issuing opinions on harmonised classification and labelling (CLH) was successfully managed despite it being almost double that for 2017. 62 CLH opinions were issued, representing a marked increase from an average of 38 opinions per year for the five-year period between 2012 and 2017. RAC successfully finalised the pilot work on occupational exposure limits (OELs) related to carcinogens and mutagens. Both RAC and SEAC also continued their work on opinions on applications for authorisation and restrictions.

In addition to appointing members based on the regular Member State nominations, RAC and SEAC appointed or reappointed co-opted members – five and four, respectively – to broaden committee expertise in the fields of worker protection, chemical exposure assessment and socio-economic analysis.

The MSC continued to take into account diverging views among Member States on various scientific and technical matters including, among others, registration dossier compliance, testing proposals by industry, and substance evaluation outcomes. This enabled ECHA to issue decisions on these topics to registrants and thereby to fill identified data gaps. In 2018, the MSC reached and surpassed the milestone of 1 000 agreements made since the start of operation.

The BPC fulfilled its mandate by preparing opinions on Union authorisation and biocidal substances for the Commission's decision making. It adopted four opinions on Union authorisation as well as 24 opinions on active substance approval, 22 of which were for the Review Programme. Seven

Check also:

- Enforcement Forum
- HelpNet and Security Officers' Network
- Infobox: Security Officers' Network
- Board of Appeal

Year in numbers

RAC: **52** members (including **5** co-opted members)

SEAC: **34** members (including **4** co-opted members)

MSC: **29** members and **22** alternate members

BPC: **28** members and **26** alternate members

BPC: **52** core/alternate members and **273** flexible members

"Collaboration is very important, but challenging each other is also a part of this."

Henrik Tyle
Danish MSC member at MSC-62

of the adopted opinions contained a proposal for non-approval, among which there were active substances used as disinfectants or preservatives. The BPC also discussed and agreed on 11 other opinions on active substance approval, but it could not formally adopt them as the assessment of endocrine disrupting properties according to the new criteria that became applicable in June 2018 had not been made.

The frequent use of smaller-scale meetings, including working group and preparatory meetings organised by ECHA, as well as written procedures helped to facilitate the assessment work of the committees. These measures allowed the committees to focus on the most challenging topics during their meetings and to deliver high-quality outcomes and opinions with a sound scientific basis. Stakeholder observers continued to participate actively and contributed to the transparency of the committees' work.

Enforcement Forum

Spotlight on internet sales and extended safety data sheets

The Forum's work in 2018 focused mainly on practical enforcement projects, where inspectors in participating Member States applied similar methods to check compliance with particular REACH, CLP, PIC and BPR obligations. The Forum increased its output to 10 parallel projects, up from nine in 2017, contributing to coordinated and harmonised practices in enforcement and to 'levelling the playing field' for companies across the common market.

Main achievements

In 2018, most of the inspections carried out under the Forum's projects focused on compliance with duties aimed at protecting consumers. Under the REF-6 project, companies in 30 EU/EEA countries were inspected regarding the classification and labelling of mixtures. The Forum also ran a smaller pilot project involving 15 countries on substance in articles with a focus on consumer articles. To allow for more inspections to be carried out, the pilot project's operational phase was extended to the end of 2018. The reports for the REF-6 project and the pilot project will both be published in 2019.

Year in numbers

5
major REACH/Biocides enforcement projects

5
pilot projects

23
active working groups

3
plenary meetings

80
enforcement trainers trained

The Forum finalised and published the reports on three enforcement projects. The results of the REF-5 project on extended safety data sheets showed that while information on safe use flows in the supply chain, registrants need to improve the quality of information so workers will be better protected from chemical hazards.

The CLP pilot project on internet sales yielded particularly striking results. Inspectors found that in 83.3 % of cases checked, the advertisements of mixtures sold online lacked the required hazard information. To help ensure more adequate control of chemicals sold online, the Forum will embark on a dedicated REF-8 project in 2019.

The results of the Forum's first pilot project on PIC showed that while most exporters comply with PIC obligations, exporters should nevertheless be better aware that the safety information on labels or safety data sheets should accompany the exported substances.

The working groups of the Forum also developed manuals for a number of enforcement projects with inspections due to start in 2019. Foremost among these is the REF-7 project, where inspectors will inspect compliance with registration duties, including the duty to update dossiers after the last registration deadline. The Forum also prepared the first major project on the Biocidal Products Regulation (BEF-1) focusing on biocidal treated articles, which are commonly available to consumers.

Tthe Forum's work programme, which describes the strategic outlook for enforcement priorities and specific activities between 2019 and 2023, was also further developed..

Trainings and other means of harmonisation

In addition to coordinated projects, a number of other initiatives to harmonise enforcement were undertaken.

The annual training for trainers of inspectors focused on best practice in enforcing REACH registration duties. In addition, a special training to help biocides inspectors harmonise the control of obligations for treated articles took place for the first time.

As enforceability is a key aspect of any regulatory measure, the Forum continued to examine proposals for new REACH restriction entries and provided advice on their enforceability.

Inspectors continued to enforce ECHA's decisions, in particular those on dossier evaluation and revoking registrations. As ECHA's process for dossier evaluation is expected to change, cooperation on this matter between ECHA and enforcement authorities will be reviewed in 2019.

Inspectors were able to use a newly upgraded version of the Portal Dashboard for National Enforcement Authorities (PD-NEA) to access the data held by ECHA that they needed.

HelpNet and Security Officers' Network

Extra support for helpdesks and companies, and extended access to IT security

The HelpNet focused on providing enhanced support to the national REACH and CLP helpdesks so companies could meet their REACH 2018 registration obligations.

The Security Officers' Network extended the security model for accessing ECHA's databases to individual experts involved in the work of ECHA's committees (acting as members, rapporteurs or advisers). In the medium-term, more than 70 experts will benefit from such an extension.

Main achievements

To help national helpdesks provide support to companies, ECHA provided for constant information exchange through workshops, training on IT tools and monthly web conferences. The Agency gave the national helpdesks access to the REACH-IT training environment so they could advise potential registrants – many of them SMEs – on any basic enquiries about REACH-IT in their own languages.

Year in numbers

1
Steering Group meeting

3
topical regulatory workshops

1
Forum training for REACH HelpNet members

4
HelpNet updates published

6
web conferences for discussing hot topics

The HelpNet continued to make best use of the network's communication tools (HelpEx) and HelpNet meetings to achieve a common understanding and alignment on questions related to chemicals regulation. The work of the network helps provide harmonised support to companies around the world.

About half of the EU/EEA national REACH and CLP helpdesks actively collaborated with the European Agency for Safety and Health at Work on their healthy workplace campaigns in 2018.

Finally, the HelpNet welcomed Montenegro as a new observer, welcoming the Nature and Environmental Protection Agency (NEPA), which is responsible for implementing the law on chemicals and the law on biocidal products in Montenegro. This saw the network grow to comprise the national helpdesks of 31 EU/EEA countries, three candidate country observers, one third-country observer, and 10 industry observers.

infobox

SECURITY OFFICERS' NETWORK

The security officers in the Member State competent authorities considered the first year of implementing the reformed standard security requirements for accessing ECHA's databases remotely to be a success.

ECHA's reformed standard security requirements are a modern prevention strategy against information security threats. They take into account the way the Agency works, are better aligned for handling current security threats and are streamlined across different organisations and practices.

The requirements also take into greater account information security in terms of the 'human factor effect', or how employees of the Member State competent authorities behave in relation to protecting information assets.

Board of Appeal

Decisions clarifying key issues

In 2018, the Board of Appeal examined several key aspects of REACH. It clarified, for example, ECHA's powers to implement the 'one substance, one registration' principle, that ECHA can verify that dose-levels used in a test are appropriate for REACH purposes, and that ECHA can request information on polymers and on metabolites under certain circumstances. It also clarified a number of significant procedural issues.

Year in numbers

15
cases closed

27
cases filed

15-month average duration for handling cases

Main achievements

The Board of Appeal adopted 15 decisions in 2018. 27 new appeals were filed, and 32 cases were pending at the end of the year. On average, the cases closed in 2018 had lasted for 15 months.

'One substance, one registration' principle

The Board of Appeal clarified how ECHA should implement the 'one substance, one registration' principle in the context of registration. It held that registrants cannot be prevented from submitting registrations as part of a joint registration by relying on a complete opt-out. However, ECHA should ensure that opt-outs are not abused. To this end, ECHA must perform a completeness check, and should prioritise the opt-out dossier for a compliance check[19].

Powers of ECHA

Under the compliance check procedure, ECHA can verify that a submitted study was performed in accordance with the relevant testing guidelines so that it provides the information required by REACH. For example, if the dose-levels used in a pre-natal development toxicity study have been set low because the test was conducted for other reasons, that study may not satisfy the relevant information requirement for REACH purposes[20].

Moreover, ECHA's discretion when performing a compliance check is limited to verifying that information submitted by a registrant complies

"To say goodbye is to die a little. But I leave to my successor a mature, independent body, with a committed team which one can take pride in."

Mercedes Ortuño
Chairman of the Board of Appeal

19 A-011-2017, REACheck Solutions
20 A-006-2017, Climax Molybdenum.

with the applicable information requirements. If there is a data gap, the registrant must fill it by providing either a study or an acceptable adaptation[21].

Under the substance evaluation procedure, ECHA can require information on the polymers derived from a monomer when evaluating that monomer. However, it must demonstrably be possible for the registrants of the monomer to generate or obtain the information in question[22]. Similarly, ECHA can require a study purely to identify the metabolites of a substance[23].

Evaluation procedures

Regarding the choice between the substance evaluation and compliance check procedures, information that is standard information for a registration can, in some cases, be requested under substance evaluation. However, if it is not clear for which tonnage bands the information in question is standard information, ECHA cannot use the substance evaluation procedure. Registrants may otherwise have to share the cost of standard information that is not required for a registration in their own tonnage band[24].

With regard to the right to be heard during the substance evaluation procedure, the Board of Appeal found that registrants must be heard not only on the information on which a decision is based, but also on the information requirements that ECHA intends to impose and the reasons for them[25].

Data sharing

In two cases under the BPR, the Board of Appeal found that ECHA made an error when assessing whether a prospective applicant had made 'every effort'[26].

Check also:

- Infobox: A new mission and vision for ECHA
- Infobox: International activities

Management

Management

Preparing the Agency for the future

ECHA's new five-year strategic plan took its final shape, establishing the Agency's priorities and the goals that it wants to achieve by 2023. The strategic plan takes on the momentum from the appointment of a new Executive Director, as well as input from the Commission's REACH Review. Realigning ECHA's organisation around competencies serves the implementation of the strategic plan and allows work on chemicals to be integrated regardless of specific pieces of legislation, optimising how ECHA serves EU citizens and protects the environment.

Main achievements

Bjorn Hansen, ECHA's new Executive Director, started in the role in January 2018. Institutions, Member States and stakeholders can rely on him to continue building upon and developing solid relationships, practices and trustful communication streams that were created by his predecessor. The smooth transition paved the way forfinalising ECHA's new strategic plan and revising the organisational structure in the year of the last registration deadline.

Manufacturers and importers of chemicals, Member States and all other stakeholders now have clarity about ECHA's aims and priorities for the years to come. The new strategic plan provides a compass for the sustainable implementation of the EU chemicals legislation for the period from 2019 to 2023.

21 A-005-2016, Cheminova; A-006-2017, Climax Molybdenum.
22 A-006-2016, SI Group-UK and Others.
23 A-004-2017, 3v Sigma.
24 A-007-2017, Infineum UK; A-008-2017, SI Group-UK and Oxiris Chemicals.
25 A-009-2016, Symrise.
26 A-007-2016, Sharda Europe; A-014-2016, Solvay Solutions.

Collaboration between the Agency and interested parties in formulating the strategic priorities allowed different views to be considered, and helped bring about a coherent, mid-term approach for implementation from 2019 onwards. The approach is based on the valuable findings of the Commission's REACH Review, and acknowledges both the multi-annual financial framework and the uncertainties related to how the EU will develop further after the UK's withdrawal. The strategic plan is a tool that enables ECHA to contribute to achieving the UN's sustainable development goals. One key part of this work will be to ensure a higher rate of compliance with the legal requirements in the legislation implemented by ECHA, in particular in the dossiers received by the Agency.

Successful implementation of the strategic plan requires internal enablers. ECHA's new Executive Director has led the revision of the Agency's internal working structure. The reorganisation groups ECHA's work around competencies, preparing the Agency for implementing the strategic plan and work on new regulatory tasks in an integrated way.

In parallel, ECHA's Management Board reflected on how it can fulfil its role and mandate more effectively in the future by conducting a self-evaluation. This will help the Board to provide more targeted steer and guidance to the Agency so that it can deliver on its priorities. At the same time, this will directly address a recommendation from the Commission's REACH Review.

"The new strategic plan goes a long way in preparing ECHA for the future – which holds many challenges, such as the new EU Financial Framework and the UK leaving the Union."

Sharon McGuinness
Chair of the Management Board

Topics on chemicals remain important to the public. The Agency continued to reach out and provide information tailored to the needs of various audiences through social media, audio-visual communications and Chemicals in our life, ECHA's website for consumers. The strong growth throughout 2018 in the number of people following the Agency in social media, the traffic to the consumer website upon its launch, and response to the videos produced visibly shows the importance of bringing such information closer to our audiences through the channels they use.

The UK's withdrawal from the EU demanded actions from the management to address issues affecting a wide range of ECHA's activities and interest groups. To help industry, ECHA created a dedicated section[27] on its website for providing relevant assistance and advice for various scenarios that companies may face. As ECHA is an employer of UK citizens, the statutory situation of staff members from the UK also needed to be clarified.

In 2018, the Agency received 18 external complaints. It followed up on them with replies in accordance with its certified quality management system.

infobox

A NEW MISSION AND VISION FOR ECHA

As part of the development of ECHA's new strategic plan, the review of the mission and vision as core and easy-to-grasp headers was straightforward. They are transparent about ECHA's current role and where the Agency wants to go in the future:

Mission – We, together with our partners, work for the safe use of chemicals.

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.

27 https://echa.europa.eu/uk-withdrawal-from-the-eu

infobox

INTERNATIONAL ACTIVITIES

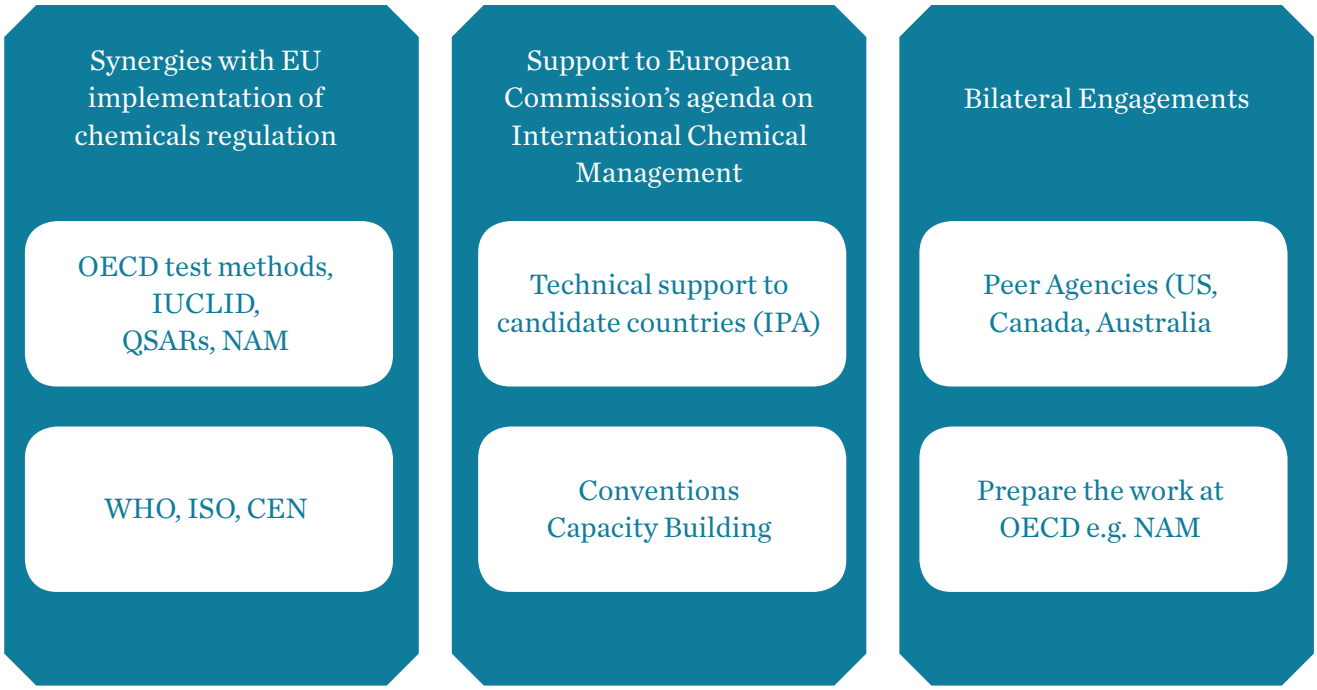
The EU's chemicals legislation remains the most ambitious and advanced in the world for safeguarding human health and the environment from potential negative effects of using chemicals. Its implementation is the EU's commitment to meeting the World Summit on Sustainable Development 2020 goals.

In 2018, ECHA reassessed some of its international commitments and priorities to further enhance their impact. ECHA's contribution to the international progress on the sound management of chemicals is partly implicit through its role in REACH and CLP implementation and partly explicit in its activities with third countries and international organisations. The core of ECHA's international activities continued to be the various contributions to the OECD Chemicals Programme, and to the implementation of the Rotterdam and Stockholm Conventions. As mentioned in the REACH Review, the influence that REACH has on chemical regulations in third countries highlights ECHA's role as a 'European and global reference centre for sustainable management of chemicals.'

Together with the European Commission, ECHA will further develop its international work, particularly in relation to strengthening support for capacity building. As a first step, ECHA has changed its approach to supporting candidate and potential candidate countries to the EU. By developing increasingly targeted actions following in-depth assessments of the capacity and readiness of the candidate countries, the Agency also strives to increase the usefulness and impact of the support.

ECHA international activities are covered by an exchange of letters between the Commission and the Agency.

FIGURE 2: ECHA's international activities



Resources

Financial resources

Handling the challenge of a mixed financing regime

ECHA financed its expenditure through a combination of EU subsidy and fee income. In 2018, accurately anticipating fee revenue from the REACH registration deadline and from incoming biocides applications was particularly challenging. ECHA closely monitored and adjusted the budget throughout the year, while maintaining high standards of financial governance.

Main achievements

ECHA is unique among decentralised EU agencies, as it manages three separate budgets – REACH/CLP, BPR and PIC/POPs – for the different chemicals regulations. In 2018, there was more fee income under REACH/CLP than expected, and less-than-foreseen fee income under the BPR. Due to the requirement to separately manage the budgets, ECHA was not able to offset these divergent outcomes.

Owing to the last REACH registration deadline, the associated fee income was exceptionally high. This allowed ECHA to reduce its EU subsidy claim for the REACH/CLP budget by 20 % (EUR 6 million). However, under the BPR, lower than expected fee revenue forced the Agency to cut expenditure throughout the year and to request an extra EU contribution of EUR 2.65 million to cover the shortfall.

Check also:

- Human resources
- Corporate services

Year in numbers

EUR: **81.6 m**
in REACH/CLP fees

EUR: **6.4 m**
in BPR fees

EUR: **117 m**
total budget spent

414
SME size checks under REACH

20
SME size checks under the BPR

Financial governance

The European Court of Auditors issued a positive audit statement confirming the reliability of the Agency's accounts and the legality and regularity of the transactions underlying the accounts. In addition, the Agency was able to meet all its financial targets for all of its regulations by closely monitoring income and expenditure developments and actively adjusting its budget to respond to unpredicted income variances.

To avoid disruption in budget planning and implementation arising from unpredicted variations in fee income, the Agency is of the view that a new financing model could be considered. The model could be one where the Agency would either be permitted to establish a time-limited reserve fund or would receive a fixed annual EU subsidy, covering all regulations implemented by the Agency, with the fee income collected being transferred to the Commission.

The Agency also continued to improve the efficiency of its financial operations by introducing a new budgeting tool, upgrading its financial information management systems and further digitising its financial workflows.

Financing details

ECHA's total fee income amounted to c. EUR 88 million, of which EUR 81.6 million came from REACH fees and charges and EUR 6.4 million from the BPR. The Agency's total budget spent was EUR 117 million, compared to EUR 109 million in 2017. ECHA's own income covered 75 % of its expenditure in 2018.

The total revenue under REACH/CLP, including the EU subsidy, was EUR 108.4 million. Based on the positive annual financial result, EUR 3.1 million will be returned to the Commission. Income from fees and charges rose from EUR

34 million in 2017 to EUR 81.6 million due to the 2018 registration deadline. The majority of the fee income came from the registration of substances manufactured or imported in volumes below 100 tonnes per year.

Under the BPR, the total revenue, including the EU subsidy, was EUR 11.5 million. This sum included a biocidal fee revenue of EUR 6.4 million, which is 22 % lower than in 2017 and 33 % lower than initially budgeted for 2018, mainly as a result of the shortfall in applications for Union authorisation. The BPR budget was balanced with an expenditure cuto f about EUR 0.9 million and an extra EU contribution of EUR 2.65 million.

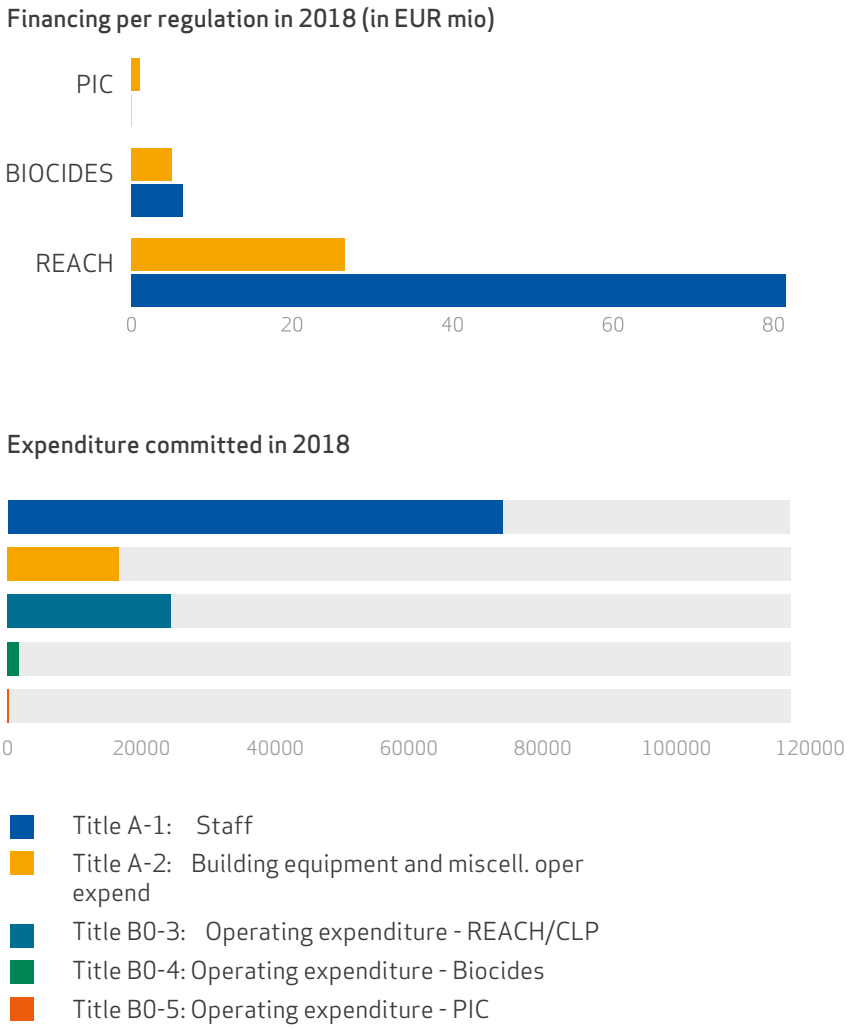
ECHA also received a EUR 1.1 million contribution from the EU for the PIC Regulation.

ECHA's financing exceeded the targets for its commitment and payment rates, with 99 % (95 % target) and 86 % (80 % target) achieved respectively.

SME status checks

The Agency continued to systematically verify the status of companies that registered as SMEs and benefited from SME fee reductions. Of the 414 companies checked, 32 % had their status changed. This identification of wrongly-declared company sizes brought in an additional EUR 2.8 million in fee corrections and administrative charges. In addition, ECHA completed an ex-ante verification of company size for 20 companies under the BPR.

FIGURE 3: Financing per regulation and expenditure committed in 2018



Human resources

Committed people working to help us achieve our goals

Throughout 2018, human resources contributed to maintaining the necessary number of motivated and skilled staff, forming a balanced learning and development plan that combined directorate, unit and individual learning needs. The turnover rate of statutory staff remained very low. All available establishment plan posts were filled, and successful staffing for the 2018 registration deadline was carried out. ECHA's human resources strategy was also established to guide the long-term direction of human resources development.

Main achievements

The recruitment target was achieved with 97 % of posts filled at the end of the year for REACH/CLP, PIC and the BPR – although the cumulative rate was 99 % throughout the year. The higher vacancy rate towards the end of 2018 was due to the Agency's ongoing reorganisation that entered into force on 1 January 2018, allowing more flexibility for human resources. This result is in line with the 2018 establishment plan – that is, six fewer posts to comply with overall staff reductions of 2% – as communicated by the Commission in its 2013 communication on programming of human and financial resources for decentralised agencies for 2014-2020. At the end of 2018, ECHA's turnover rate was 1.3% for temporary agents and 3.3% for contract agents.

Year in numbers

566
staff

97%
of establishment plan posts filled by year-end

99%
of establishment plan posts filled cumulatively throughout the year

1.3%
temporary agent turnover

3.3%
contract agent turnover

For the 2018 registration deadline, human resources played a crucial role in managing the resource needs for staffing the Agency. Posts were filled by short-term contract agents, trainees and interims to ensure that appropriate staff were in place to handle the deadline successfully.

During the latter half of 2018, major input was placed into planning, and preparing for, the Agency's reorganisation. A significant amount of work was carried out in staff allocation – through reallocating tasks, posts and staff – in accordance with the new organisational design. This design aims to be the most optimal structure for the Agency, facilitating the achievement of ECHA's strategic objectives.

On staff well-being, ECHA organised a workshop for practicing collaborative discussions which will support managers and team leaders to maintain a culture of early support while, in May 2018, ECHA launched a specific website on resilience and stress management to prepare staff before the peak workload of the 2018 registration deadline. Negotiations for a memorandum with Helsinki-Uusimaa Hospital District (HUS) were finalised in December 2018 to ensure equal treatment for ECHA staff in terms of entrance to, and pricing of, public healthcare.

In 2018, ECHA increased teleworking possibilities for staff as a further step in developing the Agency's agenda on modern ways of working. This enables staff to plan their working days more independently and allows them to be managed based on deliverables, rather than physical presence in the building. The first review of the new teleworking policy showed a high level of acceptance and delivered positive feedback from both staff members and managers.

Additionally, the efficiency of the HR portal was further developed to integrate additional HR procedures into a single IT tool in a user-friendly manner.

The proposed withdrawal of the UK from the European Union will also impact the Agency's human resources in that British staff members would no longer be eligible to work for ECHA. To prepare the Agency for the challenges related to Brexit, HR designed a process to assess and, ultimately, decide on applications for an exceptional continuation of employment of British staff members when the UK has left the EU.

Corporate services

A successful and challenging year during which high customer service delivery was maintained

The demands of a challenging year were met with increased activity in many areas of work. A significant organisational achievement was the key role thatCorporate Services played in implementing initiatives related to the project on ECHA's future building for 2020, including monitoring of its implementation. The unit ensured that staff were consulted on the new office layout, liaised and managed contracts with the developer, managed inherent building project risks, and cooperated with City of Helsinki staff on matters concerning the area surrounding ECHA's future building.

Year in numbers

9 285
external participants

16 800
virtual meetings

1 446
meetings with audiovisual support

Main achievements

Following the signing of the lease contract for ECHA's new premises in December 2017, the Corporate Services unit was heavily involved in the monitoring of the construction phase of the future building. This will help to ensure that ECHA receives a building that is compliant with the contractual and technical requirements while, simultaneously, closely monitoring the construction progress to ensure that the building will be delivered on time. In addition, the unit managed the budget for the future building efficiently and effectively, with the building due to be delivered in December 2019.

During 2018, Corporate Services, supported by Human Resources, carried out a workplace allocation exercise to identifyoffice layout requirements, by directorate, for its future building. ECHA attended several meetings with the City of Helsinki to discuss the development of the area surrounding the premises, among other things sharing and striving for the inclusion of ECHA-specific needs in the City's planning. Several procurements were initiated during 2018, including some additional procurements related to the fit-out of the new premises, which will take place during 2019.

In 2018, there were 9 285 visits from external participants to ECHA's conference and meeting facilities, a decrease of 7.5 % from 2017. 16 800 virtual connections to meetings or webinars were supported, representing an increase of 158 % compared to 2015 figures. During 2018, the audio-visual team supported 1 446 meetings and events. This was 20 % less than in 2017, which was exceptionally an busy year largely due to the REACH registration deadline preparations. The flexibility required to efficiently support meetings led ECHA to look into and, from December 2018, to partially outsource the audiovisual support and maintenance.

Finally, the annual budget under the responsibility of Corporate Services, EUR 10.4 million, was executed efficiently and effectively and all financial targets were exceeded for the year.

Risks to the Agency

ECHA conducts an annual risk assessment exercise to identify, assess and manage the potential events that could put the achievement of the objectives defined in the annual work programme at risk.

An annual risk management exercise was conducted in 2017 to identify, assess and manage potential events that could put the achievement of the objectives defined in the annual Work Programme 2018 at risk. The exercise is an integral part of preparations for the work programme). Senior management followed up the implementation and reviewed the effectiveness of the risk mitigation measures regularly during 2018. All risks were strictly monitored throughout the year to determine whether the triggers of their likelihood and impact have increased or decreased.

Based on the assessment, senior management identified eight main risks which were included in the corporate risk register. Senior management also agreed that three of these risks should be reduced through specific actions that were described in the action plan for the risk register, two should be accepted provided that they are due to external factors that ECHA has no or limited influence on, one should be avoided by changing the objectives of the work programme and one (carried over from previous years) should be shared with third parties.

The risk that the directors ranked the highest at the time of the initial risk assessment referred to insufficient fee income due to lower-than-foreseen BPR applications for active substances and Union authorisation. This risk materialised in 2018 and the shortfall of BPR fee income resulted in a request to the Commission to provide an additional EU balancing subsidy of EUR 2.65 million in total, through the appropriate tools of the amending budgets of September and December 2018.

Another risk with high impact which also materialised at the end of December 2018 was related to achieving the Biocides Review Programme target of 50 opinions per year. Even though ECHA has undertaken mitigating actions in the last three years, such as creating guiding templates, supporting the quality of assessment reports and using scenario planning to respond to different market situations, the target was not met in three consecutive years – 24 out of 50 opinions were adopted in 2018, 31 in 2017 and 41 in 2016).

In previous years, this was mainly due to the postponement of a number of deliverables by Member State competent authorities. In 2018, a new requirement to include endocrine-disrupting properties in the opinions of the Biocidal Products Committee according to the new endocrine disruptor criteria was introduced, further delaying the approval process.

The risk related to absorbing new tasks was tackled by changing the work programme objectives and by using scenario planning with different resource simulations to avoid a negative impact on the achievement of the objectives. Internal re-allocation of resources has helped to absorb some tasks under poison centres and the Waste Framework Directive. To be able to fully take these tasks,as well as tasks on occupational exposure limits and persistent organic pollutants, on board, further resources will be needed in future years and, in this respect, negotiations with the Commission are ongoing.

All the other risks did not impact the execution of the 2018 Work Programme and some of these will continue to be relevant in the future. The risk with regard to the lack of a financial balancing mechanism, present in previous years as well, did not materialise in 2018. Due to the higher than foreseen income received in 2018 – a surplus of EUR 1.3 million – ECHA was able to cover its expenditure. This risk, however, remains high for the coming years and, to mitigate it, ECHA has engaged external expert support to assist in improving its fee-related forecasting for future years.

The risk related to the smooth processing of registration dossiers for the 2018 deadline was properly managed throughout the year through scenario planning and appropriate adjustments to interim resources in accordance with the incoming number of dossiers. The scenario of an overall lower number of registrations, with a higher income level, was confirmed and, thus, the level of interim support was reduced accordingly.

The risk with regard to the lower uptake and thus the return on the investment in the cloud services during the preparations for the 2018 deadline and beyond has been investigated in depth. An ex-post evaluation of the cloud services and their added value, including a detailed comparison with the downloadable IUCLID version was performed in 2018, with the results submitted to the Management Board in December.

The risk related to a lower than planned number of compliance check and testing proposal draft decisions due to the increased complexity and time required to address groups and categories did not materialise in 2018, mostly due to the preventive measures taken to improve process efficiency and resource re-allocation.

APPENDICES

Appendix 1 – Achievements of Work Programme 2018 by activity

1.1.1 Registration dossier preparation

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Carry out the final phase of ECHA's REACH 2018 roadmap for the last registration deadline of phase-in substances, and specifically:		
Continue coordinated communication activities via various networks (such as the REACH Communicators' network), and using multiple communication channels (online, audio-visual, documentation, events and social media) in order to remind chemical companies of their REACH obligations and orient late comers towards the relevant support.	Yes	
Publish the last phase of the Roadmap ('Keep your registration dossier up-to-date').	Yes	
Support companies in fulfilling their registration obligations for the 2018 registration deadline, and specifically:		
Support national helpdesks with ad hoc training and information sharing so that they can support registrants in their own language, as well as participation in national events to provide training to companies on registration.	Yes	
Reply to an increasing number of regulatory questions from registrants in relation to the registration deadline. The topics will be on registration obligations (tonnage band calculation, possible exemptions); data and cost sharing, and joint submission obligations. In the final months before the deadline, ECHA may contact the registrants by phone, as done in 2010 and 2013.	Yes	
Tackle unexpected generic issues of broad impact in a coordinated manner by means of the Directors' Contact Group (DCG).	Yes	
Continue the progressive maintenance of IUCLID 6 and CHESAR, the IT tools necessary for the 2018 registrants, including support and training to users.	Yes	
Provide cloud services to SMEs to enable them to manage their data and prepare their IUCLID dossiers directly online on an ECHA hosted and supported platform so that they can focus their resources on data requirements matters rather than IT tools management.	Yes	
Promote the implementation of the CSR/ES Roadmap products, particularly the uptake of use maps as an input to the new registration dossiers and updates, and make them available to their users in user- and reader-friendly formats, as part of ECHA's downstream user communications strategy.	Yes	
Cooperate with industry sectors on continuous improvement of registration dossiers.	Yes	

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
SIEF management:		
Manage the expected high number of data-sharing disputes arising from the reinforcement of the "one substance, one registration" (OSOR) principle in REACH-IT to ensure that SIEF members can get access to the joint submission, and provide support and advice in this context.	Yes	
As the obligation to inquire also continues after the registration deadline, process the expected high number of inquiries, and thus provide swift access to the market for companies.	Yes	
Continue promoting appropriate use of alternative methods to animal testing by:		
Promote the QSAR Assessment Framework (QAF) and Read-Across Assessment Framework (RAAF).	Yes	
Continue to promote the QSAR Toolbox and support users by organising training and providing additional materials.	Yes	
Communicate on the outcome of the report on alternatives to animal testing and recommendations to registrants.	Yes	
Carry out a review of ECHA's guidance for nanomaterials to adapt it to the revised REACH annexes.	No	Following the Commission's proposal to amend the REACH annexes for nanoforms of substances, ECHA assessed the need to update or generate new guidance. It is expected that the new or updated guidance will be made available at the time of the amendments entering into application, January 2020. However, the timeline is dependent on the formal adoption of the Commission proposal as well as the progress of the Malta project, which aims to revise the necessary OECD Test Methods and Guidance Document for nanomaterials.
Prepare a vision on how to deliver services and tools to companies after the last registration deadline.	No	This was postponed to 2019 due to other priorities both in ECHA and industry. However, some meetings with key stakeholders were organised to get input for developing the vision.

1.1.2 Registration and dossier submission

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Manage successfully the registration deadline of 31 May 2018:		
Monitor, in cooperation with the stakeholders, the overall progress of REACH 2018 registrations.	Yes	
Process efficiently a high number of registrations within the legal timeframes.	Yes	
Perform completeness checks of the dossiers received, including a manual check where necessary, and provide advice as needed on how to complete the dossier.	Yes	

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Support registrants who need specific support with their registration dossier submission including proactive contacts as necessary and feasible.	Yes	
Deploy resources as needed – including flexible redeployment and on-boarding of new interim staff – to react promptly to any potential issues that might endanger the registration.	Yes	
Initiate a significant number of confidentiality assessments with the purpose of concluding on all confidentiality requests present in 2018 registrations during 2020.	Yes	
As part of implementation of ECHA's regulatory strategy, and depending on the resources needed to handle the peak of registrations:		
Continue to carry out retrospective completeness checks of registration dossiers submitted before the entry into force of the enhanced completeness check in June 2016, to ensure a level playing field among registrants and to ensure the availability of key information in the registration database as input for subsequent regulatory processes and dissemination.	No	The retrospective completeness check was not carried out this year due to the high processing needs stemming from the deadline. Work was done to prepare a strategy on how to perform retrospective checks in the future in line with ECHA's new strategy. This will be discussed in 2019.
Continue to stimulate dossier updates through the publication of the list of substances to be potentially addressed under compliance check, targeted letter campaigns e.g. to inform registrants that their dossiers may be targeted for dossier evaluation, verification of the intermediate status of substances of very high concern, and other measures so that the quality of registration information is further enhanced.	Yes	
Prepare and decide on the initiation of Forum pilot projects on enforcement of registration obligations.	Yes	
Further develop capacity to enhance the quality of substance identifiers used in the database e.g. to identify and remove duplicates for registrations submitted using different substance identifiers for the same substance, while promoting the consistency of substance sameness within joint registrations in general.	Yes	
Analyse inquiries, new registrations and PPORDs with the aim to track substitution, renewables and recycled or recovered materials with a view to provide information relevant to policies on circular economy and the non-toxic environment.	Partly	New registrations, inquiries and PPORDs are screened on a regular basis. Workload considerations related to the registration deadline caused the thorough analysis and reporting to be postponed.

1.1.3 Evaluation

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Perform a preliminary assessment on a broad number of substances to define which should be shortlisted for regulatory actions and which are of lower priority, thus 'mapping the universe of chemicals'.	Yes	

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
As part of implementing ECHA's regulatory strategy and in coordination with other activities, continue compliance checks addressing relevant higher tier hazard endpoints for substances of potential concern over 1 000-tonne dossiers and 100-1 000-tonne dossiers. The selection of dossiers for compliance check will continue to be based on the common screening that also serves substance evaluation and regulatory risk management.	Yes	
With the aim to accelerate closing data gaps on priority substances and endpoints, and building on the experience gained in 2017, continue addressing selected groups of priority substances using read-across or grouping approaches also through other means than compliance check, including informal interaction with registrants or sector groups and working in collaboration with Member State competent authorities.	Yes	
Establish a plan for compliance checks for 2019-2020 in view of the WSSD 2020 target to understand for which (high volume) substances more hazard data are still needed to clarify their potential concern.	Partly	Work is ongoing.
Continue providing improved visibility to the content and outcome of compliance checks through the dissemination platform and the annual evaluation report with recommendations to registrants.	Yes	
Examine any testing proposals within the set legal deadlines, giving priority to non-phase-in testing proposals and to the resubmitted 2010 testing proposals for reproduction toxicity.	Yes	
Plan the examination of testing proposals included in the registration dossiers from the 2018 deadline.	Yes	
Examine any information submitted in consequence of ECHA's dossier evaluation decisions and communicate to the Commission and Member States the information obtained and any conclusions made as well as inform the concerned national authorities in case no or insufficient information is submitted. Where appropriate, draft follow-up decisions. Ensure that the information obtained and any conclusions made are fed back into screening and regulatory risk management processes.	Yes	
Ensure, together with Member States, that substance evaluation contributes in an effective and efficient manner to the implementation of the integrated regulatory strategy and supports the regulatory risk management processes. This entails the effective interplay with dossier evaluation and risk management processes in the annual CoRAP updating and ECHA's seamless coordination of and support to substance evaluation decision-making and conclusion.	Yes	
Provide useful regulatory advice to registrants and other interested parties on information requirements, and dossier and substance evaluation processes.	Yes	

1.1.4 Communication of risk management advice through the supply chain

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Improved knowledge on what kind of information and in what format downstream users at the end of the supply chain would need from suppliers, taking into account different national requirements.	Yes	
Have further developed tools and templates to support formulators to process exposure scenarios into meaningful information for their customers, including SMEs.	Yes	
Operators have increasingly meaningful information from the exposure scenarios (and thus extended SDS) so that they can generate site-specific information (e.g. work place instruction cards) to ensure health of their workers.	Yes	
Through collaboration with the US Occupational Safety and Health Administration (OSHA), have the "Healthy Work Place campaign 2018-19" on hazardous substances contributing to the improved chemicals management in the EU and creating synergies between the implementation of OSH requirements and REACH requirements.	Yes	
Provide useful regulatory advice to stakeholders in relation to communication in the supply chain, downstream users, safety data sheets and exposure scenario, amongst other.	Yes	
Make the products emanating from the work of the ENES in accordance with the CSR/ES Roadmap publicly available to their users, in particular to small and medium-sized companies, in user- and reader-friendly formats, in line with ECHA's downstream user communications strategy.	Yes	
Report from the Forum's fifth coordinated enforcement project on extended safety data sheets (REF-5).	Yes	

1.2.1 Identifying needs for Regulatory Risk Management

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Adapt the common screening to allow the newly registered substances to be directed to the relevant REACH and CLP processes. The new registration data will be used to complete the picture of the chemicals universe. Grouping of substances at the screening phase will be used to allow more holistic and effective assessment and processing of substances that matter throughout the regulatory steps.	Yes	

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
The identification of the needs for the regulatory risk management will make full use of the further information generated by compliance check and substance evaluation. This is enhanced by further aligning the screening, regulatory management option analysis (RMOA) and evaluation processes. Integration of the risk management thinking to screening and evaluation processes will help optimise the number and sequence of the regulatory steps. Early RMOA is also used to increase transparency of foreseen regulatory actions as well as conclusions to not take further action.	Yes	
Continue coordinating and providing support to Member States in preparing RMOAs and develop them upon request by the Commission.	Yes	
The endocrine disruptor identification guidance developed in 2017 to support the use of the ED criteria is foreseen to accelerate the informal assessment process. Therefore, the ED Expert Group will need to increase its capacity to support this phase. ECHA will also continue to address more detailed guidance needs identified during the work done in 2017.	Yes	
PBT assessment work is stable and supported by the guidance updated in 2017 and the new insights on how to use a wide range of (eco)toxicological information.	Yes	
REACH data and compliance with REACH obligations can significantly contribute to the implementation of the circular economy. To this end, and depending on availability of additional resources, ECHA will continue to develop article service-life exposure assessment approaches and to support industry in improving service-life parts of their chemical safety assessment or exposure scenarios. Furthermore, together with the Commission, ECHA will explore how to improve interfaces between REACH and other legislation to support the circular economy and non-toxic environment objectives.	Partly	Due to no additional resources being available, the plastic additives project included some further work on how to assess the release potential during the service life. ECHA did not carry other work to develop article service-life exposure assessment approaches and to support industry in improving service-life parts of their chemical safety assessments or exposure scenarios. However, ECHA started to invest resources for ensuring interfaces between REACH and other legislation and, in particular, to support the circular economy and non-toxic environment objectives by reallocating its resources to the new task under the Waste Framework Directive. ECHA also took an active role in the first steps of the ongoing revision of the BREF document for the textile industry under the Industrial Emissions Directive, as well as in some EU Ecolabel-related activities.
The fourth SVHC Roadmap Progress Report (March 2018) will include a review of the implementation. The outcome of the review will be used to adapt the work during 2018-2020, where necessary, as well as to initiate discussion on the concrete follow up after 2020.	Yes	

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Based on the review carried out in 2017, the necessary changes to the coordination and cooperation structure will be implemented. Maintain high level of efforts for cooperation and coordination with all authorities of the work on SVHC Roadmap implementation and beyond.	Yes	
Continue to have up-to-date information on ECHA's website on screening and assessments providing industry better predictability on which substances will be under authorities' attention and consequently more time to plan for substitution and improving safety.	Yes	

1.2.2 Authorisation

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Process a potentially increasing number of SVHC dossiers that more often relate to PBTs, EDs or other substances of equivalent concern and hence require specific effort and involvement from the respective expert groups and from the MSC.	Yes	
Provide a well-founded Annex XIV recommendation, which takes into account the effectiveness of the whole authorisation process.	Yes	
Available approaches to identify and address concerns related to the presence of substances in articles are not as developed as those related to substances on their own and in mixtures. Furthermore, the implementation of the circular economy and toxic-free environment targets require better information, enhanced communication and further regulatory measures on substances in articles. To bridge these gaps in the knowledge and methods, ECHA continues, together with the Commission, Member States and stakeholders i) to develop the exposure assessment methods of substances in articles during their service-life and waste stage, ii) to explore effective ways to identify the relevant substances, in particular, in the imported articles, iii) to investigate how to support the development and wider implementation of communication tools and, iv) where needed, to trigger relevant regulatory actions.	Partly	Due to resources constraints and other priorities, ECHA did not continue to: - develop the exposure assessment methods of substances in articles during their service-life and waste stage, except indirectly through the plastic additives project; - explore effective ways to identify the relevant substances, in particular, in the imported articles; - investigate how to support the development and wider implementation of communication tools, where needed; and - trigger relevant regulatory actions.
Continue to raise awareness on the obligation for industry to communicate in the supply chains on the presence of SVHCs in articles and the need to notify information to ECHA.	Partly	Apart from the biannual generic reminders of the duty to notify information according to Article 7(2) REACH, ECHA did not initiate any specific awareness raising action, in particular due to the reallocation of all resources – including from communications – to the Waste Framework Directive project.

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
RAC and SEAC will evaluate and issue opinions on the first Review Reports. This experience will allow ECHA to establish whether the "bottom-up" communication between downstream users and authorisation holders about the authorised use of SVHCs has been useful. Based on this experience, ECHA will take corrective action, as necessary.	Yes	
Continue to provide timely support to applicants and authorisation holders through pre-submission information sessions, possible new versions of the Practical Guide, updated application formats, "reference" DNELs and dose-response relationships of substances.	Yes	
Support the rapporteurs and the committees in preparing opinions of "fit-for-purpose" sufficient quality and consistency to meet the expectations of the Commission, Member States and stakeholders.	Yes	
Continue to support the Commission during the decision making of authorisations, to support and learn from the national enforcement authorities in the enforcement of the granted authorisations.	Yes	
Continue to improve and adapt the communication through its web to facilitate preparing and processing "fit-for-purpose" applications for authorisation, especially for the preparation of initial authorisations.	Yes	
Implementation of ECHA's strategy on how to increase the capacity of Member States and industry to carry out analyses of the available information on alternatives and consequent successful substitution of hazardous substances. This is likely to comprise of the establishment of a network among Member States on analysis of alternatives and substitution.	Yes	
Develop further the analysis of alternatives activities under the Network of REACH SEA and Analysis of Alternatives Practitioners (NeRSAP) and hold one or two meetings to improve the knowledge and skills of European applied economists, providing industry analysis on applications for authorisation or regulatory settings for restrictions.	Yes	
Continue to provide timely support to ECHA's scientific committees through notes on methodological questions, including socio-economic issues.	Yes	
Prepare a report from the Forum pilot project on substances in articles.	No	The operational phase of the pilot project was extended for six months (until the end of 2018); the report will be prepared in 2019. However, the ECHA Secretariat kept on providing support to the implementation of the pilot project at different stages in 2018.
Perform the tasks allocated to ECHA based on the revised Directive 2008/98/EC by starting to prepare the development of a database and submission tool allowing EU suppliers to provide information to the database and providing database access to waste treatment operators as well as consumers.	Yes	

1.2.3 Restrictions

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Provide support to the Member States during their preparation of restriction dossiers, e.g. in pre-restriction information meetings, restriction workshop with Member States and other mechanisms.	Yes	
Support further development of methodologies for risk to impact assessment work (including estimations related to humans via environment) and work on improved guidance for Member States and committees on analysis of alternatives.	Yes	
Further develop and implement a capacity building programme for Member States and members of the RAC/SEAC on regulatory impact assessment, in particular on methods used in socio-economic analysis.	Yes	
Continue improving the efficiency and effectiveness of the restriction process through implementation of the Restriction Efficiency Task Force recommendations, monitoring of efficiency and identification of potential new recommendations.	Yes	
Support the Commission, stakeholders and enforcement authorities to clarify the existing restriction entries by developing Q&As.	Yes	
Further develop methodologies related to socio-economic analysis, in particular in the context of the OECD. This comprises both the valuation of health and environmental endpoints and learning lessons from regulatory risk management cases in different OECD member countries.	Yes	
Review any lessons learnt from the Forum's fourth coordinated enforcement project on restrictions (REF-4) and integrate any resulting advice in the relevant guidance (e.g. Annex XV reporting format).	Yes	

1.2.4 Classification and labelling

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Process an increasing number of incoming harmonised classification and labelling (CLH) dossiers resulting from the joint Commission, EFSA and ECHA efforts to encourage timely submission of dossiers for pesticides. Furthermore, the increased integration of CLH to REACH work, in particular, for common screening and evaluation processes, will result in more proposals on industrial chemicals.	Yes	

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Continue working together with the Commission and EFSA to reduce the overlapping work for plant protection products, biocidal products and harmonised classification and labelling processes in Member State competent authorities, committees and agencies. This will include support to the use of integrated assessment templates to reduce the workload of dossier submitters, increase efficiency of the processes as well as clarity of the outcome.	Yes	
Update the CLP guidance, as necessary, to reflect changes in information requirements as well as guidance updates for other purposes. Guidance and templates developed to apply weight of evidence, including read across, will be in use for CLH to improve the quality of the CLH dossiers.	Yes	
Continue monitoring the convergence of self-classifications; where appropriate take focused actions encouraging industry to agree on classifications and update notifications accordingly. 2018 registrations will be used to reduce the obsolete notifications related to those substances.	Yes	
Provide scientific and technical support to the European Commission in the context of the further development of the United Nations Global Harmonised System of classification and labelling of chemicals (UNGHS).	Yes	
Provide useful regulatory advice on self and harmonised classification, labelling and packaging, including the request for alternative names and interaction with safety data sheets obligations, including the work of selected GHS working groups, notably the working group on the use of non-animal testing methods for classification	Yes	
Organise regular workshops on CLP for HelpNet correspondents and observers, keeping them up to date on regulatory developments and agreeing on common understanding on issues raised by notifiers and other stakeholders.	Yes	
Further develop tools and support to facilitate data provision by companies to be used by national Poison Centres under Art 45 of the CLP Regulation:		
Finalise, maintain and host the poison centres' notification format and editor, the unique formula identifier (UFI) generator and the product categorisation system in response to feedback from stakeholders.	Yes	
Start the development of the notification portal, to enable participating Member States to receive notifications from industry in the new format and facilitate company notifications to multiple countries simultaneously.	Yes	
Provide advice and support to companies to enable them to prepare for the submission deadline of 1 January 2020.	Yes	
Carry out the Forum project on CLP (REF-6).	Yes	
Prepare a report from the Forum pilot project on CLP internet sales.	Yes	

1.3 Biocides

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Support the Member State competent authorities to prepare BPC opinions on active substances.	Yes	
Support the Member State competent authorities for the preparation of BPC opinions on Union authorisation of biocidal products with a special emphasis on the efficiency of the opinion forming process and the coordination between Member State competent authorities dealing with related applications.	Yes	
Start the identification of potential endocrine disruptors among the approved biocidal active substances, ensuring coordination with EFSA for substances that are also approved for use in plant protection products.	Yes	
Organise a workshop with competent authorities to evaluate the impact of the measures put in place in 2015 to increase the efficiency of the active substance approval process and the Review Programme and consider further measures.	No	The workshop will be held on 12-13 February 2019, with the participation of Member States, DG SANTE and accredited stakeholder organisations. ECHA has prepared the workshop programme in collaboration with some Member States in the light of the outcome of the meeting with DG SANTE and of the indications from the Member States.
Further develop the Register for Biocidal Products (R4BP 3) and the SPC editor.	Yes	
Publish updates to the Guidance on the Biocidal Products Regulation.	Yes	
Based on a vision for EUSES developed in 2017, ECHA will further work on the technical requirements with the aim to initiate IT development in 2018.	Yes	
Support exchange of information and coordination between the BPR enforcement authorities through the activities of the Forum BPR subgroup. In particular, execute a BPR-related module of Forum's coordinated enforcement project on CLP (REF-6) and prepare the next enforcement project on the BPR.	Yes	
Further develop the dissemination of information in relation to the BPR, in particular on the authorisation of biocidal products.	Yes	
Organise one workshop on the BPR for HelpNet correspondents and observers, keeping them up-to-date on regulatory developments and agreeing on a common understanding on issues raised by registrants, notifiers and other stakeholders.	Yes	

1.4 Prior Informed Consent (PIC)

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Process a continuously increasing number of notifications (25 % vs 12 % estimated increase on a yearly basis) and related tasks.	Yes	

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Produce and publish the annual report on PIC exports and imports.	Yes	
Support the Commission in establishing which chemicals to propose for inclusion in the PIC Regulation and which to notify to the Rotterdam Convention Secretariat.	No	There was no request from the Commission in 2018.

1.5 Data management and dissemination

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Extend the dissemination portal to cover additional information on authorisation of biocidal products.	Yes	
Publish registration information from the 2018 deadline for maximising public availability of information on chemicals.	Yes	
Further integration of ECHA's regulatory activities in the disseminated information, including the display of the lifecycle of evaluation decisions.	Yes	
Start the implementation of a major upgrade of the Business Intelligence Data Integration (BIDI) platform to address in particular: change of end-of-life technology; improvement of master data management of the Regulatory Master List of Substances.	Yes	
Progress in the development of a reporting system in support of the integrated regulatory strategy, in particular for mapping the chemical universe and informing which substances are of potential concern and for which a regulatory action is ongoing or planned or, alternatively, which substances can be considered as low priority for further work.	Yes	
Provide useful regulatory advice to registrants, academia, public institutions and other interested parties on what and how data is disseminated by ECHA, including its use and validity.	Yes	
Complete the piloting phase of ECHA Interact with RAC and SEAC members, and gradually deliver new collaboration features and ways of working with ECHA stakeholders.	Yes	

1.6.1 EU Observatory for Nanomaterials

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Publish the second phase of the observatory website with enhanced content (updated information on nanomaterials on the EU market, further information on products and articles where nanomaterials are present, and wider information on relevant research activities).	Yes	

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Complete first IT analysis on available databases, and based on its outcome initiate relevant development project(s).	Yes	
Start preparations for the third phase to be published in 2019.	Yes	

1.6.2 EU Chemicals Legislation Finder

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Based on the 2017 feasibility study and the delegation agreement, start the first and second phase of setting up the EU Chemicals Legislation Finder aiming to provide a comprehensive view on how a chemical substance is regulated across various legislations in Europe.	Yes	

2.1.1 Committees

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Manage membership (renewals and new appointments/ nominations) of each committee with specific focus on ensuring adequate capacity of RAC, SEAC and BPC, including co-opted members in RAC and SEAC.	Yes	
Continue implementing efficiency improvements in all Committees, including the on-going development of IT support tools and their regular integration.	Yes	
Prepare and adopt scientific opinions in support of proposals for occupational exposure limit values, requested by the Executive Director under Article 77(3)c of REACH.	Yes	
Cooperation activities with other EU bodies such as EFSA's Panels and Scientific Committee, and the Commission's Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health, Environment and Emerging Risks (SCHEER) and the Scientific Committee on Occupational Exposure Limits (SCOEL).	Yes	

2.1.2 Enforcement Forum

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Prepare the REF-7 project, and prioritise the subject for REF-8 project.	Yes	
Review the Interlinks Guide, considering experience gained since its introduction in 2016.	No	Due to foreseen changes in ECHA's process for dossier evaluation, the interlink process between ECHA and the enforcement authorities will be reviewed in 2019.

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Continue expanding the Manual of Conclusions recording the Forum agreements on enforcement practices.	Yes	
Continue work on tightening cooperation of the Forum with customs authorities.	Yes	
Prepare and organise the annual training for enforcement trainers.	Yes	
Prepare the next Forum activity plan for 2019-2021.	Yes	
Prepare the REF-7 project, and prioritise the subject for the REF-8 project.	Yes	

2.1.3 HelpNet and Security Officers' Network

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Organise one HelpNet Steering Group meeting in the second half of the year, back-to-back with three workshops: BPR, REACH and CLP.	Yes	
Keep national helpdesks up-to-date with the latest developments and advice through the regular publication of the HelpNet update, and possibly by organising an ad hoc Webex conference before the REACH registration deadline, if a clear need is identified.	Yes	
Keep the published FAQs up-to-date regarding their content by prioritising registration-related ones, and regarding their form by using clear, simple language.	Yes	
Analyse an extension of the current security model for granting access to ECHA IT systems to national authorities. The extended model would contemplate secure access for individuals acting in their capacity of experts in the ECHA committees	Yes	

2.1.4 Board of Appeal

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Process and decide on incoming appeals which are estimated to include an increased number of registration and data-sharing related cases due to the manual completeness check and the reinforcement of the OSOR principle in REACH-IT as well as a steady influx of cases in relation to substance evaluation and compliance check decisions.	Yes	
Adopt procedural decisions, as needed.	Yes	
Publish a robust body of high-quality decisions online, helping to build a set of consistent criteria for the Agency decision-making.	Yes	
Ensure effective (i.e. clear, accurate and timely) communication with the (potential) parties in relation to appeal proceedings.	Yes	

2.2 Management

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Support that relations are established between the newly appointed Executive Director and the institutional partners, in particular, the European Parliament, the Commission, Member States and other EU agencies, with a view to further increasing cooperation and supporting the implementation of ECHA's mandate.	Yes	
Support the Commission in implementing and monitoring the actions resulting from the second REACH review in 2017.	Yes	
Finalise ECHA's strategic plan for 2019-2023 (including public consultation on the plan and related review of ECHA's corporate identity, vision, mission and values) and cascade the strategic plan into annual work programmes and relevant internal monitoring systems.	Yes	
Support the Management Board in discharging its statutory responsibilities, through the organisation and preparation of plenary meetings, working groups and efficient administration of other Board proceedings.	Yes	
Support the internal coordination of ECHA's executive management, through the preparation and coordination on internal management meetings, and by facilitating the preparation of management strategies, decisions, delegations and policies.	Yes	
Manage the Agency's reputation by: gathering feedback on the Agency's performance from stakeholders though surveys and by daily media and social media monitoring; and acting on the feedback received.	Yes	
Maintain sound managerial overview of the various implemented regulations and delegated tasks, to achieve maximum integration, synergy of shared services and transparency of performance.	Yes	
Continue optimising ECHA's Integrated Management and Internal Control systems to support ECHA operations, while successfully maintaining relevant ISO standards.	Yes	
Review and update the corporate-wide efficiency development programme, its scoping and role, in line with the updated strategic direction 2019-2023.	Yes	
Perform audits and evaluations in line with the annual audit plan.	No	80 % of planned audits and evaluations were performed (target 100 %). Some audits postponed due to other priorities such as the development of the IMS tool.
Continue implementing the digitalisation of ECHA's archives.	Yes	
Respond to general requests for information on the ECHA website, the Agency's activities, and questions outside its remit.	Yes	
Coordinate ECHA's contribution to inter-agency activities via dedicated (network) meetings and joined initiatives.	Yes	

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Coordinate international cooperation activities as requested by the Commission, in line with an Exchange of Letters in 2014 between the Commission and ECHA establishing working arrangements for handling such activities, and carry out ECHA's third capacity building project for EU candidate countries and potential candidates under the IPA (Instrument for Pre-Accession) programme.	Yes	
Prepare measures which ECHA will need to put into place to accommodate the withdrawal of the United Kingdom from the European Union.	Yes	

2.3.1 Financial resources

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Prepare the Agency's budget and manage its implementation, including amendments and transfers, revenue collection and cash management, procurement and contracting, financial reporting including annual accounts.	Yes	
Continue regular exchange with Commission partner services, including reporting on actual budget implementation, communicating revenue and expenditure estimates for the future and discussing ways of handling any shortfall or surplus during the budget year.	Yes	
Monitor and report on reimbursements to Member States and prepare eventual reviews of the Management Board rules on this matter.	Yes	
Continue the streamlining and automation of ECHA financial processes, including implementation of the Financial Information Management System (FIMS), with an emphasis on electronic processing of purchase invoices, tender publications and submissions and developing a new budgeting tool.	Yes	
Continue ensuring the correctness of the SME fee reductions claimed by registrants by performing eligibility checks.	Yes	

2.3.2 Human resources

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Conduct the annual objective setting, performance appraisal and reclassification exercises.	Yes	
Maintain good relations and dialogue with the Staff Committee, the European School of Helsinki and other key stakeholders.	Yes	
Conduct the Job Screening Exercise as part of a wider inter-Agency benchmarking exercise initiated by the European Commission.	Yes	
Provide relevant learning and development activities to ensure continuous capacity-building of staff.	Yes	

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Review of ECHA's competency mapping framework.	Yes	
Ensure availability of necessary workforce for the 2018 registration deadline activities.	Yes	

2.3.3 Corporate services

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Ensure the contract for ECHA's future office building is implemented.	Yes	
Provide high quality corporate services to staff and external meeting participants and visitors.	Yes	
Implement the Events Logistics Management tool to further streamline the organisation of meetings and events.	Yes	
Publish and promote information on all regulatory developments of importance to companies as well as the general public via relevant communications tools and platforms and monitor their impact on target audiences.	Yes	
Develop further the dedicated website ('microsite') aimed for consumers and published in 2017.	Yes	
Ensure availability of necessary workforce for the 2018 registration deadline activities.	Yes	

2.3.4 ICT

Main actions and outputs specified in the Work Programme 2018	Achieved [Yes/No]	Additional information/ Explanation
Deliver the IT services for the registration 2018 deadline, including IT support for Business Continuity and ICT facilities for to the additional staffing.	Yes	
Deliver IT services for users from MSCAs, designated national authorities and national enforcement authorities.	Yes	
Manage the transition to the new framework contract for infrastructure capacity services. Prepare by refactoring the networks design towards simplification and optimisation of the managed network services.	Yes	
Complete the implementation of the sourcing strategy regarding the combined outsourcing of software development and application management services.	Yes	
Continue the evolution towards leased IT facilities for the workplace, ultimately leading to a full transition from asset based to as a service delivered.	Yes	
Ensure availability of necessary workforce for the 2018 registration deadline activities.	Yes	

Appendix 2 – Workload driver estimates and indicators

1.1.1 Registration dossier preparation

Performance indicators	2018 estimate	2018 actual
Helpdesk questions received[28]	5 000 – 10 000	3 731
Inquiries concluded	10 000	6 143
Access to data older than 12 years	1 900	142
Data-sharing disputes	170	313
Decisions on data-sharing disputes	140	57
Appeals on data-sharing decisions	8	11

1.1.2 Registration dossier submission

Performance indicators	2018 estimate	2018 actual
Registration dossiers received (including updates)	60 000	37 441
Confidentiality requests processed	3 290	365
PPORD notifications received (including requests for extension)	300	340
Helpdesk questions received[29]	5 000 – 10 000	3 570
Decisions on completeness check (negative)	1 200	345
Decisions on confidentiality requests (negative)	340	30
Decisions on PPORD notifications	50	44
Appeals submitted[30]	10	5

1.1.3 Evaluation

Performance indicators	2018 estimate	2018 actual
Substances assessed for priority for regulatory actions	280	374
Draft decisions on testing proposals	145	168
Final decisions on testing proposals	105	130
Compliance checks concluded	200	286
Final decisions on compliance checks	180	144
Follow-up evaluations on dossier evaluation decisions concluded	330	229
Number of substances on the CoRAP list to be evaluated by the MSs[31]	40	21
Final decisions on substance evaluation	30	21
Appeals submitted	18	10
Helpdesk questions received[32]	500	123

28 Regulatory and non-regulatory questions related to dossier preparation only.
29 Regulatory and non-regulatory questions related to dossier preparation only.
30 Calculated as a percentage of negative decisions, where the percentage is based on
31 The declining trend in the number of substances under substance evaluation is mainly due to the refined interplay between substance evaluation and compliance check, i.e. more substances are first addressed under compliance check also for the endpoints relevant for the substance evaluation. This temporary trend is expected to turn in 2018.
32 Regulatory and non-regulatory questions related to evaluation only.

1.1.4 Communication of risk management advice through the supply chain

Performance indicators	2018 estimate	2018 actual
Number of events organised with industry to improve the uptake of Roadmap products	5	5
Helpdesk questions received[33]	250	299

1.2.1 Identifying needs for regulatory risk management

Performance indicators	2018 estimate	2018 actual
Upon request by the Commission, support provided for the development of RMO analyses and/or SVHC dossiers.	5	0
Number of expert and coordination meetings (PBT and ED Expert groups and Risk Management Expert Meetings - RiME)	9	8

1.2.2 Authorisation

Performance indicators	2018 estimate	2018 actual
Number of proposals for identifying SVHCs[34]	20	14
Recommendation for inclusion of substances in the authorisation list	1	1
Number of received applications for authorisation (number of uses)	15	6
RAC & SEAC opinions[35] on applications for authorisation	11	22
Helpdesk questions received[36]	500	197

1.2.3 Restriction

Performance indicators	2018 estimate	2018 actual
Restriction proposals submitted by MS and ECHA (Annex XV)	8	3
Annex XV restriction dossiers (or preparatory reports) prepared on request by the Commission	5	0
Restriction proposals or reports developed under Article 69(2)	1	0
RAC & SEAC opinions on restriction proposals	6	4
Helpdesk questions received[37]	500	168

33 Regulatory and non-regulatory questions related to communication of risk management advice through the supply chain only.
34 The expected number of proposals for identification of SVHCs stems from the extrapolation of yearly consultation with the Member States Competent Authorities on their plans for developing such dossiers and adjusted by intelligence from the processes
35 One opinion refers to a compiled version of the final opinions of RAC and SEAC for each use.
36 Regulatory and non-regulatory questions related to authorisation only.
37 Regulatory and non-regulatory questions related to restrictions only.

1.2.4 Classification and labelling

Performance indicators	2018 estimate	2018 actual
Proposals for harmonised classification and labelling	75	65
RAC opinions on proposals for harmonised classification and labelling	80	62
Alternative name requests	50	35
Helpdesk questions received[38]	500	359

1.3 Biocides

Performance indicators	2018 estimate	2018 actual
Opinions on active substances approval (under the Review programme)	50	24
Biocides Inquiries received	50	36
Biocides Data sharing disputes	5	1
Applications for new active substance approval	28	35
Applications for renewal or review of active substances	11	4
Applications for Union authorisation for biocidal products	30	18
Applications for active substance suppliers (Article 95)	25	39
Assessment of technical equivalence	45	35
Submissions to Member States	3 000	1 041
Appeals submitted	1	1
Helpdesk questions received[39]	3 000	1 797

1.4 Prior Informed Consent (PIC)[40]

Performance indicators	2018 estimate	2018 actual
Export notifications	10 700	8 302
Helpdesk questions received[40]	375	138
Scientific and technical requests from the Commission, EU and non-EU DNAs	2 800	2 550

1.5 Data management and dissemination

Performance indicators	2018 estimate	2018 actual
Number of dossiers to be disseminated	56 000	25 006
Number of external requests for data	50	46

38 Regulatory and non-regulatory questions related to classification and labelling only.
39 Regulatory and non-regulatory questions related to biocides only.
40 Regulatory and non-regulatory questions related to PIC only.

2.1.1 Committees

Performance indicators	2018 estimate	2018 actual
MSC meetings	5	5
RAC meetings	4	6
SEAC meetings	4	4
BPC meetings	6	5

2.1.2 Enforcement Forum

Performance indicators	2018 estimate	2018 actual
Number of REF projects (at any stage of project life cycle)	4	5
Number of pilot projects (at any stage of project life cycle)	4	5
Forum meetings	3	3
Active working groups	11	23

2.1.3 HelpNet and Security Officers Network

Performance indicators	2018 estimate	2018 actual
Number of HelpNet events	7	12
Number of SON events	1	1

2.1.4 Board of Appeal

Performance indicators	2018 REACH estimate	2018 REACH actual	2018 BPR estimate	2018 BPR actual
Appeals submitted	36	26	1	1
Procedural decisions	23	19	1	1
Cases closed	24	13	1	2

2.2 Management

Performance indicators	2018 estimate	2018 actual
Number of corporate management meetings[41]	75	83
Number of audits and evaluations to take place in a year[42]	15	12

2.3.1 Financial resources

Performance indicators	2018 estimate	2018 actual
SME status checks for REACH/CLP	400	414

41 Includes the Directors Coordination Meeting, Business Programme Board, IT Directors Programme Board, Management Board and its working group meetings and MSCA Directors meeting.

42 Includes the internal audits and their follow-up performed by the European Commission's Internal Audit Service (IAS) and ECHA's Internal Audit Capability (IAC) as well as ECHA's Integrated Quality Management System audits and financial evaluations.

2.3.3 Corporate services

Performance indicators	2018 estimate	2018 actual
Number of meetings held at ECHA Conference Centre (including internal meetings)	1 650	1 446
Number of new publications produced	40	33
Number of pages translated into 22 languages	800	702

2.3.4 ICT

Performance indicators	2018 estimate	2018 actual
Number of IT related incidents	5 600	5 822
Number of IT contracts to be managed in a year[43]	100	131
Number of Agency-wide IT applications in operation	66	66

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ECHA's main activity drivers	2018 estimate	2018 actual
Registration dossiers (including updates)	60 000	37 441
Testing proposals	240	334
Confidentiality requests	3 290	562
Access to data older than 12 years	390	142
PPORD notifications (incl. requests for prolongation)	300	340
Inquiries concluded[44]	1 900	6 143
Data sharing disputes	170	313
Restriction proposals submitted by MS and ECHA (REACH Annex XV)	8	3
Restriction proposals (or reports)	3 000	52
developed by ECHA on behalf of the Commission	5	1
Restrictions proposals (or reports) developed under Article 69(2)	1	0
Proposals for harmonised classification and labelling (CLP Annex VI)	75	65
Proposals for identification as SVHC (REACH Annex XV)[45]	20	14
Authorisation applications received	15	6
Alternative name requests	50	35
Substances on the CoRAP to be evaluated by MSs	40	21
Notifications of information for Poison Centres[46]	0	0

43 ECHA's own established IT Framework contracts and the major service contracts managed under HANSEL (Finnish Administration Procurement) including specific contracts implementing ECHA's own established IT Framework contracts and major service contracts managed under HANSEL (the specific contract amount to c.a. 100 per year).
44 The late pre-registration ends June 2017, which will potentially result in an increase in the number of inquiries.
45 The actual number of SVHC dossiers arriving will depend on the outcome of the RMO analyses.
46 The number of expected notifications to poison centres is calculated on the basis of the estimates provided in the cost and benefits study published in 2015 by the Commission together with assumptions of 80 % of notifications to be submitted through the centralised portal and a 20-30 % reformulation rate. These numbers may increase for 2019 due to the ongoing discussions on the interpretation of mixtures intended for industrial use.

ECHA's main activity drivers	2018 estimate	2018 actual
Evaluation decisions		
- Testing proposal	105	130
- Compliance Check	180	145
- Substance evaluation	30	18
Decisions on data sharing	140	57
Decisions on PPORD	50	44
Decisions on completeness check (negative)[47]	1 200	345
Decisions on confidentiality requests (negative) [48]	340	30
Appeals		
Appeals submitted	37	27
Cases closed	25	15
Others		
Updates of the CoRAP for substances subject to substance evaluation	1	0
Recommendations to the European Commission for the Authorisation List	1	1

Appendix 3 – Work Programme 2018 performance indicators

1.1.1 Registration dossier preparation

Performance indicators	2018 estimate	2018 actual
Percentage of inquiries concluded within the target timeframe (20 working days)	80 %	96 %
Effective working time of ECHA staff used per inquiry concluded	1.8-2 person days	0.5 person days
Percentage of received data sharing disputes handled within relevant timeframes[49]	80 %	95 %
Effective working time of ECHA staff used per data sharing decision	16-18 person days	13 person days
Percentage of ECHA Helpdesk questions related to dossier preparation, answered within established timeframe (15 working days)	90 %	90 %

47 Calculated as a percentage of number of dossiers received, where the percentage is based on the historical data of actual negative decisions in 2011-2015 (i.e. 1 %), increased with an estimated 1 % for the enhanced and retrospective completeness checks starting in mid-2016.

48 Calculated as a percentage of number of confidentiality requests received, where the percentage is based on the historical data of actual negative decisions in 2011-2015.

49 Disputes for non-phase-in substances have a legal deadline of one month while disputes for phase-in substance do not have a legal deadline (only an internal deadline of 40 working days).

1.1.2 Registration and dossier submission

Performance indicators	2018 estimate	2018 actual
Level of satisfaction of interested parties with dossier submission and dissemination activities of ECHA	High	High
Percentage of dossiers where the first completeness check is performed within 15 days (working days) (time between starting and finishing the check)[50]	90 %	97 %
Effective working time of ECHA staff used per processed registration dossier (incl. updates)	0.55–0.6 person days	0.36 person days
Percentage of ECHA Helpdesk questions related to dossier submission and substance identity, answered within established timeframe (15 working days)	90 %	93 %
Percentage of ECHA Helpdesk questions related to dossier preparation, answered within established timeframe (15 working days)	90 %	90 %

1.1.3 Evaluation

Performance indicators	2018 estimate	2018 actual
Level of satisfaction of MSCAs with ECHA's coordination and support to substance evaluation	High	High
Level of satisfaction of MSC members and stakeholder observers with the quality of the scientific, technical and regulatory support provided by the ECHA Secretariat	High	High
Percentage of unanimous MSC agreements on evaluation decisions	80 %	100 %
Percentage of concluded compliance checks (draft decision sent or closed with no action) addressing the relevant higher tier hazard endpoint as portion of all concluded compliance checks in a year	→75 %	69 %
Effective working time of ECHA staff used per main, final dossier evaluation output (compliance checks concluded with no draft decision, decisions on testing proposals and compliance checks)	25–28 person days	23.4 person days
Percentage of Follow-up evaluations performed within six months from the deadline set in a Decision (testing proposals and compliance checks)	80 %	80 %
Percentage of substance evaluation decisions adopted within 45 days from the MSCA/MSC agreement	90 %	100 %
Percentage of ECHA Helpdesk questions related to evaluation, answered within established timeframe (15 working days)	90 %	83 %

50 REACH provides 15 working days as a deadline to perform the first completeness check of a dossier since its submission date. An extended deadline is granted in Article 20(2) for dossiers submitted up to two months before the registration deadline (i.e. a first completeness check must be performed within three months after the registration deadline). To preserve the efficiency of the process, ECHA aims to remain within 15 working days from the start until the finalisation of the first completeness check for all dossiers regardless of their submission date. This means that while the completeness check of a dossier submitted between 1 April and 31 May may be opened at any point in the three-month period after the deadline, ECHA aims to resolve 90 % of cases in a period no longer than three weeks throughout 2018.

1.1.4 Communication of risk management advice through the supply chain

Performance indicators	2018 estimate	2018 actual
Level of satisfaction of the interested parties with the quality of the support provided by the ECHA secretariat in the area of supply chain communication[51]	High	Medium
Percentage of ECHA Helpdesk questions related to communication of risk management advice through the supply chain, answered within established timeframe (15 working days)	90 %	90 %

1.2.1 Identifying needs for Regulatory Risk Management

Performance indicators	2018 estimate	2018 actual
Level of satisfaction of Commission, MSCAs, ECHA Committees, industry, NGOs and other interested parties with the quality of the scientific, technical and administrative support provided by the ECHA Secretariat	High	High
Effective working time of ECHA staff used per SVHC dossier	38–47 person days	45.9 person days

1.2.2 Authorisation

Performance indicators	2018 estimate	2018 actual
Level of satisfaction of Commission, MSCAs, ECHA Committees, industry, NGOs and other interested parties with the quality of the scientific, technical and administrative support provided by the ECHA Secretariat	High	High
Average time to process an application for authorisation	13 months	12.7 months
Effective working time of ECHA staff used per authorisation opinion	38–46 person days	36 person days

1.2.3 Restrictions

Performance indicators	2018 estimate	2018 actual
Level of satisfaction of Commission, MSCAs, ECHA Committees, industry, NGOs and other interested parties with the quality of the scientific, technical and administrative support provided by the ECHA Secretariat	High	High
Average time to deliver an opinion on a Restriction proposal	15 months	15 months
Effective working time of ECHA staff used per restrictions opinion	200–255 person days	155 person days

51 Changes in the methodology between 2017 and 2018 impact the interpretation of results. Measuring the performance of the work of the Agency in the area of supply chain communication is challenging as the satisfaction level measured in the stakeholder survey of ECHA relates to the actual information provided or received in the supply chain and not to ECHA's activities directly. The results are hence rather showing the overall functioning of the communication up and down in the supply safety.

1.2.4 Classification and Labelling

Performance indicators	2018 estimate	2018 actual
Level of satisfaction of Commission, MSCAs, ECHA Committees, industry, NGOs and other interested parties with the quality of the scientific, technical and administrative support provided by the ECHA Secretariat	High	High
Average time to deliver an opinion on a CLH proposal	10 months	13.1 months
Effective working time of ECHA staff used per CLH opinion	45–55 person days	30.3 person days
Percentage of ECHA Helpdesk questions related to C&L, answered within the established timeframe (15 working days)	90 %	96 %

1.3 Biocides

Performance indicators	2018 estimate	2018 actual
Level of satisfaction of the members of the BPC (incl. its Working Groups), Coordination Group, the Commission, MSCAs and industry with the quality of the scientific, technical and regulatory support provided.	High	High
Percentage of BPR inquiries concluded within the target timeframe (20 working days)	90 %	100 %
Percentage of received BPR data sharing disputes handled within 60 days	100 %	100 %
Average time to process an active substance dossier (from competent authority evaluation report to BPC opinion)	9 months	12 months
Effective working time of ECHA staff used per active substance opinion	27–33 person days	31 person days
Percentage of ECHA Helpdesk questions related to Biocides, answered within established timeframe (15 working days)	80 %	83 %

1.4 Prior Informed Consent (PIC)

Performance indicators	2018 estimate	2018 actual
Percentage of export notifications processed within the legal timeframe	100 %	99.6 %
Level of satisfaction with the quality of scientific, technical, and administrative support provided to the Commission, Member State DNAs and industry	High	High
Average time to respond to scientific and technical requests from stakeholders	<15 days	3.5 days

1.5 Data management and dissemination

Performance indicators	2018 estimate	2018 actual
Level of Member States' and Commissions user satisfaction with data management services	High	High
Level of satisfaction of stakeholders with dissemination activities of ECHA.	High	High

Performance indicators	2018 estimate	2018 actual
Maximum continuous downtime (% non-availability) of the website, Portal Dashboard, S-CIRCA and Dynamic Case	2 %	0.2 %
Percentage of registered dossiers published on the Dissemination Portal within 20 working days from completing the registration process	70 %	96.7 %

2.1.1 Committees

Performance indicators	2018 estimate	2018 actual
Level of satisfaction of ECHA Committees with the quality of the scientific, technical and administrative support provided by the ECHA Secretariat	High	High
Percentage of members acting as rapporteurs in RAC and SEAC	>60 %	66 %

2.1.2 Enforcement Forum

Performance indicators	2018 estimate	2018 actual
Level of satisfaction of the members and other participants with the functioning of the Forum Secretariat	High	High
Number of REF project phases completed within the planned timeline	4	5

2.1.3 HelpNet and Security Officers Network

Performance indicators	2018 estimate	2018 actual
Level of satisfaction of HelpNet members with the HelpNet Secretariat support	High	High
Quality of the advice provided by SON as perceived by the Management Board members	High	High

2.1.4 Board of Appeal

Performance indicators	2018 estimate	2018 actual
Percentage of final Board of Appeal decisions made within 90 working days of the closure of the written or oral procedure	80 %	60 %
Average time to process an appeal	15 months	15 months
Effective working time of Board of Appeal and its Registry to conclude an appeal case against ECHA's decision	85-90 person days	80 person days

2.2 Management

Performance indicators	2018 estimate	2018 actual
Percentage of very important audit recommendations implemented within the deadline (IAS, IAC, CoA)[52].	100 %	80 %

52 European Commission's Internal Audit Service (IAS), ECHA's Internal Audit Capability (IAC), Court of Auditors (CoA).

Performance indicators	2018 estimate	2018 actual
Decisions equivalent (No. of weighted decisions/opinions divided by the maximum annual staff capacity)	2 % increase	achieved
Level of satisfaction of MB Members with ECHA Secretariat's support to their governing role	High	High
Proportion of work programme indicators for which the set targets were achieved	95 %	84%

2.3.1 Financial resources

Performance indicators	2018 estimate	2018 actual
Commitment rate (of commitment appropriations at the end of the year).	95 %	99 %
Payment rate (of payment appropriations at the end of the year).	80 %	86 %
Carryover rate (% of committed funds carried over into the next year)	<20 %	13 %
Percentage of payments made within the legal/contractual deadlines	→95 %	99 %

2.3.2 Human resources

Performance indicators	2018 estimate	2018 actual
Percentage of Establishment Plan posts filled	98 %	98.8 %
Turnover of TAs	< 5 %	2 %
Turnover of CAs (excluding short-term CAs)	< 10 %	4.6 %

2.3.3 Corporate services

Performance indicators	2018 estimate	2018 actual
Level of satisfaction of the Committees, Forum and MB members with the functioning of the conference centre	High	High
Level of accredited stakeholder satisfaction with the information they receive and their engagement with ECHA.	High	High
Level of reader satisfaction with ECHA's written output, including language availability measured in terms of timeliness, content and usability	High	n/a[53]
Level of satisfaction of the staff with the corporate services	High	High

2.3.4 ICT

Performance indicators	2018 estimate	2018 actual
Availability of mission-critical systems for externally used IT systems (i.e. uptime during service hours).	98 %	99.8 %
Level of internal users satisfaction with the ICT services	High	High
Average time to resolve an internal, ICT service related request	<2 days	2.1 days

53 This survey is conducted every other year, no survey in 2018.

Appendix 4 – Meeting strategic objectives – 2018 results

ECHA defined four strategic objectives in its Multi-Annual Work Programme 2014-2018.

The progress made towards meeting these objectives in 2018 demonstrates the impact of ECHA's work, as do the individual achievements under each activity. Keeping a focus on the objectives also helped to identify how the Agency wants to work in the future. As a whole, this work over the past years paved the way for identifying new priorities as set out in ECHA's Strategic Plan 2019-2023[54].

Objective 1: Maximise the availability of high-quality data to enable the safe manufacture and use of chemicals

The Agency measures progress on the first strategic objective (SO1) with four indicators covering different parts of the registration dossier and diverse aspects of quality: shortcomings in substance identification; inconsistencies in the reported uses of substances registered as intermediates; the level of non-compliance with harmonised classification; and deficiencies identified in the data on physico-chemical, environmental, and human health hazards.

These indicators are not a direct measure of information compliance per se, but are measurements of certain identified anomalies or inconsistencies in the data provided by REACH registrants.

ECHA's past observations on low data quality have been reinforced by the Commission's REACH Review that found that the overall quality of the information obtained is not at the expected level despite the positive trends shown by the indicators. In the coming years, ECHA's strategic priority 1 will continue to assess the availability and quality of data.

Because of the improvements to the IUCLID formats, the changes in the completeness check, and the introduction of the manual verification at the completeness check, a significant number of the elements ECHA used to measure the indicator for strategic objective 1 no longer exist. With these improvements, inconsistencies and mistakes that can be picked up during the completeness check can no longer be made in dossiers. With every new or updated dossier, the issues have to be resolved by the registrants before they can successfully submit the dossiers.

ECHA has carried out a number of analyses and made observations that show a positive trend in aspects of dossier quality. Changes in format and in manual verification have had a positive effect by reducing the number of dossiers with severe issues relating to substance identity. Currently about 15% of substances have shortcomings that need to be resolved before a hazard assessment can start. Also, hazard and use information is better structured, leading to significantly fewer inconsistencies. In addition, in 2018 about 20-25 % of the incoming dossiers were manually checked at completeness, covering also verification of waiving statements.

Objective 2: Mobilise authorities to use data intelligently in order to identify and address chemicals of concern

ECHA implements a common screening approach for all REACH and CLP processes, including evaluation, to identify the substances and uses that matter the most and for which there may be a need to initiate regulatory action. Ultimately, these processes should enable the identification of substances that are of no or low priority for further regulatory action.

54 https://echa.europa.eu/about-us/the-way-we-work/plans-and-reports.

Of the 135 substances screened by Member States in 2018, 102 substances – mostly screened as group members and 17 screened as individual substances – were found to require further follow-up actions. Additionally, follow-up actions are pending for 34 substances, depending on the outcome of ongoing regulatory actions on that or a related substance. Also, the screening of a few large groups of substances will continue still in 2019. About 76 % of groups (or a part of a group) and 88 % of the individual substances required further follow-up actions.

With substance evaluation still incomplete for most substances, continuing to measure impact and identifying substances of concern under ECHA's new 2019 strategic priority 1 will remain key. Since 2012, Member States have evaluated 243 substances and concluded on 95 (39 %). In 49 % of the concluded cases, the evaluators identified a need for further regulatory risk management. In terms of follow-up assessment, of the 243 substances evaluated, 27 % are waiting for the information to be submitted by the registrants, 11 % are undergoing an actual follow-up assessment of the data already submitted, and 1.6 % are at the stage of the conclusion being prepared. The rest are either in the decision-making phase or waiting for requested information to be submitted.

Overall, under substance evaluation, ECHA has requested information on 129 substances. Fewer Member States carried out substance evaluations in 2018 than in 2017 (down from 12 to 8) mainly due to the difficulty of including suitable substances on the Community rolling action plan (CoRAP) and the number of cases still pending.

11 Member States submitted proposals for regulatory risk management measures under REACH or CLP, which is slightly less than in 2016 and 2017. Since 2017, 94 % of risk management options analysis (RMOA) conclusions were followed up with relevant action. SVHC identification and restriction proposals have also been followed up. Furthermore, there were three conclusions on the need to develop harmonised classification and labelling (CLH) proposals. This follows the trend observed in 2017 and confirms that Member States, that are responsible for taking initiative for new risk management measures, act on most RMOA conclusions. However, both the analysis and the translation of the conclusions into concrete proposals for regulatory risk management require significant time.

Objective 3: Address the scientific challenges by serving as a hub for scientific and regulatory capacity building of Member States, European institutions and other actors

This objective aims to ensure that ECHA bases its regulatory work on the latest scientific knowledge. The activities focus on ECHA's regulatory science strategy, capacity building in-house, and work as a regulatory science hub.

In line with this objective, the Agency significantly invested in improving its scientific capacity and in sharing its knowledge with stakeholders.

ECHA enhanced the capacity of staff in various areas of regulatory science, including in assessing endocrine disruption, and alternative methods and approaches. In particular, experts gained knowledge on new approach methodologies in ecotoxicology and on the developments in the in vitro testing battery for the assessment of developmental neurotoxicity. As the majority of such work is based on in vitro methods or performed on non-vertebrates, this capacity building is also important for making progress in reducing testing on vertebrate animals. Furthermore, ECHA's experts developed their understanding of toxicokinetics as a basis for analysing read-across and grouping approaches, as well as of quantitative structure–activity relationship (QSAR) modelling as further alternatives to classic experimental studies.

ECHA also stayed aligned with the scientific community and the OECD on themes such as socio-economic analysis, and research and development. As a digital-by-default and data-driven organisation, ECHA laid down

the foundations for a data strategy, which sets out how to facilitate the use of the information held by ECHA by relevant actors in applying and implementing the EU's chemicals legislation. Finally, the results of the 2018 stakeholder survey showed a positive trend for robust scientific support provided by the Agency to the Member State Committee on scientific questions.

Objective 4: Embrace current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints

Under this objective, ECHA measures the overall improvement in efficiency according to the ratio of ECHA's weighted outputs to the resources employed.

During the five years of implementing strategic objective 4, a continuous positive trend in the score shows that the measures and efforts put in place to develop a higher level of efficiency brought the desired results. However, in 2018, the limitations of the measurement method became apparent, as the score for 2018 was highly influenced by the registration deadline outputs and by the corresponding workload peak, handled with short-term interim staff resources. The resulting increase in the efficiency score for 2018 compared to 2017 is exceptionally high, which renders the quantitative comparison of the 2018 score with the scores from previous years unreliable.

Following the second REACH Review, the execution of the last REACH registration deadline and the adoption of ECHA's new strategic plan 2019-2023, in 2018 the Agency shifted the level of its operational improvement and efficiency focus, moving from optimising individual processes to reviewing its overall operational model and organisational structure.

ECHA aims to implement the new strategic plan internally by working better and more efficiently together, including with Member States. The alignment of ECHA's new organisation around competencies integrates different pieces of regulatory work and moves ECHA towards an agile, cross-functional organisation – thereby serving the needs of both the legislators and stakeholders in a more coherent way. At the same time, the implementation of ECHA's new human resources strategy, focused on competence development, flexibility and collaborative ways of working, will ensure further growth of ECHA's capability and adaptability.

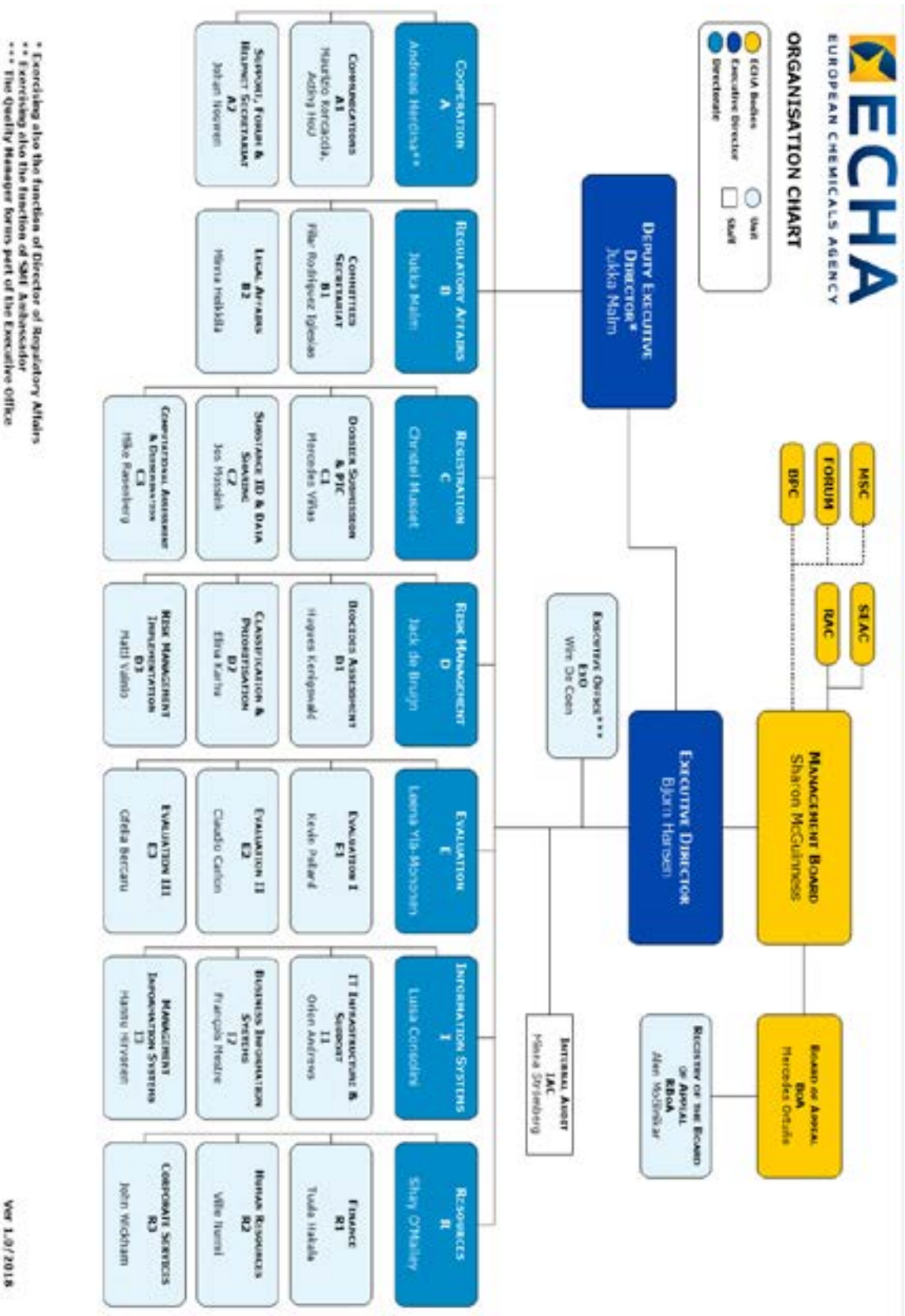
The aim of the 2018 reorganisation is to ensure that all stakeholders of the Agency can, and will in the future be able to, rely on flexible and efficient delivery of the processes entrusted to ECHA. The new organisation and operating mode aims to improve foresight, planning and deployment of needed competencies and resources in all areas of ECHA's work

Appendix 5 – Resources 2018

WP 2018 Activity	2018 planned FTEs (TA+CA)	Actual FTEs 2018	Initial budget	Budget 2018 - actuals
1.1.1 Registration dossier preparation	50	48	12 503 085	13 034 385
1.1.2 Registration and dossier submission	45	44	11 454 871	11 678 167
1.1.3 Evaluation	106	103	19 095 180	19 373 943
1.1.4 Communication of risk management advice through the supply chain	17	17	2 911 108	2 993 286
1.2.1 Identifying needs for Regulatory Risk Management	17	17	3 163 176	3 332 154
1.2.2 Authorisation	26	26	4 657 389	4 838 618
1.2.3 Restrictions	24	23	4 251 330	4 258 805
1.2.4 Classification and Labelling	27	27	4 762 036	4 867 220
1.3 Biocides	64	64	11 899 055	10 891 326
1.4 Prior Informed Consent	8	8	1 096 320	1 074 353
1.5 Data management and dissemination	40	40	10 441 117	12 487 871
1.6 Delegated tasks	3	3	1 600 000	1 101 588
2.1.1 Committees	16	14	3 043 994	2 908 720
2.1.2 Forum	8	6	1 795 489	1 252 305
2.1.3 HelpNet and Security Officers Network	2	1	334 708	177 391
2.1.4 Board of Appeal	11	11	1 805 558	1 836 278
2.2 Management	36	36	6 965 826	6 809 746
2.3.1 Financial resources	26	23	4 145 478	3 817 507
2.3.2 Human resources	24	21	3 771 337	3 426 873
2.3.3 Corporate services	20	18	3 142 701	2 936 824
2.3.4 ICT	24	22	3 771 398	3 589 900
TOTAL	**594**	**572**	**116 611 156**	**116 687 259**

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

Appendix 6 – ECHA organisation 2018



* Exercising also the function of Director of Regulatory Affairs
** If exercising also the function of SME Ambassador
*** The Quality Manager forms part of the Executive Office

Ver 1.0/2018

Appendix 7 – Members of the Management Board at 31 December 2018

Chair: MCGUINNESS Sharon (Ireland)

Deputy-Chair: LARSEN Henrik Søren (Denmark)

Representatives of the Member States	
ANFALT Lisa	Sweden
BAILEY Keith	United Kingdom
BAJANÍKOVÁ Miroslava	Slovakia
BIRÓ Krisztina	Hungary
BORG Ingrid	Malta
DIMITRIOU Kassandra	Greece
DIPĀNE Judīte	Latvia
GIANNOTTI Francesca	Italy
GONZALEZ SANCHEZ Oscar	Spain
GRABNER Alojz	Slovenia
KOLESNIKOVA Tatjana	Czech Republic
KORHONEN Hanna	Finland
KRAJNIK Paul	Austria
LEBSANFT Jörg	Germany
LULEVA Parvoleta (Successor nomination pending)	Bulgaria
MARTINS Ana Lília	Portugal
MEIJER Hans	Netherlands
METAYER Marie-Laure	France
RASQUÉ Paul	Luxembourg
RIHOUX Anne-France	Belgium
TERIOSINA Marija	Lithuania
TÎRCHILĂ Luminița	Romania
VESKIMÄE Enda	Estonia
VIDOVIĆ Bojan	Croatia
WĄSOWICZ Lidia	Poland
YIANNAKI Anastassios	Cyprus

Representatives of the Commission
JÜLICHER Sabine
PELTOMÄKI Antti
SADAUSKAS Kestutis

Independent individuals appointed by the European Parliament
BERNAERTS Kristel
MARTIN Olwenn

Individuals appointed by the Commission to represent interested parties without voting rights
LYNCH Esther
SCHEUER Stefan
SMITH Peter

Observers nominated by EEA-EFTA and other countries	
JAHRE Sverre Thomas	Norway
SÆMUNDSDÓTTIR Sigurbjörg	Iceland

Appendix 8 – Members of ECHA committees and Forum on 31 December 2018

Nominating state	Member State Committee (MSC) Chair: Watze DE WOLF	Committee for Risk Assessment (RAC) Chair: Tim BOWMER	Committee for Socio-economic Analysis Chair: Tomas ÖBERG	Biocidal Products Committee (BPC) Chair: Erik VAN DE PLASSCHE	Forum for Exchange of Information on Enforcement Chair: Katja VOM HOFE BPRS: Eugen ANWANDER
Austria	Helmut STESSEL	Sonja KAPELARI, Annemarie LOSERT	Simone FANKHAUSER, Georg KNOFLACH	Nina JOHN	Eugen ANWANDER BPRS: Eugen ANWANDER
Belgium	Kelly VANDERSTEEN	Julie SÉBA	Simon COGEN, Benjamin DELCOURT		Boris VAN BERLO BPRS: Helmut DE VOS
Bulgaria	Rada DIMITROVA	Stephka CHANKOVA-PETROVA, Irina KARADJOVA	Elina Velinova STOYANOVA-LAZAROVA	-	Elena ZIDAROVA BPRS: Viktoriya HRISTOVA
Croatia	Dubravka Marija KREKOVIĆ	Veda Marija VARNAI, Davor ZELJEZIC	Silva KAJIĆ	Ivana VRHOVAC FILIPOVIC	Dubravka Marija KREKOVIC BPRS: Ivana VRHOVAC FILIPOVIC
Cyprus	Maria PALEOMILITOU	Kostas ANDREOU, Agapios AGAPIOU	Leandros NICOLAIDES, Christos ANASTASIOU	Alexandros GAVRIEL	Tasoula KYPRIANIDOU-LEONTIDOU BPRS: Alexandros GAVRIEL
Czech Republic	Pavlina KULHANKOVA	Marian RUCKI, Michal MARTINEK	Karel BLAHA	Tomáš VACEK	Oldřich JAROLÍM BPRS: Oldřich JAROLÍM
Denmark	Rune HJORTH	Lea Stine TOBIASSEN, Peter Hammer SØRENSEN	Lars FOCK	Nina Falk GREGERSEN	Birte Nielsen BØRGLUM BPRS: Lise BACH HANSEN
Estonia	Jaanika AAVIK	Raili MOLDOV, Urs SCHLÜTER	Andreas LÜDEKE	Anu MERISTE	Aljona HONGA BPRS: Annemari LINNO
Finland	Eeva RISSANEN	Riitta LEINONEN, Tiina SANTONEN	Johanna KIISKI	Sanna KOIVISTO	Mervi ASSMANN BPRS: Päivi KARNANI
France	Michel FRANZ	Nathalie PRINTEMPS, Laure GEOFFROY	Jean-Marc BRIGNON, Karine FIORE-TARDIEU	Aurélie CHEZEAU	Clotilde PIONNEAU BPRS: Gilles CROIZE-POURCELET

Nominating state	Member State Committee (MSC) Chair: Watze DE WOLF	Committee for Risk Assessment (RAC) Chair: Tim BOWMER	Committee for Socio-economic Analysis Chair: Tomas ÖBERG	Biocidal Products Committee (BPC) Chair: Erik VAN DE PLASSCHE	Forum for Exchange of Information on Enforcement Chair: Katja VOM HOFE BPRS: Eugen ANWANDER
Germany	Helene FINDENEGG	Ivan DOBREV, Ralf STAHLMANN	Karen THIELE, Klaus URBAN	Stefanie JÄGER	Katja VOM HOFE BPRS: Katja VOM HOFE
Greece	Aglaia KOUTSODIMOU	Nikolaos SPETSERIS, Christina TSITSIMPIKOU		Vasileios VAGIAS	Eleni FOUFA BPRS: Dimitra GKILPATHI
Hungary	Szilvia DEIM	Anna BIRO, Katalin GRUIZ	Endre SCHUCHTÁR	Emese SZÁNTÓ	Szilvia DEIM BPRS: Balázs NEMET
Iceland	-	-	-	-	Ísak Sigurjón BRAGASON BPRS: Hafdis INGVARSDOTTIR
Ireland	Louise CONWAY	Brendan MURRAY, Yvonne MULLOOLY	Eimear LEAHY	Finbar BROWN	Sinead MCMICKAN BPRS: Michelle WHELAN
Italy	Leonello ATTIAS	Pietro PARIS, Gabriele AQUILINA	Stefano CASTELLI, Luisa CAVALIERI	Maristella RUBBIANI	Mariano ALESSI BPRS: Francesca RAVAIOLI
Latvia	Anta JANTONE	Normunds KADIKIS	Ivars BERGS, Jānis LOČS	Julija BROVKINA	Jana NEIMANE BPRS: Sintija ELFERTE
Liechtenstein	-	-	-	-	Manfred FRICK BPRS: Manfred FRICK
Lithuania	Lina DUNAUSKINE	Lina DUNAUSKIENE, Žilvinas UŽOMECKAS	Karolis RUZGYS	-	Otilija SPŪRIENĖ BPRS: Palmira HAKAITE
Luxembourg	Alex WAGENER	Ruth MOELLER, Michael NEUMANN	-	Jeff ZIGRAND	Kim ENGELS BPRS: Kim ENGELS
Malta	Nathanael ELLUL	-	-	Joanne BORG GALEA	Michael CASSAR BPRS: Bernice FARRUGIA
Netherlands	Jan WIJMENGA	Betty HAKKERT, Marja PRONK	Richard LUIT, Martinus JANSSEN	Martine LANS	Jos VAN DEN BERG BPRS: Marianne BRAAM
Norway	Linda REIERSON	Christine BJØRGE, Stine HUSA	-	Marit RANDALL	Gro HAGEN BPRS: Cathrine SKJARGARD

Nominating state	Member State Committee (MSC) Chair: Watze DE WOLF	Committee for Risk Assessment (RAC) Chair: Tim BOWMER	Committee for Socio-economic Analysis Chair: Tomas ÖBERG	Biocidal Products Committee (BPC) Chair: Erik VAN DE PLASSCHE	Forum for Exchange of Information on Enforcement Chair: Katja VOM HOFE BPRS: Eugen ANWANDER
Poland	Michal ANDRIJEWSKI	Boguslaw BARANSKI, Sławomir CZERCZAK	Dorota DOMINIAK	Anna HADAM	Marta OSÓWNIAK BPRS: Dominik PISAREK
Portugal	Inês ALMEIDA	João CARVALHO	João ALEXANDRE	Teresa BORGES	Graca BRAVO BPRS: Ines ALMEIDA
Romania	Mariana MIHALCEA UDREA	Mihaela ILIE, Mihaela I. PRIBU	Adrian Stefan ZAMFIR	Mihaela-Simona DRAGOIU	Maria MIJA BPRS: Cristiana CIRLAN
Slovakia	Alexandra HORSKA	Helena POLAKOVICOVA	-	Denisa MIKOLASKOVA	Miriam POČAROVSKÁ BPRS: Miriam POČAROVSKÁ
Slovenia	Tatjana HUMAR-JURIČ	Anja MENARD SRPČIČ, Agnes SCHULTE	Karmen KRAJNC	Petra ČEBAŠEK	Vesna NOVAK BPRS: Vesna NOVAK
Spain	Esther MARTÍN	Miguel SOGORB, Ignacio de la FLOR TEJERO	Adolfo NARROS	M Luisa GONZALEZ MARQUEZ	Pablo SÁNCHEZ-PEÑA BPRS: Margarita VAZQUEZ
Sweden	Ivar LUNDBERGH	Anne-Lee GUSTAFSON, Bert-Ove LUND	Jenny JANS	Edda HAHLBECK	Henrik HEDLUND BPRS: Emma BERGSTRÖM
Switzerland	-	-	-	Manuel RUSCONI	BPRS: Heribert BUERGY
United Kingdom	Amanda COCKSHOTT	Stephen DUNGEY, Andrew SMITH	Gary DOUGHERTY, Stavros GEORGIOU	Michael COSTIGAN	Mike POTTS BPRS: Mike POTTS
n/a (Co-opted)		Radu BRANISTEANU	Dora RONKAINEN		
n/a (Co-opted)		Elena-Ruxandra CHIURTU	Aart ROUW		
n/a (Co-opted)		Andrea HARTWIG	John JOYCE		
n/a (Co-opted)		Dick HEERERIK, Rudolf van der HAAR	Nikolinka SHAKHRA-MANYAN		

Appendix 9 – Candidate List of substances of very high concern (SVHCs)

Substances added to Candidate List in 2018

Substance name	EC	CAS	Date of inclusion	Reason for inclusion	Decision	Submitted by
1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one 3-benzylidene camphor; 3-BC	239-139-9	15087-24-8	15/01/2019	Endocrine disrupting properties (Article 57(f) - environment)	ED/88/2018 EU/2018/2013	Germany
2,2-bis(4'-hydroxyphenyl)-4-methylpentane	401-720-1	6807-17-6	15/01/2019	Toxic for reproduction (Article 57c)	ED/88/2018	
Benzo[k]fluoranthene	205-916-6	207-08-9	15/01/2019	Carcinogenic (Article 57a) PBT (Article 57d) vPvB (Article 57e)	ED/88/2018	
Fluoranthene	205-912-4	206-44-0; 93951-69-0	15/01/2019	PBT (Article 57d) vPvB (Article 57e)	ED/88/2018	
Phenanthrene	201-581-5	85-01-8	15/01/2019	vPvB (Article 57e)	ED/88/2018	
Pyrene	204-927-3	129-00-0; 1718-52-1	15/01/2019	PBT (Article 57d) vPvB (Article 57e)	ED/88/2018	
Benzene-1,2,4-tricarboxylic acid 1,2 anhydride trimellitic anhydride; TMA	209-008-0	552-30-7	27/06/2018	Respiratory sensitising properties (Article 57(f) - human health)	ED/61/2018 EU/2018/594	
Benzo[ghi]perylene	205-883-8	191-24-2	27/06/2018	PBT (Article 57d) vPvB (Article 57e)	ED/61/2018	
Decamethylcyclopentasiloxane D5	208-764-9	541-02-6	27/06/2018	PBT (Article 57d) vPvB (Article 57e)	ED/61/2018	

Substance name	EC	CAS	Date of inclusion	Reason for inclusion	Decision	Submitted by
Dicyclohexyl phthalate DCHP	201-545-9	84-61-7	27/06/2018	Toxic for reproduction (Article 57c) Endocrine disrupting properties (Article 57(f) - human health)	ED/61/2018 EU/2018/636	
Disodium octaborate	234-541-0	12008-41-2	27/06/2018	Toxic for reproduction (Article 57c)	ED/61/2018	
Dodecamethylcyclohexasiloxane D6	208-762-8	540-97-6	27/06/2018	PBT (Article 57d) vPvB (Article 57e	ED/61/2018	
Ethylenediamine EDA	203-468-6	107-15-3	27/06/2018	Respiratory sensitising properties (Article 57(f) - human health)	ED/61/2018	
Lead	231-100-4	7439-92-1	27/06/2018	Toxic for reproduction (Article 57c)	ED/61/2018	
Octamethylcyclotetrasiloxane D4	209-136-7	556-67-2	27/06/2018	PBT (Article 57d) vPvB (Article 57e)	ED/61/2018	
Terphenyl, hydrogenated	262-967-7	61788-32-7	27/06/2018	vPvB (Article 57e)	ED/61/2018	

Appendix 10 – Assessment of the Consolidated Annual Activity Report of the Authorising Officer for 2018

In assessing the Consolidated Annual Activity Report 2018, the Management Board makes the following observations :

1. The report provides a detailed account of the activities carried out by ECHA in 2018, a comprehensive overview of activities, 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.

2. In the view of the Management Board, the overall performance and quality of the outputs was high. Despite the risks and constraints in some areas, ECHA achieved 58 out of the 69 performance targets set in the Work Programme 2018.

3. The Management Board welcomes the steps that ECHA has taken to implement the 13 recommendations of last year's Management Board assessment, noting that some of these recommendations are of an ongoing nature and still relevant.

The Management Board welcomes in particular the following achievements:

1. With the reorganisation and the adoption of its new strategic priorities, ECHA took relevant actions towards implementing the recommendations of the second REACH Review. ECHA undertook a reorganisation – effective as of 1 January 2019 – in order to meet stakeholders' needs and expectations. The new organisation aims to create a new organisational structure tailored to the Agency's activities, processes and competences, and supporting up-to-date staff development opportunities, efficient and flexible ways of working, while allowing the on-boarding of new tasks in a smooth way. Focus areas and priorities for the years to come changed towards more impact-oriented ones.

2. ECHA's new strategic priorities link closely to the United Nations Sustainable Development Goals. The input from the Commission's REACH Review helped to focus ECHA's priorities on where they matter most for protecting human health and the environment. By developing its new strategy, the Agency prepared for future challenges in efficiently and effectively carrying out core tasks under REACH, CLP, BPR and PIC together with new areas of work such as for Poison Centres, Occupational Exposure Limits, the Waste Framework Directive, the EU Chemicals Legislation Finder and Persistent Organic Pollutants.

3. The performance management model of the Agency was revised in line with ECHA's new strategic priorities, with the purpose of defining more outcome and impact-oriented indicators to allow for the future measurement of the intermediate and long-term impact of the Agency's actions in protecting human health and the environment.

4. The Management Board highly appreciates the work performed by the Agency in successfully managing the last REACH registration deadline on 31 May 2018, with extensive amounts of information on chemicals on the European market now being publicly available. Companies received support for registering 37 441 dossiers and benefitted from enhanced support to prepare their registration dossiers.

5. ECHA has developed an approach to map the chemical universe of REACH registered substances to support achieving the aim of the Integrated Regulatory Strategy and increasing transparency on how authorities address all substances on the EU market in a proportionate manner.

6. ECHA continued to focus on generating substance information required to clarify the long-term effects on human health and the environment, and increased the efficiency of evaluation by addressing groups of substances.

7. The Management Board appreciates the work performed by ECHA to prepare for the United Kingdom's withdrawal from the European Union, and in particular the dedicated section on ECHA's website providing relevant assistance and advice for various scenarios that companies may face.

8. The Agency achieved a high degree of budget execution and low degree of vacancies, and the Management Board notes that the Agency collected higher than estimated volumes of fees and charges under the REACH Regulation, which generated a surplus.

9. As a high priority, the Agency followed up 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.

10. ECHA developed a significant number of draft restriction proposals for submission in 2019 at the request of the Commission or in collaboration with Member States. Some of these were of particular public interest, such as the restriction proposal on microplastics.

11. Building on its Substitution Strategy, ECHA supported substitution by improving access to its public database, increasing the capacity of Member States and stakeholders to analyse alternatives, and enhancing networking opportunities.

12. The EU Observatory for Nanomaterials was further expanded with information on research and innovation and the decision to build an EU Chemicals Legislation Finder has been taken following the conclusion of the (first phase) feasibility study.

13. The first set of tools for harmonised notification has been provided to industry, and the decision was taken to develop the Poison Centres' notification portal for authorities.

14. ECHA has started to provide earlier and increased support to Member States to speed up the Biocides Review Programme. The first Union authorisations have been granted allowing companies to have their biocidal products on the entire EU market with one application.

15. Improved quality of regulatory information in export notifications under the PIC Regulation has enabled non-EU authorities to take decisions more easily and in a more informed way.

16. ECHA's Committee for Risk Assessment (RAC) provided opinions on 62 proposals for harmonised classification and labelling (CLH) in 2018. This almost doubled from the previous year and is the highest number in one year since ECHA started work.

The Management Board recommends for 2019 to:

a. Carefully follow the implementation of the new organisational structure with regards to its objectives as stipulated in paragraph 1 of the achievements above, ensure that it delivers the expected outcomes 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 2019.

b. Continue working on the performance management model of the Agency, including on the further development of outcome and impact oriented indicators that can be shared publicly. This should include continuing to work on the approach to map the chemical universe of REACH registered substances to support achieving the aim of the Integrated Regulatory Strategy and increasing transparency on how authorities address all substances on the EU market in a proportionate manner.

c. Following the REACH Review recommendations and taking due account of the public and political attention, convincingly address the challenge of non-compliance of registration dossiers and make efficient use of the resources allocated for this task in the 2019 Work Programme, e.g. by further advancing in the grouping approach.

d. Implement any measures arising from European Court judgements to ensure that the Agency acts in accordance with the legal text when assessing authorisation applications and drafting opinions; take due account of the relevant European Parliament resolutions and report back to the Management Board regularly on the progress made.

e. In light of the reoccurring lower than expected outcome of the Biocide Review Programme and in light of the increasing workload from the Union authorisations, ensure that relevant actions are taken in cooperation with the Commission and Member States in order to increase the output.

f. In alignment with the Commission, seek sustained funding of the work required of the Agency under Article 9 of the Waste Framework Directive, thus contributing to the Circular Economy Action Plan of the EU. Communicate clearly to the Management Board and the Commission any postponement or deviation from the planning that could jeopardise the fulfilment of legal obligations, and ensure there is a continuous risk assessment with relevant scenarios planned, in particular, if there is no timely solution on sustained funding and staff.

g. Building on the results and insights gained from the initiated studies and external support on the possibilities to forecast fees and charges, including the level of precision and margin of error, and the experiences from 2018, revise, as appropriate, the approach of the Agency to forecast income from fees and charges and agree with the Commission on the level of precision expected on the forecast of fees and charges.

h. Continue to focus on meeting targets on budget execution and report on a four-monthly basis to the Management Board Working Group on Planning and Reporting including on fees and charges income and the state of play of SME status verification. Present a clear and workable plan to the Management Board on the future approach of SME verifications to absorb the 'backlog'.

i. To allow the Agency to carry over appropriations without breaching the budget annuality principle, the budget of the Agency shall contain differentiated appropriations where justified by operational needs (appropriations of multiannual nature). These appropriations shall consist of commitment appropriations and payment appropriations.

j. Closely follow that the ECHA building project progresses as planned to ensure the smooth relocation of the Agency's staff from the current to the new building, and take any measures necessary to mitigate delays or other deviations.

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

l. Implement the necessary measures, as far as possible, to minimise disruption to ECHA's activities and the EU Internal Market due to the United Kingdom's withdrawal from the Union.

Appendix 11 – List of abbreviations

ACEA	European Automobile Manufacturers Association
ACT	Activities coordination tool
ATP	Adaptation to Technical Progress
A.I.S.E.	International Association for Soaps, Detergents and Maintenance Products
BEF	Biocides enforcement project
BIDI	Business intelligence data integration
BPC	Biocidal Products Committee
BPR	Biocidal Products Regulation
CA	Contact agent
Cefic	European Chemical Industry Council
CheMI	European Platform for Chemicals Using Manufacturing Industries
CLH	Harmonised classification and labelling
CLP	Classification, labelling and packaging
Concawe	Environmental Science for European Refining
CoA	Court of Auditors
CoRAP	Community rolling action plan
C&L	Classification and Labelling Inventory
DCG	Directors' Contact Group
DMF	Dimethylformamide
DUCC	Downstream Users of Chemicals Co-ordination Group
EC	European Community
ECHA	European Chemicals Agency
ECPA	European Crop Protection Association
ED	Endocrine disruptor
EFCC	European Federation for Construction Chemicals
EFSA	European Food Safety Authority
ENES	Exchange Network on Exposure Scenarios
EOGRTS	Extended one-generation reproductivity toxicity study
ESIG	European Solvents Industry Group
EU	European Union

EUCLEF	European Union Chemicals Legislation Finder
EUON	European Union Observatory for Nanomaterials
EU-OSHA	European Agency for Safety and Health at Work
FEICA	Association of the European Adhesive and Sealant Industry
FIEC	European Construction Industry Federation
FIMS	Financial information management system
GHS	Globally Harmonised System
HANSEL	Finnish administration procurement system
HUS	Helsinki-Uusimaa Hospital District
IAC	Internal audit capability
IAS	Internal audit service
IPA	Instrument for pre-accession
JRC	Joint Research Centre
MoA	Mode of action
MS	Member State
MSC	Member State Committee
NEPA	Nature and Environment Protection Agency
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational exposure limit
Orgalime	European Engineering Industries Association
OSOR	One substance, one registration principle
PACT	Public activities coordination tool
PAH	Polycyclic aromatic hydrocarbon
PBT	Persistent, bioaccumulative and toxic
PD-NEA	Portal dashboard for national enforcement authorities
PIC	Prior informed consent
PFCA	Perfluoralkylcarboxilic acid
PPORD	Product and process orientated research and development
PVC	Polyvinyl chloride
QAF	QSAR assessment framework
QSAR	Quantitative structure-activity relationship

RAAF	Read-across assessment framework
RAC	Committee for Risk Assessment
REACH	Registration, evaluation, authorisation and restriction of chemicals
REF	REACH enforcement project
RMOA	Regulatory management option analysis
R4BP	Registry for Biocidal Products
SCCS	Scientific Committee on Consumer Safety
SCHEER	Scientific Committee on Health, Environmental and Emerging Risks
SCOEL	Scientific Committee on Occupational Exposure Limits
SDAP	Scientific data analysis platform
SDS	Safety data sheet
SEA	Socio-economic analysis
SEAC	Committee for Socio-economic analysis
SMEUnited	Crafts and SMEs in Europe
SO	Strategic Objective
SPC	Summary of product characteristics
SVHC	Substance of very high concern
TA	Temporary agent
UFI	Unique formula identifier
vPvB	Very persistent, very bioaccumulative
WoE	Weight of evidence