ECHA
EUROPEAN CHEMICALS AGENCY

General Report 2016

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List of acronyms

BPC	Biocidal Products Committee
BPR	Biocidal Products Regulation
C & L	Classification and labelling
CA	Contract agent
CCH	Compliance check
Chesar	Chemical Safety Assessment and Reporting tool
CLH	Harmonised classification and labelling
CLP	Classification, labelling and packaging
CMR	Carcinogenic, mutagenic or toxic to reproduction
CoRAP	Community rolling action plan
CSA	Chemical safety assessment
CSR	Chemical safety report
DNA	Designated national authority
eChemPortal	OECD Global Portal to Information on Chemical Substances
ECHA	European Chemicals Agency
ECM	Enterprise Content Management
EFSA	European Food Safety Authority
ENES	ECHA-Stakeholder Exchange Network on Exposure Scenarios
ES	Exposure scenario
EU	European Union
FAQs	Frequently asked questions
Forum	Forum for Exchange of Information on Enforcement
HelpNet	ECHA Helpdesk and the national BPR, CLP and REACH helpdesks
HR	Human resources
IAS	Internal Audit Service of the Commission
ICT	Information Communications Technology
IPA	Instrument for Pre-Accession Assistance
IQMS	Integrated Quality Management System
IR	Information requirements
ISO	International Organisation for Standardization
IT	Information Technology
IUCLID	International Uniform Chemical Information Database
JRC	European Commission's Joint Research Centre

MAWP	Multi-Annual Work Programme
MB	Management Board
MS	Member State
MSC	Member State Committee
MSCA	Member State competent authority
OECD	Organisation for Economic Cooperation and Development
Odyssey	ECHA's tool to support evaluation tasks
PBT	Persistent, bioaccumulative and toxic
PIC	Prior Informed Consent
PPORD	Product and Process Oriented Research and Development
(Q)SAR	(Quantitative) Structure-Activity Relationship
R4BP 3	Register for Biocidal Products
RAC	Committee for Risk Assessment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REACH-IT	REACH-IT is the central IT system providing support for REACH
REF	REACH Enforcement Project
RIPE	REACH Information Portal for Enforcement
RMO	Risk management option
RMOA	Risk management options analysis
SCOEL	Scientific Committee on Occupational Exposure Limits
SEA	Socio-economic analysis
SEAC	Socio-Economic Analysis Committee
SME	Small and medium-sized enterprise
SONC	Statement of non-compliance following a dossier evaluation decision
SPC	Summary of product characteristics
SVHC	Substance of very high concern
TA	Temporary agent
TP	Testing proposal
TPE	Testing proposal examination
UN	United Nations
UN GHS	United Nations Global Harmonised System of classification and labelling of chemicals
UVCB	Unknown or variable composition, complex reaction products or biological materials
WP	Work Programme
WSSD	World Summit on Sustainable Development 2020

Foreword by the Executive Director

'2016, the year of authorisation'

REACH aims to protect human health and the environment from the adverse effects of chemicals. At the same time, its goal is to enhance the competitiveness and innovation of European industry. Nowhere are these two objectives brought into sharper balance than in authorisation.

Authorisation starts from the identification of substances of very high concern (SVHCs) which have serious irreversible implications for human health and the environment, that are added on the Candidate List. It ends with applications for authorisation which can lead to authorisations that provide the legal ground for users of SVHCs on the Authorisation List to continue their activities after the sunset date.

The ultimate goal of authorisation is to phase out the SVHCs. But that phasing out may have unintended socio-economic impacts which must also be considered. Thus, by law, the positive implications of phasing out SVHCs for health and the environment have to be balanced with the potential socio-economic impact of doing so.

Therefore, companies wishing to continue using an SVHC must make an application based on their ability to manage the risks of the substance and the potentially negative impact on their and their customers' business. ECHA analyses these applications and provides opinions on their risks and socio-economic impacts to inform the European Commission's decision making.

Examining applications is a multifaceted developing process where everyone is learning – the companies about making applications, providers of alternatives about commenting, ECHA about managing the process and providing opinions, and the European Commission and Member States about taking decisions.

The process is also the focus of keen attention from stakeholders and Members of the European Parliament, who want to ensure that the opinions and decisions are robust and transparent. We appreciate that scrutiny and concern, and have responded by working with the key players to improve the entire process and the functioning of ECHA's scientific committees and render it more transparent. Consequently, in 2016 the process matured and became clearer. Further improvement actions are also planned this year.

It is important both for civil society and for individual companies that this process works. Substances on the Candidate and Authorisation Lists are clearly being phased out by early embracers of alternative technologies and substances. Where companies currently have no workable or suitable alternative and can manage the risks, being granted authorisation to use SVHCs gives them a further time window in which they can – and must – find a safer alternative. In all cases, citizens have the right to see that happening.

There are now 173 SVHCs on the Candidate List, five of which were added in 2016 and January 2017. ECHA has also recommended a further nine SVHCs to be added to the Authorisation List bringing the total of recommended substances to 67. On the other hand, after almost a two-year stand-still, in 2016 the Commission began including 12 new substances in the Authorisation List, which currently contains 31 substances.

In parallel, the Agency received applications for 112 uses of SVHCs and provided 63 opinions on such applications bringing the total to 119 by the end of 2016. This proved that ECHA can manage a flood of applications well, which, in 2016, were generated by the widely used chromium VI compounds.

Referring back to the objectives of REACH, authorisation is the most visible change that the legislation makes in market and consumer behaviour. This change brings tangible societal benefits through substitution, innovation and risk reduction to European workers and consumers. I am confident that these benefits for society are higher than the overall expenditures to industry that the application system has induced.

Geert Dancet
Executive Director

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. Certain tasks related to PIC were transferred from the Joint Research Centre of the European Commission to ECHA in 2014.

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

Mission

ECHA is the driving force among regulatory authorities in implementing the EU's ground-breaking chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness.

ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern.

Vision

ECHA aspires to become the world's leading regulatory authority on the safety of chemicals.

Values

Transparent

We actively involve 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.

Highlights 2016

This was the third year of implementing ECHA's five-year strategy, described in the Multi-Annual Work Programme 2014-18, involving further activities in pursuit of the Agency's four strategic objectives. Complementing these four objectives, specific actions were also carried out supporting small and medium-sized enterprises (SMEs) – particularly since many registrants for the final REACH registration deadline of 31 May 2018 for lower tonnage substances – are expected to be SMEs.

ECHA made significant progress in defining its future strategy by agreeing on an ambition for 2025. Furthermore, 2016 saw the continued implementation of the 'integrated regulatory strategy'. This strategy brings together the REACH and CLP processes to create synergies that focus the regulatory work on substances of potential concern with the aim of meeting the World Summit on Sustainable Development (WSSD) 2020 goals.

A wide consultation process was also undertaken to reach a common understanding among all stakeholders on the success factors and the measures needed to achieve the WSSD goals.

1. Maximise the availability of high-quality information to enable the safe manufacture and use of chemicals

2016 was a crucial year for ECHA's preparation for the final REACH registration deadline for phase-in substances. Significant efforts were made to ensure the tools and guidance were user-friendly and stable to enable registrants to start submitting their registration dossiers early, during 2016.

Under the framework of the REACH 2018 Roadmap, ECHA's IT tools and support material for registration (REACH-IT) and dossier preparation (IUCLID and Chesar) have been significantly upgraded, bearing in mind the specific needs of SMEs. A new generation of these IT tools was released as planned, in the first half of 2016, making it easier for registrants to provide information that meets the REACH requirements.

A phased support package aimed at SMEs and inexperienced companies, that facilitates navigation and understanding of the registration requirements, was completed, made available in 23 official EU languages and widely publicised in 2016. New supporting material on alternatives to animal testing was also made available to registrants. Finally, to further simplify the registration process and with the support of the European Commission, ECHA decided in June to offer a free cloud-based service for SMEs starting from 2017, preparations for which are underway.

In parallel, ECHA implemented an enhanced registration process in June 2016 which is improving the quality of registration data and providing a level playing field for companies. Certain data in registration dossiers is now verified manually when it cannot be assessed automatically, and technical steps are taken to prevent companies from illegally submitting registrations outside a joint submission. Thanks to the updated guidance, SMEs now have structured support for their data-sharing negotiations and the enhanced data-sharing dispute mechanism leads to clearer outcomes for the concerned parties.

Of particular benefit to the public, ECHA's dissemination portal was upgraded in January, providing access to gathered data in three levels of detail, ensuring it is tailored to the needs of the user. It was further improved in December with the classification inventory which can now be updated more frequently and the publication of information for which request for confidentiality was not accepted by ECHA.

A new version of Chesar, the chemical safety assessment and reporting tool, was also released. It allows complex substances to be assessed and includes practical guides to help downstream users. These tools are expected to improve the quality of registrations and help the transfer of information in supply chains. In October 2016, the manufacturers (Cefic), users of chemicals (DUCC) and ECHA made a joint commitment to intensify the use of the new tools, such as 'use maps'.

This commitment and the recommendations of the interim evaluation of the joint activity of the Chemical Safety Report/Exposure Scenario (CSR/ES) Roadmap underpin the further development of ECHA's work with industry on using chemicals more safely during the full lifecycle in 2017-2020.

Dossier evaluation continued to progress in 2016 and registrants of high-volume priority substances received more than 140 compliance check (draft) decisions to address data gaps in their registration dossiers for endpoints critical for longer term human health and environmental hazards. Similarly, the last registrants with testing proposals from the 2013 registration deadline received draft decisions by the legal deadline of 1 June 2016.

For both processes ECHA adopted 270 decisions. Through further integration of REACH and CLP processes - e.g. synchronisation of dossier and substance evaluation – any identified concerns are expected to be resolved more efficiently.

2. Mobilise authorities to use information intelligently to identify and address chemicals of concern

In line with the integrated regulatory strategy, the common screening process of the data ECHA holds on substances was used to a greater extent in 2016 by Member States and ECHA to identify and evaluate substances that matter and to initiate further data collection or, directly, regulatory risk management in a coherent way. Screening of ECHA's data resulted in 162 substances being identified because of their hazard properties and widespread uses.

Substance evaluation continued in 2016 and will generate information that enables the regulatory risk management processes under REACH and CLP to start. Following the adoption of the updated Community rolling action plan (CoRAP) 2016–2018 in March, evaluating Member States began to evaluate 39 substances. ECHA took 26 decisions based on previous evaluations.

In preparation for further decisions, Member States evaluated 48 substances and concluded that 32 required further information from registrants to clarify the possible concerns. Out of 20 substance evaluation conclusion documents prepared by the evaluating Member States in 2016, the conclusion was that regulatory follow-up action was necessary in nine cases.

REACH risk management processes continued to deliver tangible benefits for society in 2016. Based on 10 proposals submitted by Member States, five more substances of very high concern (SVHCs) were added to the Candidate List which by January 2017 contained 173 substances. In November, ECHA recommended to the Commission that nine prioritised SVHCs should be added to the Authorisation List.

The two-year peak in the authorisation process that began at the end of 2015 reached its summit in 2016. In total, ECHA received 77 applications for 112 uses, each subject to an opinion from both RAC and SEAC within 15 months. Under this time pressure, the authorisation system worked with increased efficiency and maturity. In total, RAC and SEAC opinions on applications for authorisation for 63 uses were sent to the Commission. The high workload on ECHA opinion-forming will continue in 2017.

Additional work was carried out to improve the process, in particular through the Task Force on the Workability of Applications for Authorisation, which considered how to simplify and streamline the application for authorisation process.

The practical guides on 'How to Apply for Authorisation' and 'Checklists for Applicants', published in December, help applicants to prepare 'fit-for-purpose' applications. These provide the information required for ECHA's committees to evaluate efficiently and provide the Commission with meaningful opinions. ECHA also undertook extra efforts to promote the participation of providers of alternative substances and techniques during the public consultation and invited an increased number of them to the trialogue meetings that precede the opinion-forming process.

Apart from the opinions on authorisation applications, RAC and SEAC issued two opinions on restrictions and RAC adopted 35 opinions on harmonised classification and labelling, which further shows the high work volume of these two committees. Both committees made progress on many other dossiers, with the proposed classification of glyphosate, in particular, raising high public interest.

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

ECHA's Endocrine Disruptor (ED) and Persistent, Bioaccumulative and Toxic (PBT) Expert Groups continued to support the Member States in assessing these complex hazard properties.

At the request of the European Commission, ECHA together with the European Food Safety Authority (EFSA) and the Commission's Joint Research Centre (JRC) began developing guidance on ED hazard identification. This guidance is necessary to implement legislation that will set scientific criteria for identifying substances with endocrine-disrupting properties. This guidance primarily aims to support work under the biocides and pesticides regulations. It will be drafted so that it can also be used for ED hazard assessment under other relevant legislation.

ECHA also published updates to guidance documents on registration, data sharing and information requirements concerning testing for endpoints relevant below 100 tonnes. These updates will help registrants preparing for the final registration deadline and help to avoid unnecessary animal testing. The guidance updates on nanomaterials also progressed in 2016, but will be completed in 2017 and should clarify registration requirements for substances in this form despite further delays incurred by the Commission in revising the relevant REACH annexes.

ECHA further developed its Read-Across Assessment Framework to include environmental endpoints, in addition to the currently available framework for human health. This will further increase the transparency of ECHA's assessment of read-across cases developed by industry and will help registrants to update their dossiers, thereby helping to avoid vertebrate animal testing and related costs. To ensure it fully takes into account feedback on the draft document from accredited stakeholders, the final publication of the RAAF for environmental endpoints was postponed until February 2017.

In April 2016, ECHA organised a well attended science workshop which addressed the use of data and information from new approach methodologies. The new approach methodologies aim to help reduce, refine or replace vertebrate animal testing, thus supporting regulatory decisions for the use of chemical substances. This may lead to further guidance updates in the future.

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

During 2016, ECHA completed a major upgrade of its ICT infrastructure and services, which will primarily benefit all ECHA stakeholders who have access to an increasingly integrated data set and a higher quality service on ECHA's website.

In support of the integrated regulatory strategy, ECHA continued to develop novel means to integrate information on chemicals generated by industry in a central platform for all legislation under ECHA's responsibility. This enabled more effective use of data mining and analysis methods leading also to significant steps in providing information to the general public and authorities.

With the launch of IUCLID 6, ECHA achieved the planned international harmonisation of templates used by industry with regard to uses and exposures, which will make REACH implementation and dissemination more efficient. This will also assist companies and in particular SMEs to standardise communication in the supply chain and identify new opportunities for innovation.

Good progress was made in creating further synergies between the REACH/CLP and BPR processes to the benefit of the review programme regarding existing biocidal active substances, the approval of new active substances and of biocidal products. ECHA also contributed to the finalisation of a Commission study on the review of the Fee Regulation and the assessment of the required resources for ECHA up to 2020. This helped to secure adequate resources for 2017. Good progress has also been made in the guidance work and in keeping the industry well informed of the opportunities that the regulation offers for smart operators.

With the PIC Regulation's established processes, the EU can show the global community a high level of compliance with the Rotterdam Convention. In 2016, the number of notifications that ECHA received on PIC-relevant substances was 30 % higher than in 2015, and 20 % higher than anticipated. An upgrade of the ePIC submission tool and excellent synergies with the other legislation, allowed ECHA to manage this spectacular increase without asking for more resources.

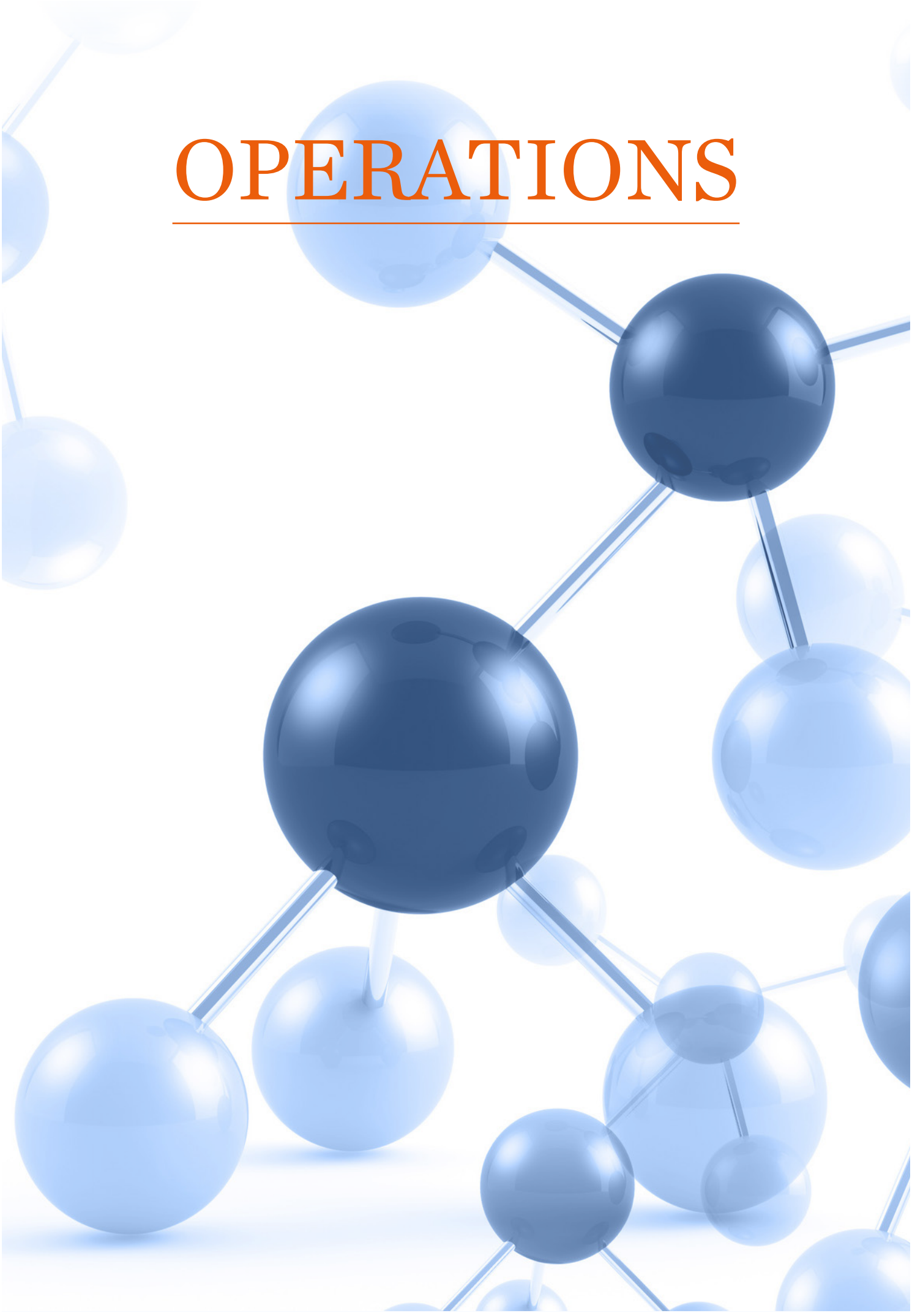
ECHA's scientific committees, the Forum, the Board of Appeal and ECHA's networks, such as the HelpNet, performed well under an increasing workload, displaying their maturity. In particular, it is noteworthy that in addition to the commitment of the regular committee members, the involvement of co-opted members in RAC and SEAC proved very helpful in strengthening specific expertise and handling the workload peak.

In anticipation of new legislation based on the CLP Regulation taking effect, ECHA's Poison Centres' website was launched in April providing information on upcoming legal requirements and tools. The technical guidance was published in November.

ECHA also agreed with the Commission to undertake three initiatives next year: to launch a feasibility study for assessing whether a one-stop-notification portal for submitting information to the Poison Centres would be suitable; to build an EU-wide observatory for nanomaterials aiming to deliver objective and reliable information on their safety aspects in the EU market; and to carry out a feasibility study for developing an EU chemicals legislation finder. Preparatory work was undertaken for all three during 2016 without new resources.

Taking on board feedback from all stakeholders, ECHA published the second five-year report on the operation of REACH/CLP which contributed to the European Commission's preparatory studies for the REFIT evaluation of REACH.

OPERATIONS



REACH dossier management and assessment

ECHA provides assistance and tools to companies for elaborating and submitting their registration dossiers through its helpdesk, guidance and communication activities. The Agency processes the dossiers and assigns registration numbers so that companies can manufacture, import or place their substances on the European market.

ECHA evaluates substance identity, hazard, use and exposure information as well as testing proposals submitted by companies to improve the safety information and thereby risk management of chemicals, and to support the identification of candidates for regulatory risk management measures. The Member States evaluate substances to clarify whether a given substance may pose a risk to either human health or the environment.

Enforcement of the REACH Regulation is the responsibility of EU Member States. However, the Forum for Exchange of Information on Enforcement (the Forum), provides a network of Member State authorities responsible for enforcement with the aim of harmonising their approach to enforcing REACH registration and evaluation provisions.

Registration dossier preparation

Support for registrants enhanced

Companies now have extensive support to help them meet the 2018 registration deadline. ECHA has paid specific attention to guiding small and medium-sized enterprises (SMEs) through the process. This includes structured support to help SMEs meet data-sharing rules, which the European Commission has clarified. In addition, all companies benefit from an enhanced data-sharing dispute mechanism, which leads to clearer outcomes.

Companies also benefit from new versions of IT registration tools – IUCLID for dossier preparation and Chesar for chemical safety assessment – which help them provide the information needed to meet REACH requirements. For example, new features clearly outline which data authorities expect them to provide. The tools also give authorities better accessibility to conduct further analysis, for example, on regulatory risk management.

Main achievements

ECHA had committed to providing companies, by the end of 2016, with a stable regulatory and IT environment in which to prepare their registrations. This included the targeted support to SMEs foreseen in ECHA's REACH 2018 Roadmap[1], finalising all the guidance updates relevant to registration and publishing new, more user-friendly versions of the tools used to prepare the registration, namely IUCLID for dossier preparation and Chesar for chemical safety assessment.

A wealth of information targeted at SME registrants was made available. Following the breaking down of the registration process leading up to the 2018 deadline into six phases in ECHA's REACH 2018 Roadmap, ranging from knowing your portfolio to submitting your registration, inexperienced registrants can now find targeted advice for the successful submission of their dossiers on ECHA's website. The support package, completed in 2016, comprises new web pages in a simple language, and additional material presented in three levels of complexity to enable a stepwise introduction to the content.

Specifically, the practical guide on fulfilling the information requirements for registrations at tonnages of 1-10 and 10-100 tonnes per year is expected to be important for SMEs. SME managers

1 https://echa.europa.eu/documents/10162/13552/reach_roadmap_2018_web_final_en.pdf

The year in numbers

230 000
visits to REACH 2018 web pages since October 2014

3 611
new subscribers to the IUCLID and Chesar websites

3 326
helpdesk questions answered

5
data sharing disputes handles

1235
inquires cncluded

> *We have made a big investment to understand the hurdles of registration for SMEs. The lessons we learned are now reflected in the IT tools for registration and in our support dedicated to SMEs which you can find on our REACH 2018 web pages. I invite all SMEs to have a look to take full benefit of it.*
>
> Andreas Herdina, Director of Cooperation

and REACH coordinators can make use of this document, which explains REACH information requirements in a simple language from a managers' perspective internally and when engaging with service providers about their needs. This guide, and other material on the web pages, is available in 23 official EU languages. The written material is complemented by explanatory webinars outlining the main features of each phase to complete registration. Prompted by ECHA, some national actors took on the task of translating the REACH 2018 webinars into their national language.

By the end of 2016, ECHA's REACH 2018 material had attracted over 200 000 readers as the Agency promoted the web pages through its newsletter, ECHA Weekly and social media channels. Various networks involving partners were also crucial in reaching out to potential registrants: HelpNet, the network of national helpdesks; the Forum, and the *ad hoc* REACH 2018 Communicators' Network were active throughout the year and distributed information on the available support material to their own audiences.

The actions on social media proved to be particularly effective: nearly 1 million followers were reached during the campaigns conducted by ECHA towards the end of 2016. The awareness raising also included major regulatory conferences in Canada, China, Turkey and the USA.

In response to SMEs' concerns, the principles of data sharing were clarified in an implementing regulation issued by the Commission in January[2]. New provisions were taken into account in the support package on data sharing developed for SMEs under ECHA's REACH 2018 Roadmap. It includes step-by-step instructions on how to conduct data-sharing negotiations both when joining an existing substance information exchange forum (SIEF) and when starting a new one, a fact sheet on typical cost elements, and best practice advice for data-sharing negotiations. The number of disputes remained low, and half of those notified were resolved among the parties without an ECHA decision.

Inquiries – the other data-sharing route foreseen in REACH – remained at a similar activity level as in 2015. Inquiries concern newcomers to the market, and in 2016 nearly 30 % of them concerned new substances. This illustrates the dynamics within the chemical market in the EU/EEA. A larger proportion of inquiries (78 %) than in 2015 led to registration; the median time from an inquiry to registration was 87 days.

The implementing regulation prompted the need to revise the guidance documents relating to registration. In May, to give some perspective to companies preparing their dossiers, ECHA

2 Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

communicated the state of play regarding the reviews, and provided draft documents on its website. By the end of the year, all critical generic documents had been published, namely updates to the *Guidance on registration and data-sharing*, as well as the new appendix on substance identification and joint submission in the *Guidance for identification and naming of substances*. Some guidance documents are still under consultation, mainly those related to recommendations on information requirements for nanoforms. The drafts, together with the estimated publication dates, are available on ECHA's website.

Finally, certain industry sectors, such as inorganic pigments and essential oils, benefited from more targeted support from ECHA. As the sectors were able to formulate their specific problems regarding registration, the Agency was able to cooperate with them to provide practical solutions. As a concrete result, the essential oils sector published a guide on the environmental assessment of their substances.

To maximise what ECHA can do to impact the quality of registration information, it published drastically revised dossier preparation tools based on feedback from stakeholders. With the new IUCLID, registrants can better understand what authorities expect and how to submit a compliant dossier. To specifically support SMEs, the installation of IUCLID was streamlined and the application can now be installed with a few clicks as one package. In addition, access to help was simplified and the help documentation was reduced and is now accessible directly through IUCLID.

Furthermore, companies that are members of a joint submission and fully rely on the lead registrant's dossier can now prepare their registrations directly in REACH-IT without having to use IUCLID. To further reduce the technical burden on SMEs, ECHA began preparations to provide IUCLID to SMEs as a cloud service. ECHA's cloud services for SMEs will be launched in three steps during 2017.

Chesar, ECHA's free tool for conducting chemical safety assessments was also upgraded and now supports the assessment of complex cases, such as multi-constituent substances or those with unknown or variable composition, complex reaction products or biological materials (UVCB). In addition, Chesar was adapted to the format of the latest version of IUCLID and now exchanges data with IUCLID more effectively than before. Thus, chemical safety assessments and reports can be created in an easy and harmonised way directly from IUCLID data.

With the aim of supporting registrants to use QSAR models rather than vertebrate animal tests to predict acute toxicity, ECHA published a practical example of how to use the OECD QSAR Toolbox to fill this data gap. New supporting material on alternative methods was published: a practical guide, updated guidance on

REACH registration plays a crucial role

To register a chemical under REACH, a company must document its properties and intended uses and show that the conditions for its safe use are in place.

Registration guides companies to ensure the safe manufacture, import and use of chemicals. Companies that manufacture or import a substance at volumes of one or more tonnes per year, gather and generate the information on the properties and uses of their substances. They document the information in a registration dossier, where they also show that the substances can be used safely.

Under REACH, companies registering the same substance have to prepare their registrations together to reduce costs and avoid unnecessary testing on animals. There are two ways of bringing potential registrants of the same substance together: pre-registration for phase-in substances, and inquiry for non-phase-in substances and phase-in substances not pre-registered. Registration for pre-registered phase-in substances is done in specific groups established for this purpose, known as substance information exchange forums (SIEFs).

Co-registrants must share the existing data among themselves and agree on a cost-sharing model that is fair, transparent and non-discriminatory. In addition, they must agree who will conduct new tests, if they are required. If data-sharing negotiations fail after every effort has been made to ensure their success, a dispute can be raised with ECHA.

various information requirements where new methods have become available, new web pages and a webinar. Finally, to reduce future needs for using animals for testing chemicals, a significant work stream was initiated. ECHA held an international workshop on new approach methodologies, during which the process for developing new methods for replacing animal tests for higher human-health-related end points, such as carcinogenicity, mutagenicity and genotoxicity, was outlined.

IUCLID 6 PROVIDES ENHANCED SUPPORT FOR DATA COLLECTION AND INPUT

Several new features were implemented in IUCLID which support registrants in understanding what kind of information authorities expect, and enable them to better report their specific circumstances in a structured manner. The enhancements were developed based on input from stakeholders. The most prominent changes are:

- A **substance identification profile** which brings clarity on what the hazard data, classification and labelling as well as the hazard and PBT assessments should cover when they are submitted jointly on behalf of several co-registrants.
- An explicit declaration that the registration covers **nanoforms** and the fields for reporting key characteristics of nanomaterials for such compositions.
- Reporting **data-waiving justifications** structured around the REACH framework to make it easier for both assessors and registrants to report and evaluate the information.
- Improved **reporting of alternative methods** by adding fields with templates to report the read-across proposals, QSAR documentation and the considerations made before proposing animal testing as to why the adaptation possibilities provided by REACH could not be used.
- The formats for **reporting identified uses** now supporting the connection between use description and exposure assessment. Instead of a use being defined with a 'flat' list of descriptors, it is now described by defining contributing activities that group the use descriptors. The contributing activities connect directly to contributing scenarios of the exposure assessment.
- The **assessment entity** concept which supports the documentation of complex assessments in the registration dossier. These types of assessments are needed, for example, when the substance transforms during its life cycle into another substance with different properties.
- Possibility to document reasons why the registrant considers that the substance does not meet the **REACH Annex III criteria** and can therefore be registered with lower information requirements. The data template is implemented as a checklist which can also help inexperienced registrants decide whether or not they are following the correct approach in their registration strategy.

Registration and dossier submission

A better, more structured registration process levels the playing field for companies and improves the quality of submissions

Progress towards the third and final registration deadline slowly increased in 2016. Almost half of the registrations for the last deadline came from outside the EU/EEA, and no significant increase in the proportion of SME registrants was observed.

The enhanced registration process, implemented in 2016, has levelled the playing field for companies. They are now forced to respect the 'one substance, one registration principle' foreseen in REACH, which is in place to make sure that no company gains undue benefit.

The revised completeness check works towards improving the information received in registrations. Specifically, the addition of manual checks for information that cannot be automatically assessed, ensures that all the information required by the legislation has been included in the registration dossier.

Main achievements

In 2016, companies' registration activity exceeded the predicted level, with more than 10 000 registration dossiers overall received by ECHA (see Table 1), while inquiries and product and process oriented research and development (PPORD) notifications sent by companies were slightly less than anticipated.

The year in numbers

10 660

registration dossiers received (~60 % updates, 40 % new registrations)

1 263

substances registered for the first time

668

companies made their first registration ever

203

PPORD notifications

TABLE 1: number of dossiers (including updates) submitted (input) in 2016 compared to the workload estimates in Work Programme 2016

Dossier type	Actual 2015	Actual 2016	WP 2016 estimates
Registrations	8 243	10 660	10 000
Full registrations	6 933	8 805	-
Transported isolated			
intermediates	962	1 352	-
On site isolated intermediates	348	503	-
Other types of dossiers			
PPORD notifications	247	203	400
Inquiries received	1 368	1 218	1 600

We now have a solid implementation on what the completeness check entails, and can apply it effectively both for new and already submitted dossiers. Complemented with the strengthened implementation of the "one substance, one registration" principle, we can make sure that no company gains an undue benefit.

Christel Musset, Director of Registration

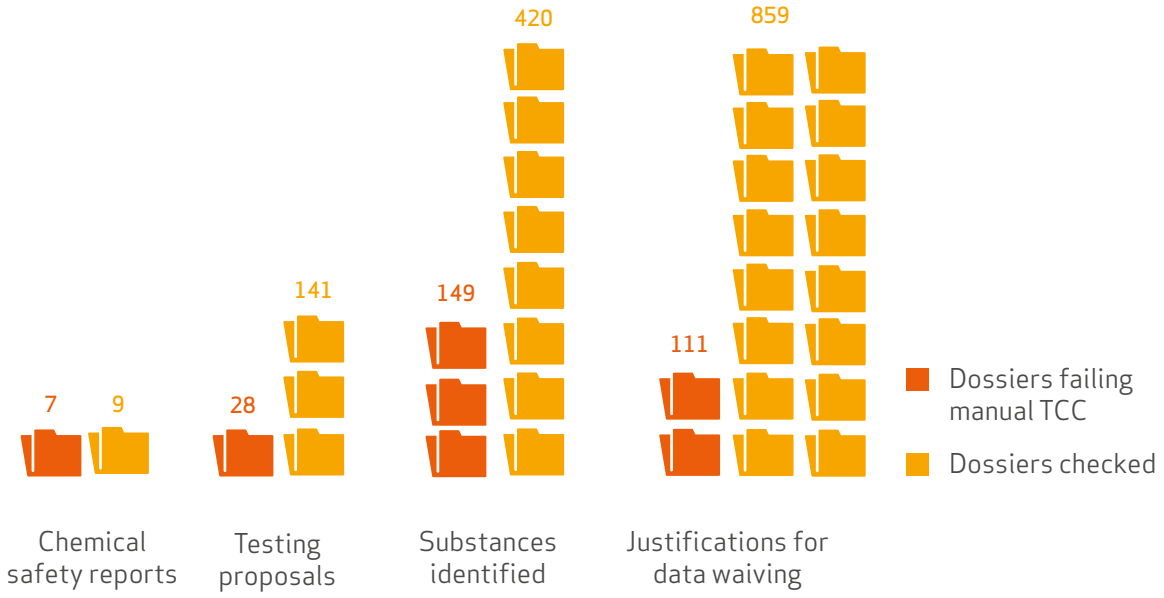
One-quarter of the registrations were relevant for the last registration deadline of phase-in substances. Of these, 40 % came from manufacturers outside the EU/EEA through importers and only representatives, confirming the expectation that a considerable portion of the substances to be registered by the last deadline will be of non-EU/EEA origin.

Finally, only 20 % of the registrations for 2018-relevant substances were done by SMEs – roughly the same proportion as in 2015 – which indicates that these companies have not yet started their registration activities *en masse*. This is not significantly higher than previous years. Thus, it seems that activities for the last deadline are only picking up slowly, and that SMEs are not particularly active yet.

On a wider scale, the continuing interest of new market players in high-production volume chemicals can be observed. A number of substances, mostly commodities, continue to be registered every year in high volumes. This was the case for over 100 substances in 2016. It is anticipated that this trend reflects, and will continue to reflect the natural market turnover.

In 2016, approximately the same number of PPORD notifications were submitted as in 2015, providing information about company R&D activities for new substances and for new processes on existing substances. ECHA contacted 20 % of the notifiers and requested them to clarify their PPORD activity. 70 % of these companies provided the requested information, while the rest either informed ECHA about ceased activity or proceeded with registering the

FIGURE 1: Types of information requested for the 267 dossiers that failed the completeness check upon manual verification by ECHA staff. One dossier may fail in one or several areas



substance. Cooperation with the Member States on PPORDs was enhanced as the communication tool was improved over the year

When companies become active, especially SMEs, they can benefit from the revamped REACH-IT, the IT tool through which companies submit registrations to ECHA, which was published in June. The tool is now more innovative and user-friendly as it has a redesigned front page with quick links to submissions, tasks and substances, and integrated help texts and checklists. External submission manuals (of which there were 22) are no longer needed. The help texts will be available in 23 languages in early 2017.

In 2016, significant enhancements were implemented in the registration process, improving the availability of high-quality information in incoming registrations and levelling the playing field for companies. First, ECHA made changes to the completeness check, introducing also a manual check, based on the experience gained since the beginning of REACH implementation. Secondly, with the new implementing regulation on joint submission of data and data-sharing, ECHA strengthened the 'one substance, one registration principle' in practice to ensure that registrants of the same substance do it jointly when it is submitted.

In parallel with this enhanced registration process for new registrations, ECHA started to retrospectively verify the completeness of previously submitted dossiers in the database, focusing on data waivers for hazard data that had not been substantiated by justifications.

The high update rate of companies contacted (92 % in four months) shows that the retrospective completeness check can be successful in bringing existing registrations to the level of the current completeness check implementation, and ensuring that they contain the data elements intended by REACH as an input for subsequent regulatory processes. If companies do not react by the deadline stipulated by ECHA, their registrations are revoked.

The preliminary results show that the manual checks done by ECHA staff do bring improvements especially in substance identification where manufacturing process descriptions and a breakdown of the composition of UVCB substances have all improved, resulting in clearer substance identity. For well-defined substances, the manual checks have made some registrants reconsider the substance type they are registering.

For data waivers, registrants either refined their justifications to align them with REACH, provided study summaries, or used a read-across approach instead.

Enhanced completeness check

The enhanced completeness check, which was applied as of 21 June 2016, improves the way ECHA checks that all the required elements are provided in the registration dossier and that the information submitted is relevant within the context of REACH.

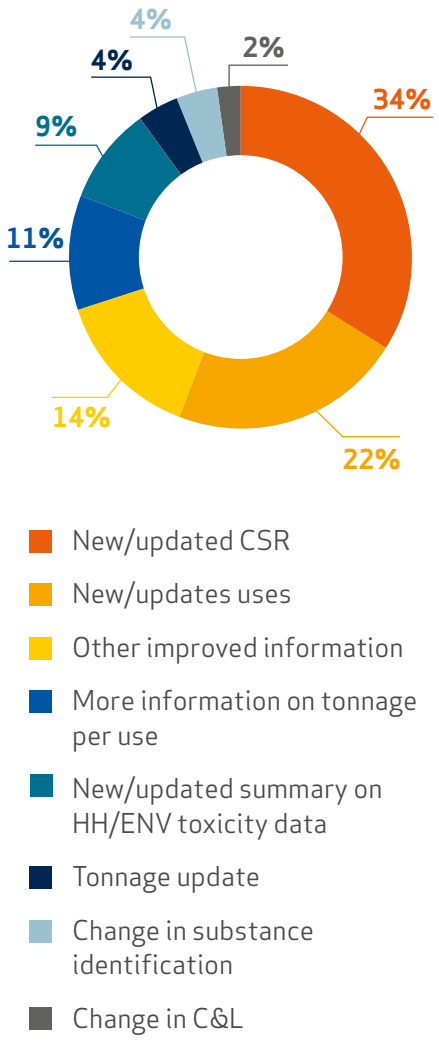
It applies equally to new registrations and updated ones previously submitted. The updated completeness check includes additional manual verifications by ECHA staff where completeness cannot be verified automatically.

The purpose of this is to ensure that when registrants waive or deviate from the information requirements, they provide justifications foreseen by REACH, and that proposals for tests on vertebrate animals are accompanied by considerations as to why none of the REACH adaptation possibilities could be used.

Since the application of the enhanced completeness check until the end of 2016, approximately 33 % of the incoming registration dossiers –1 297 – were stopped for manual verification by ECHA staff. In 20 % of the verified dossiers, registrants were requested to improve the information submitted. In 95 % of these cases, registrants were able to amend the dossiers as requested, and the submissions passed the completeness check at the second attempt.

Figure 1 shows the areas in which the manual verification identified that the information intended by REACH was lacking.

FIGURE 2: Reasons for updating the registration dossier after prompted by ECHA as the substance was put in the list of potential regulatory actions in 2016.



The checks on justifications for omitting the chemical safety report (CSR) mainly prompted registrants to improve their reasoning on why the CSR is not needed, although in some cases the CSR was submitted.

In a similar manner, the decision issued by ECHA's Board of Appeal on 15 March 20163 clarified the possibility for ECHA to retrospectively tackle cases where there was more than one joint submission, or individual registrations outside a joint submission.

The substances within the scope of two appeals related to a joint submission were treated as a priority. Individual registrants of these substances can either:

i. agree and join the joint submission, or
ii. if no agreement can be reached, file a data-sharing dispute within six months.

If the companies do not react within the deadline given by ECHA, their registrations will be revoked.

Companies were also invited to improve their dossiers by other measures. In 2016, ECHA addressed the registrants of the substances shortlisted for substance evaluation or regulatory risk management measures, prompting them to update their registrations before other actions were taken by authorities.

For 40 % of the substances covered by this campaign (2 367 dossiers, 1 426 companies, 270 substances), the registration dossier of the lead registrant at least was updated within four months. The result of the campaign was a 36 % increase in the number of registration updates compared to 2015. Figure 2 presents the reasons for updating the dossiers.

3 Case A-022-2013

ECHA CHECKS INCOMING DATA FOR COMPLETENESS AND TO SEE IF IT RESPECTS THE 'ONE SUBSTANCE, ONE REGISTRATION' PRINCIPLE

At the time of a submission, ECHA checks that the incoming dossier is part of the joint submission for the substance, if this exists. Before assigning a registration number, ECHA verifies the completeness of the information and payment of the registration fee.

Thanks to the registration process, ECHA holds a unique database on chemicals which can be used efficiently in further regulatory processes, especially when identifying whether certain chemicals deserve EU-wide risk management measures and informing the general public.

The registration information is also the starting point for companies to develop their safety data sheets in which they communicate the conditions for safe use further down the supply chain, making the safe use of chemicals a reality for tens of thousands of downstream users and their customers. Thus, it is crucial that the registration information is good enough to achieve the key REACH objectives. In practice, this means that the information is compliant with the regulations, fit for purpose, and readily accessible to all parties.

ECHA also receives other types of dossiers. REACH allows exemption from registration for substances used in product and process-oriented research and development, if such activities are notified to ECHA (in 'PPORD notifications'). ECHA assesses them and may impose additional conditions on the activity. Furthermore, when a prolongation is requested, ECHA can grant an extension to the exemption, in consultation with the MSCAs.

The year in numbers

184
new compliance checks concluded

› 1 200
priority endpoints checked for compliance

164
testing proposals examined

355
follow-up evaluations concluded

46
substance evaluations finalised with a decision or a conclusion

Evaluation

Key information on priority substances checked, requested and generated

Registrants of high volume priority substances received decisions adopted by ECHA following a compliance check and requiring them to close identified gaps in key information in their registration dossiers. Such key information is critical for identifying substances with longer-term human health and environmental hazards and closing the data gaps is essential to ensure the safe use of these substances. ECHA significantly increased the number of new priority compliance checks in 2016.

Registrants continue responding well to ECHA decisions: in the vast majority of the cases ECHA could conclude that the updated dossier is compliant with the information requirements addressed in the decision. Due to further integration of REACH and CLP processes, Member State authorities are now better informed of any conclusions made by ECHA in dossier evaluation on the need for further regulatory action.

ECHA paid specific attention to optimisation of the interface between substance and dossier evaluation processes in 2016: The processes are now better synchronised to resolve identified concerns in a faster and more efficient and effective manner for the purpose to identify substances that require further risk management.

Main achievements[4]

Progress on dossier evaluation

ECHA significantly increased the number of priority **compliance checks** in 2016. From the 156 checks concluded, ECHA found that there were relevant data gaps, prepared a draft decision and sent it for the registrant's comments in 142 cases. This means that the information in the dossier was adequate in only 14 cases. These results confirm that there are important data gaps in the dossiers of substances of potential concern that registrants are required to fill to ensure safe use of their substance.

Registrants submitting valid **testing proposals** when registering their substance for the 2013 deadline have now received a draft decision, and in many cases the adopted decision, too. The legal

4 The annual progress report on evaluation provides a detailed description of ECHA's evaluation and related other activities in 2016. It is available at https://echa.europa.eu/documents/10162/13628/evaluation_report_2016_en.pdf

FOLLOW-UP EVALUATION PROVES THE IMPACT OF ECHA DECISIONS

In 2016, ECHA passed the mark of 1 000 positively concluded follow-up evaluations, in most cases covering more than one endpoint. This illustrates the scale of dossier evaluation and the impact it has on ensuring that registrants provide the information in line with the legal requirements.

Table 2 provides a summary of the outcome of the follow-up evaluations performed in 2016 at the endpoint level. The numbers illustrate the types of requests in ECHA decisions in recent years and the volume of new, usually experimental data that has been missing and is now being generated as a result of the decisions.

TABLE 2: Number and outcome of the follow-up evaluations conducted in 2016, by endpoint.

Endpoint	Outcome		
	Fully compliant	Compliant with deviations*	Non-compliant
Substance identity	90	53	4
Physical/chemical properties	23	12	3
Biodegradation	15	1	1
Bioaccumulation	0	0	1
Other environmental fate/ behaviour	3	2	1
Long-term aquatic toxicity	20	9	1
Other ecotoxicological hazard	6	2	4
Mutagenicity/genotoxicity	30	15	4
Carcinogenicity	0	0	2
Repeated dose toxicity	42	8	7
Pre-natal developmental toxicity	64	35	14
Reproduction toxicity	1	1	0
Other human health hazard	3	2	0
Chemical safety report	67	61	5
Total	**364**	**201**	**47**

*)The registrant provided the information requested in the decision, but ECHA observes that adaptations have been used, or there are deviations from guideline standards or from reporting standards. However, the information is still judged to fulfil the information requirement, which is the basis for the decision.

The information received through the dossier evaluation processes is screened to identify substances where further regulatory actions may be needed. The number of such substances is expected to increase in the future due to the integrated regulatory strategy to address substances and dossiers of potential concern.

FIGURE 3: Final decisions sent to Registrants in 2016 per dossier evaluation type

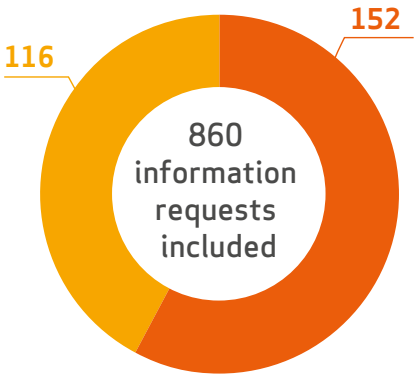
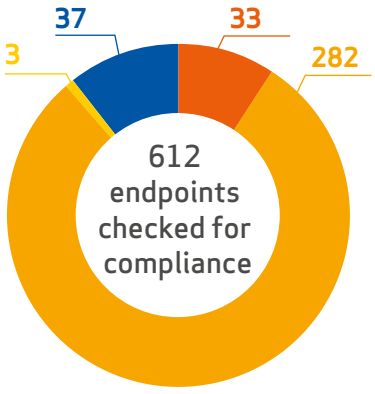


FIGURE 4: Follow-up evaluations concluded (355) in 2016 per type of outcome



deadline set by REACH for ECHA to examine these testing proposals was 1 June 2016, which the Agency successfully met. Otherwise, the number of testing proposals evaluated was lower than estimated. This was due to a delay in receiving the testing proposals on reproduction toxicity, which are expected to be re-submitted after decisions on the 216 cases referred to the Commission for decision. ECHA nevertheless supported the Commission in processing these cases and on compliance check, where more resources than planned were required to address registrants' comments and Member State competent authorities' proposals for amendment.

After the deadline set for the registrant in the decision, the ECHA Secretariat examines the information submitted in a **follow-up evaluation** and concludes whether or not the dossier now complies with the REACH information requirements addressed in the decision. The vast majority of registrants respond in time to ECHA's decisions by updating their dossiers with the requested information. As presented in Figure 4, from the 355 follow-up examinations performed in 2016, ECHA's conclusion was positive in 319 cases and it informed the Member States and registrants accordingly. In 36 of the cases, the registrant had either not submitted any information or the information was not adequate – consequently, ECHA informed the Member State authorities, inviting them to consider enforcement action.

In line with the integrated regulatory strategy's objectives, ECHA further improved the way it draws and records conclusions made in the different dossier evaluation steps and how it communicates the need for further regulatory action to the Member State authorities.

Progress on substance evaluation

Following the adoption of the updated Community rolling action plan 2016-2018 in March 2016, evaluating Member States started evaluating 39 substances – a task with a 12-month deadline, i.e. March 2017.

Substance and dossier evaluation processes are now better synchronised to resolve identified concerns in a faster and more effective manner. In 2016, in collaboration with the Member States, ECHA clarified the interplay between these two evaluation processes. The aim is to speed up the identification of substances that require regulatory risk management measures by using the most effective way to get the necessary information and draw conclusions.

In October, ECHA forwarded the next draft rolling plan for 2017-2019 to the Member State Committee for its opinion. The draft proposes only 24 substance evaluations for 2017. This number, which is lower than expected, is mainly due to the need to wait for important standard information gaps to be closed under a preceding compliance check. This standard information is considered necessary

in deciding what further information should be requested under substance evaluation and, in some cases, it may even be sufficient to draw conclusions on the concern. In other cases, the quickest and most efficient approach has been to perform a compliance check at the same time as substance evaluation.

Of the 48 substances evaluated during the previous year, the evaluating Member States concluded that 32 required further information to clarify the suspected concerns. Consequently, ECHA sent draft decisions to the registrants of these substances. In 2016, ECHA also offered extra support for drafting to evaluating Member States with the aim of having consistent and clear decisions and ensuring smooth decision-making.

Following the earlier annual rounds of evaluation, ECHA adopted 26 substance evaluation decisions requesting further information from registrants to clarify the suspected concerns. The most frequent

> *In this second year of implementing our integrated regulatory strategy, we have made real progress in getting all the work we do in dossier and substance evaluation to deliver efficiently towards identifying substances that require risk management measures.*
>
> **Leena Ylä-Mononen, Director of Evaluation**

THE ROLE AND BENEFITS OF AN EFFICIENT EVALUATION PROCESS.

ECHA evaluates the information submitted by registrants to examine the compliance of the registration dossiers and testing proposals. Since 2015, the compliance checks have focused on priority substances of potential concern and on the key endpoints, i.e. mutagenicity/genotoxicity, repeated-dose toxicity, prenatal developmental toxicity, reproduction toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation and bioaccumulation.

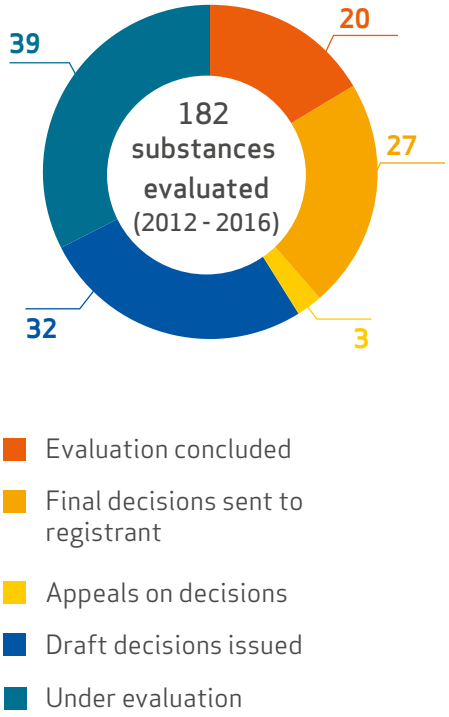
Information on these endpoints is critical for identifying substances with longer-term human health and environmental hazards, while closing the data gaps is essential to ensure the safe use of these substances. ECHA selects the priorities based on a common screening which, at the same time, serves to identify candidates for substance evaluation and regulatory risk management measures.

Once the missing data requested in ECHA's decisions has been generated and made available, registrants can ensure that they themselves have correctly classified and labelled the substance and that their chemical safety assessments and exposure scenarios are adequate to show safe use. Furthermore, authorities can conclude whether further evaluation or regulatory measures are needed or, in the best case scenario, to set the substance aside as it is of low priority for further action.

The purpose of substance evaluation is to clarify if a given substance is a risk either to human health or the environment. Member States evaluate the substances included in the three-year Community rolling action plan and as a result may prepare a draft decision requesting the necessary information to clarify the concern.

ECHA's role is to coordinate the process, ensure its interplay with other REACH and CLP processes, support the Member States in their work and adopt the decisions on substance evaluation. The conclusion document prepared by the evaluating Member State and published by ECHA provides the Member State's view on whether the concerns have been removed or whether regulatory risk management measures are needed to ensure safety. These conclusions inform the authorities, registrants, downstream users and civil society on the safety of the evaluated substance.

FIGURE 5: Status of substance evaluations in 2016



requests in these decisions related to information on exposure and risk assessment, simulation biodegradation testing, mutagenicity and testing on endocrine-disrupting properties.

In 2016, ECHA published 20 substance evaluation conclusion documents prepared by the evaluating Member States. These complete the substance evaluation process and present the conclusions on whether the risks are sufficiently controlled under existing measures, or whether EU-wide risk management measures might be needed. In nine of the cases, the evaluating Member States concluded that regulatory follow-up action would be necessary.

Communication of risk management advice through the supply chain

Better information flow to improve safety

Companies now have a suite of tools and guidance to enable them to improve the information they must provide on chemical use and exposure and meet the 2018 registration deadline. As a result, downstream users will receive more helpful and consistent advice on the safe use of chemicals and mixtures.

Main achievements

In October 2016, the European Chemical Industry Council (Cefic), the Downstream Users of Chemicals Co-ordination group (DUCC) and ECHA agreed to continue their collaboration on improving communication in the supply chain for the use of chemical products in the EU.

Within the Exchange Network on Exposure Scenarios (ENES), a set of tools, templates and guidance were finalised. These support the efficient generation and communication of information on use from downstream sectors to registrants.

These tools – called 'sector use maps' – are templates where sectors can share how they are using different chemicals. They enable the registrants to carry out a realistic chemical safety assessment (CSA). The advice on safe use resulting from the CSA can be communicated down the supply chain in a harmonised electronic format – called the Exposure Scenario Communication (EScom) standard.

The year in numbers

4
sector use maps

2
Chesar releases

4
ENES meetings

5
Guidance documents

COMMITMENTS OF CEFIC, DUCC AND ECHA ON SECTOR USE MAPS, 6 OCTOBER 2016

Cefic will raise awareness and encourage its member companies to utilise sector use map information in their 2018 registrations and when updating previously submitted registrations. Furthermore, it will encourage the customer sectors downstream to provide this information to the fullest extent feasible.

DUCC will continue raising awareness among downstream industry organisations to produce sector use maps to support registrants in generating meaningful exposure scenarios.

ECHA will support industry in ensuring that the communication on safe use up and down the supply chain is comprehensive, effective and easy to understand, including the provision of tools and dissemination of lessons learned.

Use map packages gives sector-based overview of chemicals use

The use map package has been developed to support downstream user organisations collect structured information on how chemicals are used in their sectors. Examples of such sectors include:

i. adhesives and sealants;
ii. construction;
iii. imaging and printing;
iv. cosmetics and personal care products; and
v. soaps and detergents.
They provide this information in a harmonised way to registrants through a use map package, which has four templates:

- One for the general description of uses; and
- Three to report the information needed to assess exposure to workers (SWEDs), the environment (SPERCs) and consumers (SCEDs) for those uses.

Four sectors published use maps in 2016. The use map template gives a simple overview of the most common uses in a sector along with the related conditions of use in the sector. The three exposure assessment templates are linked to the use map template. These map out the life-cycle stages of how a substance is used.

One benefit of use maps is that registrants no longer need to contact external experts to help out in the generation or updating of their registration dossiers. Obviously, registrants need to start using the use maps to get the associated benefits.

ECHA, with the help of external reviewers, performed an interim evaluation of the CSA programme, the CSR/ES Roadmap and ENES. In October, it recommended that ECHA continue its work to maximise the take-up and use of the ENES products. It also recommended that the ENES produces a communication plan to actively promote the work, particularly to those companies and industry organisations currently not involved. In particular, this concerns end-users of chemicals in the form of mixtures, and their information needs. Finally, the evaluation recommended that the ENES skill set, which is consistent with the requirements of targeted marketing, needs to be improved. Welcoming the recommendations, ECHA, together with stakeholders, will prepare an enhanced programme to improve the communication of risk management advice through the supply chain for 2017-2020.

ECHA upgraded its online guide to safety data sheets and exposure scenarios to a more interactive and user-friendly format. This helps SMEs in particular.

Throughout 2016, ECHA gave advice to downstream users in its newsletter, as well as in factsheets and tips for users of chemicals in the workplace. ECHA also made downstream user information more accessible over the web and informed them on topical issues through social media and other communication channels.

ECHA supported the scope and design of the fifth European Enforcement Project (REF-5). This project helps to check the consistency of exposure scenarios with the safety data sheets and the chemical safety report. Field work is carried out by national enforcement authorities in 2017.

> *The joint commitment of October 2016 between manufacturers and users of chemicals and ECHA will underpin our future cooperation for making the use of chemicals safer in the years to come. The external evaluation of our joint activity proved the worth of this cooperation. We can develop this work for 2017-2020.*
>
> **Geert Dancet, Executive Director**

SAFETY INFORMATION COMMUNICATED THROUGHOUT THE SUPPLY CHAIN

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Risk management

ECHA supports the implementation of the restrictions and authorisation titles under REACH.

The authorisation procedure aims to assure that the risks from substances of very high concern (SVHCs) are properly controlled and that the substances are progressively replaced by suitable alternatives while ensuring the functioning of the EU's internal market.

Restrictions are designed to address unacceptable risks from chemicals at the EU level. They limit or ban the manufacture, placing on the market or use of certain substances within the EU. Through its Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC), ECHA provides opinions for the Commission on authorisation applications and proposals for restrictions.

The CLP Regulation ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the EU through the classification and labelling of chemicals. ECHA manages the process with regard to harmonised classifications and, through RAC, provides opinions for the Commission on proposals for harmonised classification and labelling of substances. ECHA maintains a classification and labelling inventory. It also decides on alternative name requests where a company wishes to keep the real name of a substance used in a mixture confidential.

ECHA keeps duty holders and national helpdesks updated on developments through its helpdesk, communications and HelpNet as well as through its guidance activities.

ECHA maintains contacts with peer agencies in Australia, Canada, Japan and the United States of America to exchange knowledge and experience, particularly on risk identification and risk management topics.

Identifying needs for regulatory risk management

Common screening approach focuses resources on top risks

A common screening approach allows ECHA and Member States to focus on substances which are potentially harmful to workers, consumers or the environment. The common screening of all available data helps to avoid overlapping work and results in the most efficient use of resources. Requests for additional information or regulatory actions can then be made in a coherent manner.

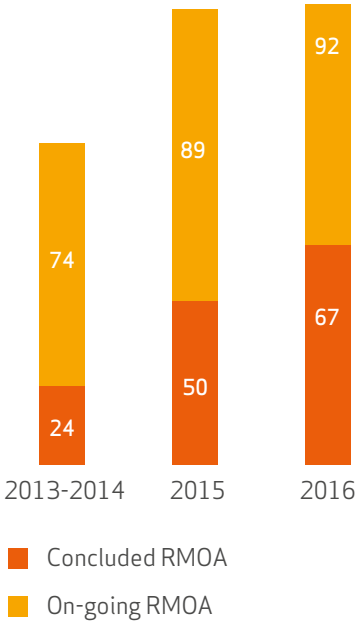
Main achievements

Together with the Member States, ECHA has set up a common screening process to identify substances for different REACH and CLP processes. The two previous screening rounds have addressed most of the substances where the current registrations and C&L inventory include sufficient data to conclude that further information must be generated or further regulatory action taken. Therefore, the third screening round carried out in 2016 focused more on the use of information from other sources, namely hazard prediction methods, structural similarities and the work of regulatory bodies and assessment groups outside the EU.

The third screening round resulted in the listing of 162 substances. All these substances show indications of potential exposure of workers, consumers or the environment due to wide dispersive uses. The potential hazards identified cover all hazard classes which are regarded as of highest concern (carcinogenic, mutagenic and reprotoxic substances (CMRs), sensitisers, endocrine disruptors (EDs), substances that are persistent, bioaccumulative and toxic (PBTs)). The follow-up processes expected to be carried out after the manual verification of the IT-screening results also vary (compliance check, substance evaluation, further assessment of PBT/ED properties, risk management option analysis, dossier preparation for harmonised classification and labelling or for other risk management measures).

The PBT and ED expert groups continued their work to support the Member States which are assessing the substances either to conclude on PBT and ED properties based on the available data or to define whether and what further information should be requested to conclude on these properties.

FIGURE 7: Overview of substances in RMOA (cumulative)



The benefits of a collaborative EU approach to screening

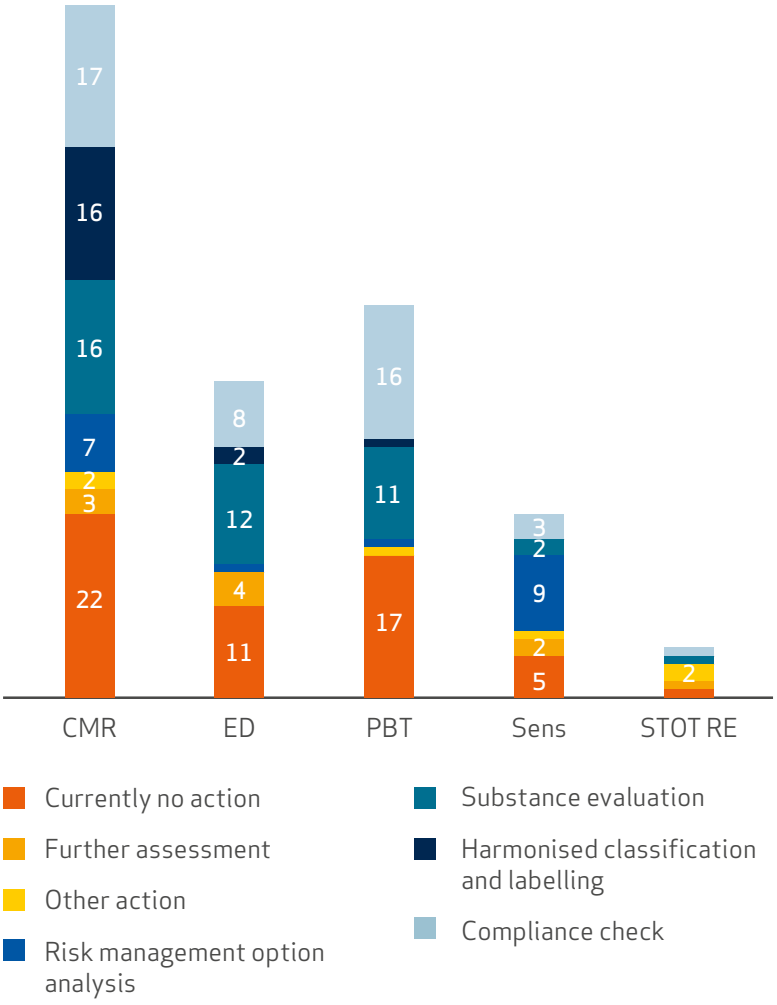
The joint screening of all available data saves Member States' resources by helping to avoid overlapping work. To this end, MSCAs select substances for further work from a shortlist of candidates provided by ECHA. This list also includes substances provided by Member States which reflect national priorities. ECHA collects input from all parties throughout the screening process to ensure that national information is used and national priorities are taken into account when identifying potential concerns. Furthermore, collaboration structures

Evaluating Member States now bring the majority of the substances they consider under substance evaluation and for SVHC identification to the expert groups due to their potential PBT or ED properties. The expert groups also help to draw conclusions that a substance is unlikely to be a PBT or ED, thereby avoiding unnecessary testing.

Cooperation in the ED expert group enabled ECHA to promptly initiate the development of the guidance on ED hazard identification, which will support the application of the criteria for EDs for active substances under the Biocidal Products (BPR) and Plant Protection Products (PPP) regulations.

This guidance development follows a request by the Commission and will be carried out together with EFSA and the JRC. While the guidance was initiated to support work under biocides and pesticides regulations, the hazard identification is not dependent on the use of the substance. Hence, it will be drafted so that it can also be used to support ED hazard assessment under other relevant legislation.

FIGURE 6: Manual screening outcome per property



Risk management option analysis (RMOA) is a voluntary step which aims to enable early exchange among authorities on the selection of the most appropriate regulatory action to address identified concerns.

The Member States' and EC/ECHA's intentions to carry out an RMOA and the conclusions of RMOAs are published to increase the transparency and predictability of the authorities' work.

In 2016, ECHA continued to support the RMOA process by further specifying how specific situations can be addressed within an RMOA, for instance, cases where the concern is related to an impurity in the substance. In addition, the interface between REACH and occupational health legislation has been further investigated.

In 2016, the number of new RMOAs initiated fell compared to previous years. The number of concluded RMOAs remained at the earlier low level. The reasons for the reduced activity and ways of improving the situation will be explored during 2017.

are in place to allow Member States to work both among themselves and with ECHA on similar substances.

All substances placed on the EU market are screened making full use of all REACH and CLP data and also incorporating information from other regions and sources. The common screening provides a level playing field for industry by encouraging authorities to collaborate, take similar approaches and set similar requirements for substances on the EU market.

Substitution is meaningful for the protection of health and the environment and for businesses only if the alternatives are of little or no health and environmental concern and will not immediately need to be replaced themselves. To support sustainable substitution, the common screening identifies structurally similar substances which are, for instance, notified in the EU but not (yet) registered. This gives companies an early indication of substances that may require more careful assessment before they are proposed or used as alternatives.

Industry can be more proactive and better plan its business strategies thanks to the wealth of information available on ECHA's website detailing which substances are on the authorities' radar screen and how these are assessed and addressed.

AN EXAMPLE OF COOPERATION BETWEEN MSCAS AND ECHA

ECHA and a number of Member States are working in close cooperation to regulate poly- and perfluorinated alkyl substances (PFASs) that have PBT or other properties which merit SVHC identification.

A significant number (more than 100) of PFASs have been notified to ECHA and are in the C&L Inventory. Many have also been registered and it is anticipated that a very high number of related substances and precursors will enter the EU in articles.

PFASs are the first large group of substances for which the screening, evaluation, CLH, SVHC and restriction processes have been utilised and scheduled in a targeted way, applying the possibilities for grouping and read across to gain efficiency and ensure timely risk management. In 2016, approximately ten further substance-precursor groups were under examination.

Nonadecafluorodecanoic acid (PFDA), its salts and precursors are one example of this work. Although not (yet) registered, PFDA and its precursors are found, e.g., in textiles, human blood and house dust in Europe. These indicate that this group of substances would enter Europe in many small import volume streams (e.g., imports in articles) and causes exposure. To provide solid basis for the further regulatory actions, the first step was to confirm and establish the hazard properties. Due to carcinogenicity and toxicity to reproduction, a Harmonised Classification and Labelling (CLH) was first established for PFDA, the terminal degradation product of this group. This was followed by SVHC-identification and inclusion in the Candidate List due to Persistent, Bioaccumulative and Toxic properties. The inclusion in the Candidate List obliges the article producers and importers to inform their customers and to notify to ECHA if their articles contain more than 0.1 % of these substances. The PFDA -group is further included in a restriction proposal under preparation which covers also related long-chained PFASs and their precursors.

Authorisation

Authorisation system promotes substitution

An increasingly efficient authorisation system has encouraged more and more companies to take innovative approaches to finding safer alternatives. ECHA intends to do more to support this trend.

In 2016, ECHA and its scientific committees worked on a peak of authorisation applications. Based on the concerns expressed by the European Parliament, ECHA undertook specific actions. For instance, a workshop on the role of socio-economic analysis was held in June and a practical guide for applicants was issued in December.

Furthermore, ECHA continued adding new substances of very high concern (SVHC) to the Candidate List for Authorisation. ECHA recommended that the Commission include nine SVHCs from the Candidate List in the Authorisation List.

Main achievements

Based on 10 proposals submitted by Member States, five substances of very high concern were added to the Candidate List in June 2016 and January 2017. The Member State Committee (MSC) submitted to the Commission its opinions on the five remaining substances which were not included now in the Candidate List. By the end of January 2017, a total of 173 SVHC substances are included in the Candidate List.

In November, ECHA recommended nine SVHCs5 to the Commission for inclusion in the REACH Authorisation List. These substances were prioritised from the Candidate List because of their high volume and widespread uses, which may pose a threat to human health, or may be used to replace other substances already on the Authorisation List. ECHA's recommendation, the MSC opinion and all background documentation are publicly available on ECHA's website.

ECHA and its scientific committees worked on the peak of applications related to chromium compounds, 1,2-dichloroethane and diglyme, among others. The main achievement was that ECHA concluded 63 opinions on applications for authorisation and sent them to the Commission. A functioning authorisation system paved the way for the Commission to propose to add more SVHCs to the

5 Link to the list of SVHCs recommended to be added to REACH Authorisation List in 2016

The year in numbers

5
SVHCs added to the Candidate List

9
SVHCs recommended for the Authorisation List

7
DNELs and dose-response relationships

10
AfA pre-submission information sessions

63
combined opinions of RAC and SEAC on AfAs

1
Practical guide for applicants

Authorisation: a way to achieve safety through substitution

Authorisation concerns two different activities: first is the identification of substances of very high concern (SVHC) which are included in the Candidate List, and their prioritisation into the Authorisation List (Annex XIV). As the use of these substances may pose high risks for human health or the environment, they should eventually be substituted or at least used as safely as possible. The MS competent authorities manage this activity while members of the public can contribute by participating in public consultations. The Commission decides with Member States which substances are placed on the Authorisation List.

The second activity takes place when companies request authorisation from ECHA to use or continue to use substances on the Authorisation List. ECHA manages applications for authorisation processes and provides companies with information and training. The Agency's scientific committees give opinions on each application. These are sent to the Commission which decides, with Member States, whether the authorisation is granted, including its review period and possible conditions.

Authorisation List in 2016.

One milestone in 2016 was the recommendation to authorise the continued use of chromium trioxide under strict conditions in the largest application for authorisation, submitted by a consortium of importers and formulators of chromium trioxide. The consortium members sell the substance to a substantial part of the European chrome-plating industry. This industry serves many important sectors in the EU, such as the automotive and aerospace industry, manufacturing of precision parts, general engineering and printing. The continued use of chromium trioxide has major positive implications for the competitiveness of European industry. At the same time, with the strict conditions proposed in ECHA's opinion imposed, it is expected that the health of workers using the substance will be improved considerably. The Commission is due to adopt the decision on this and many other applications in 2017. The opinion-making system is becoming increasingly efficient as the time needed for ECHA staff to process an average case decreased by about 10 % in 2016. Thanks to the efficiency gains since the beginning of the processing of opinions, ECHA has saved about six full-time equivalents in staff time in 2016. This meant that ECHA was able to provide a better service to applicants, third parties and the authorities during opinion-forming.

Despite good progress, additional work was carried out to improve the application process. In particular, ECHA worked with the Task Force on the Workability of Applications for Authorisation to simplify and streamline the application process.

As a result of this seminal work, ECHA published a practical guide for applicants in December 2016. The guide explains how to:

TABLE 3: 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
Total	**111 (195)**	**180**	**119**	**266**	**64**

i. develop an application strategy;
ii. describe the use applied for;
iii. prepare the main elements (called assessment reports) of the application; and
iv. gather relevant data.

It illustrates these with examples from previous applications and outlines how the review report would be prepared should the applicant need to reapply.

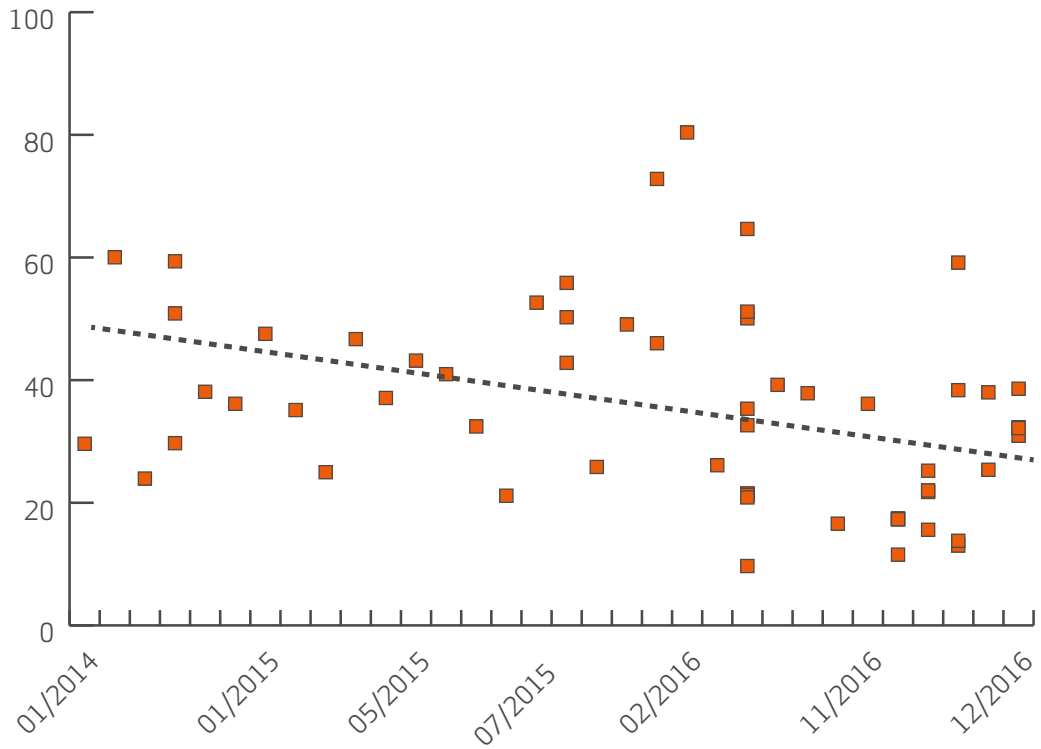
In 2016, ECHA also published checklists to help applicants provide relevant information in the application. The guide and the checklists support applicants in preparing 'fit-for-purpose' applications which can be evaluated in a meaningful way by ECHA's scientific committees, and enable the Commission to take decisions with a clear understanding of their impact.

ECHA also made public standardised 'opinion trees' which facilitated both the opinion-making in the committees and made the process transparent and understandable to the applicants. With the assistance of the Management Board's Advisory Group on the Dissemination of Public Information on Chemical Substances, ECHA undertook extra efforts to promote the participation of providers of alternative substances and techniques during the public consultation and invited an increasing number of them to the trialogue meetings that precede the opinion-forming process.

State of play of applications at the end of 2016

So far, 111 applications for authorisation to use SVHCs have been received by ECHA. These applications cover 22 SVHCs, whose use may only continue if an authorisation is granted. For chromium trioxide, 27 applications have been submitted for 48 uses. By the end of 2016, ECHA's scientific committees have agreed on draft opinions for 140 uses and final opinions for 119 uses. These final opinions are sent to the Commission, which has so far made 64 decisions per use and per applicant.

FIGURE 8: Amount of ECHA's staff time used per authorisation opinion 2014-16 (working days)



> *An increasingly mature opinion-forming process on applications for authorisation has reduced the risks of SVHCs to workers, citizens and the environment in the EU. European companies have also substituted substances with safer alternatives.*
>
> **Jack de Bruijn, Director of Risk Management**

The European Parliament expressed concerns about the authorisation process in its Resolution of 25 November 2015 on the granting of the authorisation for DEHP6. This resolution was deliberated by ECHA's Management Board and specific action areas were identified for the Agency to further improve the application for the authorisation process under REACH and the functioning of ECHA's scientific committees7.

In this context, in June, the Commission and ECHA jointly organised a workshop on the role of socio-economic analysis in applications for authorisation and restrictions. It was concluded that socio-economic analysis does not replace decision-making but supports both opinion and decision-making by providing information on the potential impacts in a transparent manner. It was emphasised that the results must be interpreted with skill and care and that quantification bias must be avoided.

Applicants and authorisation holders may be bought by other companies or change ownership in other ways. Such changes in legal entity need to be notified to both ECHA and the Commission. ECHA has established a standardised way that companies can make these notifications. They now have an easy way to inform ECHA and the Commission about changes in legal entity and to receive a quick response as to whether or not the changes are considered valid.

In 2016, ECHA set up the notification system for downstream users that were using substances based on the Commission's authorisation decisions granted to their suppliers. At the end of 2016, ECHA had received 230 such notifications.

Overall, the authorisation system has encouraged more and more companies to take innovative approaches to finding safer alternatives. This was seen, for instance, by several companies having invested in chromium trioxide-free surface treatment methods, companies informing ECHA that they have found substitutes and thus not applied for authorisation and downstream users notifying ECHA that they have ceased to use lead chromates. Furthermore, as ECHA has not received any applications for a third of the substances on the Authorisation List, this is a further indication of substitution taking place.

In 2016, ECHA worked on substitution with stakeholders with the intent to establish business friendly ways to encourage **substitution**. ECHA published a study that made suggestions on how ECHA, the Commission and Member States could support substitution and how business operators act. Based on this, ECHA started to develop a

6 http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2015-0409+0+DOC+XML+V0//EN

7 https://echa.europa.eu/documents/10162/2200151/final_mb_05_2016_role_echa_committees_en.pdf/a913950d-98e7-41f8-be0c-5dc2326648cb

strategy and concrete actions for the Agency and others for 2017.

ECHA continued to co-chair the OECD Ad Hoc Group on Substitution of Harmful Chemicals and held webinars and published articles on substitution.

APPLICATIONS PROCESS ENSURES USE OF SVHCS FACES EVEN GREATER SCRUTINY

As part of the application process, it is expected that the exposure to SVHCs will be reduced in many workplaces.

In numerous cases, ECHA's scientific committees recommended to the Commission that the authorisations it grants should be subject to additional conditions on the way the substance is used.

For instance, for the cancer-causing substance, chromium trioxide, some applicants have proposed that the risk management measures and operating conditions would result in an exposure of 0.1 micrograms per cubic metre. Currently, exposures in many EU workplaces are often up to five micrograms per cubic metre. Thus, through the applications for authorisation of uses of chromium trioxide, there is a potential to improve the working conditions of thousands of European workers.

Many companies are substituting SVHCs with less-harmful chemicals. For instance, the flame retardant HBCDD (hexabromocyclododecane) is being substituted by a brominated polymer (pFR) in expanded polystyrene.

Furthermore, ECHA has observed that European markets are gradually substituting chromium trioxide with less-harmful or chromium-free alternatives, such as in the decorative plating of plastics and in the passivation of tin-plated steel.

SUBSTANCES IN ARTICLES

The purpose of ECHA's activity on substances in articles is to promote safer use of articles by enhancing the knowledge within industry on their current obligations and supporting the development of approaches and tools that will improve knowledge transfer on substances in, often complex, supply chains. Ultimately, this should substantially improve the availability of information to ECHA and the Member States concerning which substances are present in articles in Europe, which is a prerequisite in light of establishing a non-toxic environment and developing a circular economy.

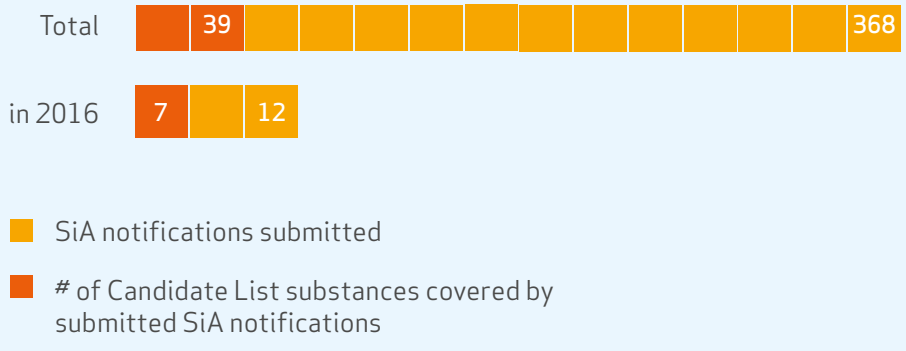
On 10 September 2015, the European Court of Justice (ECJ) clarified how to calculate the 0.1 % threshold for Candidate List substances in articles. Based on this, ECHA started to update its Guidance on requirements for substances in articles. The main aim was to provide producers and importers of articles with practical approaches they can apply to identify and communicate relevant information on the safe use of their articles, at all life-cycle stages, in the most efficient way. Furthermore, the structure and content of the guidance document was streamlined. An exceptionally high number of comments were received in the PEG consultation (more than 700 written comments). By the end of 2016, the main principles had been agreed allowing for the guidance document's finalisation in summer 2017.

Clarifications by the ECJ also attracted a lot of attention and questions from various actors outside Europe. To support companies in understanding their obligations better, ECHA conducted some initial awareness-raising activities in 2016, in particular for non-EU actors exporting products to Europe. There is a growing interest from industry and institutional stakeholders, both in and outside the EU, for ECHA to continue investing in this field in the future.

The Forum for Exchange of Information on Enforcement (the Forum) agreed in November 2016 on a pilot enforcement project on substances in articles, which will be implemented in 2017/2018.

ECHA follows various initiatives, inside and outside Europe, for the development of supply-chain communication tools, as well as for enhanced information for consumers on substances in articles (e.g. mobile phone apps). ECHA is considering greater involvement in this field in the future as its contribution to the practical implementation of the principles of Article 33 in REACH.

Finally, in view of the possible contribution of REACH and CLP to other policy and work areas, ECHA invested somewhat limited resources in discussions with institutional, industrial and non-governmental partners on already existing or potential interfaces and synergies between, for example, REACH and product (e.g. EU Ecolabel) or waste (circular economy package) legislation.



Restrictions

ECHA proposed the restriction of four phthalates and continued to encourage Member States to be active on restrictions.

ECHA proposed that four classified phthalates should be restricted for articles used indoors due to their harmful effects on human fertility. Meanwhile, ongoing work to improve the restriction process also aims to encourage Member States to make new proposals on other substances that matter. An analysis of all 2011-2015 restrictions clearly shows that the benefits outweigh the costs.

Main achievements

In cooperation with the Danish Environmental Protection Agency, ECHA proposed to restrict the use of four classified phthalates (DEHP, DBP, BBP and DDP) in certain articles in April. This will promote further substitution of these substances which are harmful to fertility. ECHA proposed this restriction based on the requirement to consider restricting SVHC substances subject to authorisation, when their presence in articles is a risk that is not adequately controlled[8]. Moreover, the RAC and SEAC adopted joint opinions on two proposals by the Member States

8 Article 69(2) of the REACH Regulation

The year in numbers

4
Workshops

2
Opinions

1
Guideline

1
Report on costs and benefits of Restrictions

TABLE 4: Status of received restrictions per year

	Received intentions	Restriction dossiers by Member States	Restrictions prepared by ECHA	RAC-SEAC opinions	Commission decisions
2009	4	0	0	0	0
2010	1	3	1	0	0
2011	2	1	0	4	0
2012	2	1	1	1	4
2013	7	3	1	2	0
2014	4	4	2	5	3
2015	4	3	0	6	3
2016	**2**	**2**	**2**	**2**	**4**
Total	**26**	**17**	**7**	**20**	**14**

Benefits outweigh the costs

The estimated annual cost of all restrictions for which ECHA's committees gave favourable opinions during 2011-15 was about EUR 300 million. The five most expensive restrictions represent around 88 % of the total costs.

The monetised health benefits (over EUR 700 million per annum) as well as the quantified (reduced emissions of PBTs, very persistent, very bioaccumlative substances (vPvBs) and other substances of concern by about 190 tonnes per annum) and qualitatively assessed benefits of these restrictions clearly outweigh these costs.

to restrict the use of (1) *methanol*[9] as a constituent of windshield washing fluids in concentrations higher or equal to 3.0 %, and as an additive to denaturated alcohol in concentrations higher or equal to 3.0 %, and of (2) *Octamethylcyclotetrasiloxane (D4)*[10], *Decamethylcyclopentasiloxane (D5)* in wash-off personal care products in concentrations higher than 0.1 % of D4, or more than 0.1 % of D5.

ECHA's output in terms of processing restriction opinions was lower than expected in 2016 as only two dossiers were received from Member States. This highlights the importance of the continuing work on making the restriction process increasingly 'fit-for-purpose'. Such work will also encourage Member States to prepare new restriction proposals. However, despite the lack of Member State dossiers, ECHA's work on developing restriction proposals, reports, guidelines and reviews increased significantly in 2016, including work on the high-profile issue of rubber granules in artificial sports fields.

9 Submitted by Poland
10 Submitted by the UK

SOCIO-ECONOMIC ANALYSIS SUPPORTS RISK MANAGEMENT OF CHEMICALS

ECHA has worked with the Commission, the OECD and the Member States to improve understanding on how socio-economic analysis (SEA) is used in regulatory decision-making, in particular in restrictions and applications for authorisation. In 2016, three workshops were held in Helsinki, Brussels and London.

- 'Socio-economic analysis in applications for authorisation and restriction under REACH' was organised by ECHA and the Commission in June. It was concluded that SEA has qualitative, quantitative and monetised information, which is presented in a structured, transparent manner. In particular, it was recognised that SEA helps – but does not replace – opinion and decision-making related to the reduction of risks using chemicals.

- In July, ECHA helped the OECD organise a workshop on 'Socio-economic impact assessment of chemicals management'. As a result, the OECD decided to establish a regular forum to share risk management case studies – including risk management approaches and associated socio-economic impact assessment – to inform decision-making. In addition, the OECD decided to conduct coordinated valuation studies in different member countries in relation to morbidity and environmental endpoints relevant to chemicals.

- The Network of REACH SEA and Analysis of Alternatives practitioners (NeRSAP) held its fifth meeting under the auspices of the Royal Society of Chemistry in London in May. The focus was the improvement of benefit assessment of chemicals control policy. The work of ECHA and Member States on benefit assessment will continue in 2017 based on this symposium.

- In January, ECHA organised a workshop on "Valuing the Health Impacts of Chemicals" to present and review the values that are used. The results were presented in the report "Summary of the Results and a Critical Review of the ECHA study".

Furthermore, the Commission has asked ECHA to prepare several restrictions[11] which will be submitted to ECHA's scientific committees for opinion-forming in 2017. ECHA published a summary of the costs and benefits of all the restrictions it had managed during 2011-2015. The benefits of such restrictions clearly outweighed the costs.

In November, ECHA – together with the Scientific Committee on Occupational Exposure Limits (SCOEL) – issued a joint opinion to the Commission on how to align the occupational limit value and derived no-effect level (DNEL) for 1-methyl-2-pyrrolidone (NMP).

The opinion was based on close collaboration between ECHA's Committee for Risk Assessment (RAC) and SCOEL of the Commission's Directorate-General for Employment, Social Affairs and Inclusion.

While the ECHA Secretariat and RAC spent a considerable amount of effort on this task, in the end, the two committees did not agree on a joint limit value. However, this work will be valuable in further considering the roles of RAC and SCOEL in the scientific evaluation needed for setting occupational limit values. In addition, ECHA contributed significantly to advancing the Commission's wider mandate to harmonise the RAC and SCOEL methodologies related to worker protection issues.

11 Lead as a stabiliser in PVC (submitted in December 2016), lead shots over wetlands (ongoing), restriction related to tattoo inks and permanent make-up (ongoing). More can be found at: https://echa.europa.eu/addressing-chemicals-of-concern/restriction/echas-activities-on-restrictions

ECHA's proposal for restricting the use of DEHP and three other phthalates in certain articles in the EU was a milestone. This was the first restriction of SVHCs in articles, based on Article 69(2).

Matti Vainio, Head of Risk Management Implementation Unit

How do restrictions work in REACH?

Restrictions are a tool to protect human health and the environment from unacceptable risks posed by chemicals in the EU. Restrictions may limit or ban the manufacture, placing on the market or use of a substance. A restriction can apply to any substance on its own, in a mixture or in an article, including those that do not require registration. It can also apply to imports.

At the request of the Commission, a Member State or ECHA can propose restrictions if they find that a risk needs to be addressed on an EU-wide basis. ECHA can also propose a restriction on articles containing substances that are in the Authorisation List (Annex XIV), based on Article 69(2).

Anyone can comment on a proposal to restrict a substance both in the EU and beyond. Those most likely to be interested are companies, organisations representing industry or civil society, individual citizens, as well as public authorities. ECHA's committees on risk assessment and socio-economic analysis provide scientific opinions on all proposed restrictions.

The committees' chairpersons are from ECHA while the members come from Member States but are independent of any influence. Stakeholders observe the work of the committees. The committees' opinions help the Commission, together with the Member States, to take the final decision if a restriction is needed.

Classification and labelling

Consistent approach ensures predictability and transparency

Half of the substances, biocides and pesticides entered or updated for classification and labelling during the year pose long-term health hazards to humans. Due to these actions, their risk to humans or the environment is expected to be significantly reduced. ECHA has continued to consistently implement the classification and labelling process to ensure predictability and transparency for industry and national authorities.

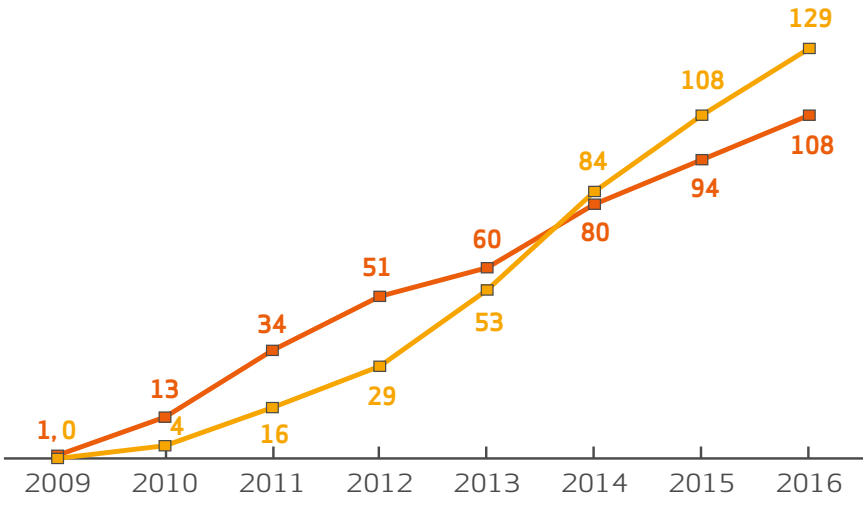
Main achievements

ECHA's Committee for Risk Assessment (RAC) provided opinions on 35 proposals for harmonised classification and labelling (CLH) in 2016.

Half of these CLH cases concerned substances for which the classification had not been harmonised, and half were revisions of existing entries in CLP.

New and revised harmonised classifications require industry to check whether their registrations and SDSs need to be updated and whether new regulatory requirements apply under other legislation. They also

FIGURE 9: Total number of CLH opinions adopted by RAC since 2009



provide authorities with a basis upon which to take action – for instance, to identify a substance as an SVHC because of its CMR properties.

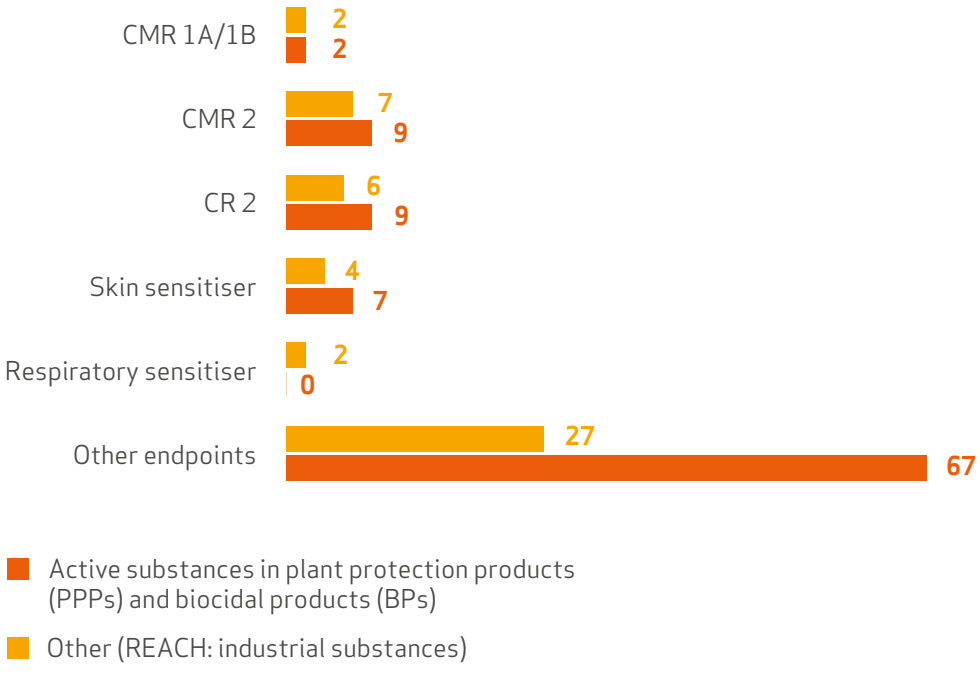
The predictability and transparency of the harmonised classification process is critical due to its importance for both the safe use of chemicals and other 'downstream' legal obligations. Therefore, industry and other stakeholders, such as trade unions, should know which substances are proposed for harmonised classification, and be prepared to comment during the public consultation and later to comply with the possible new obligations. While this was not a new or unique issue in 2016, ECHA has continued to ensure the consistent and robust implementation of the CLH process.

Half of these new or updated entries in CLP are for substances with CMR hazard properties. In addition, for some other entries, the RAC assessed the available information in detail and concluded that it did not support classification as CMR. Confirmation of the absence of CMR properties is important in identifying safer chemical alternatives.

Classification of active substances may have a major impact on the approval process of active substances contained in plant protection products (PPPs) and/or biocidal products (BPs). In 2016, a solid foundation was laid down to conclude on the hazard classification of glyphosate, used in PPPs in accordance with the CLP Regulation in 2017.

This included collecting further information and comments through a public consultation (292 comments were received). RAC

FIGURE 10: Number of endpoints classified by RAC in 2016



Harmonised classification brings benefits to industry

Harmonised classification (CLH) provides a solid basis for industry to carry out their safety assessments and to communicate hazards to users, including consumers.

It has a major impact on the obligations of those manufacturing and importing chemicals. These obligations apply regardless of volumes involved, i.e. also to actors which do not need to register under REACH due to the low volumes manufactured or imported.

Harmonised classification triggers some obligations under other legislation. Furthermore, it enables authorities to take action under other legislation.

CLH also enhances the level playing field in industry which is placing these substances on the market, and triggers more consistent risk management advice to downstream users of substances and mixtures.

This is in particular important as the alignment of self-classifications is proceeding very slowly.

discussed the key issues of a proposal from Germany to classify and label glyphosate. Interested parties (EFSA, IARC, the WHO/FAO JMPR, HEAL representing civil society, the Glyphosate Task Force representing industry, and representatives from Germany as the dossier submitter) were invited to present their views in a plenary session of the RAC, which concluded with a presentation of the appointed RAC rapporteurs. The presentations are posted on ECHA's website[12].

Despite the importance of harmonised classification for the safe use of chemicals, ECHA does not receive CLH dossiers for all pesticides which are already approved in the EU and are in the renewal process under the PPP Regulation. In 2016, RAC concluded only six new entries for REACH substances (chemicals with industrial and/or consumer use), although it has the capacity to handle more dossiers. It is, therefore, essential to increase the MSCAs' capacity to prepare CLH dossiers. It is also important to ensure that the scarce resources are used to address substances that matter for safe use, i.e. substances for which a substantial effect on their safety can be expected from harmonising their classification and labelling. To this end, ECHA has included the identification of CLH candidates in the common screening approach that identifies substances of potential concern. In addition, in May, ECHA organised a workshop for MSCAs to discuss and build a common understanding on which substances would benefit most from the CLH.

Industry has to self-classify substances and endpoints which do not have harmonised classification under the CLP, and to notify these self-classifications in ECHA's classification and labelling inventory.

Although different companies placing the same substance on the EU market have a legal obligation to make every effort to agree on a single classification, there are still many divergences in their classifications.

As the inventory is an important source of information to enhance the safe use of chemicals, in 2016, ECHA made substantial efforts to improve the visibility of self-classification on its dissemination site. For instance, now the endpoints with a harmonised classification are highlighted and the share of notifiers with a certain classification is provided. Furthermore, classification by REACH registrants is differentiated from that provided by notifiers.

ECHA carried out a second pilot project together with the Commission and industry associations aimed at finding an efficient means to help industry carry out its responsibility to agree on self-classification. Although industry had selected substances based on their adverse effects on the diverging classifications for businesses, the pilot project did not result in reducing these divergences.

12 https://echa.europa.eu/-/the-committee-for-risk-assessment-starts-discussing-the-harmonised-classification-for-glyphosate

Biocides

Review programme makes further progress

Progress made in 2016 in delivering opinions on active substances used in biocides helps to achieve the goal of having all such substances currently in use evaluated by 2024. Ultimately, only products for which the risks are assessed as acceptable will remain available for use by workers and consumers.

Main achievements

Thanks to the active contribution of the Member States and the support of its working groups, the Biocidal Products Committee (BPC) adopted 41 opinions on existing active substances in 2016. Although this is lower than the annual target of delivering 50 such opinions and there are concerns about the ability of Member States to continue the timely delivery of their assessments, compared to the past, there is overall more certainty that the review programme on existing active substances will be finalised in 2024 as planned.

These opinions directly support the protection of public health and the environment as the evaluation of an existing active substance leads to either an approval or a non-approval decision on the active substance itself by the Commission.

When an active substance is not approved, the corresponding products must be removed from the market. When it is approved, the corresponding products have to be authorised within three years to stay on the market and the authorisation is only granted when the risks are assessed as acceptable.

The BPC has also adopted eight opinions on the renewal of anticoagulant rodenticide active substances. This is a significant milestone as these are the first opinions on the renewal of approved active substances. In practice, these substances are used to control rodents (for example, rats and mice) indoors, in and around farms, buildings, sewers and open areas like waste dumps where they can be a major nuisance to human activity.

They are all highly toxic substances that carry risks of poisoning for both humans and other animal species besides the targeted rodents. For this reason, the opinions specify a number of conditions to be met and elements to consider when granting or renewing the authorisation of the biocidal products. Since these active substances are meeting the exclusion criteria, the Member States will have to

The year in numbers

24

applications authorisation for Union

2

applications for new active substance

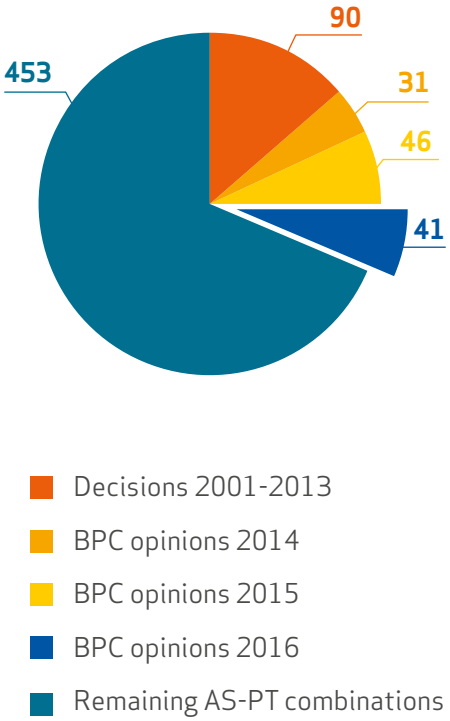
1

opinions on active substances

Thanks to the sustained efforts of Member States and ECHA to evaluate the existing active substances, the biocides market is becoming safer every year. We have to ensure the availability of sufficient resources at both levels to finalise the review programme by 2024

Hugues Kenigswald, Head of Biocides Unit

FIGURE 11: Opinions on active substance/product type (AS-PT) adopted in the review programme



take into account whether suitable alternative products or methods are already available before deciding if it is necessary to grant or renew the authorisation of the biocidal products.

ECHA is becoming increasingly involved in supporting national biocidal product authorisations. In 2016, these support activities took the form of:

- Developing new exposure scenarios for humans and the environment as the additional uses proposed for product authorisation were not previously considered when the active substance was assessed; this helps companies to prepare their applications for product authorisations, and Member States to evaluate them in a consistent manner before authorising the products;

- Identifying sentences frequently used in the summary of product characteristics and their translation into all EU official languages; this helps companies prepare their applications for product authorisations in several countries, and Member States to check the information given to the users before authorising these products.

2016 marked an important breakthrough in the development of the European biocides IT tools. The system now supports the handling of sub-families for biocidal product families, and the new possibilities offered by the revised 'same biocidal products' regulation have been implemented. This increases the flexibility for companies to manage their product portfolio while reducing the corresponding administrative burden for them and the Member States.

Following the deadline of 1 September 2015 for companies to submit applications for inclusion in the list of active substances suppliers, the number of disputes and inquiries fell in 2016 as expected. The dispute process intends to offer a low threshold mechanism to resolve disagreements on data sharing, in particular

PROPOSED NON-APPROVAL FOR A SUBSTANCE TO DISINFECT DRINKING WATER FOR ANIMALS

In October 2016, the BPC adopted an opinion proposing the non-approval of polyhexamethylene biguanide hydrochloride (PHMB) (1 600; 1.8). This active substance, proposed to be used to disinfect drinking water for animals, was considered to present unacceptable risks for the environment. This opinion follows two previous opinions adopted in 2015 which also proposed the non-approval of this substance for other uses: hygienic hand wash and preservation of textiles because of the too high risk that may result from the potential exposure of toddlers and infants through wearing the treated textiles or putting them in their mouths.

for SMEs. In 2016, four appeals were brought before ECHA's Board of Appeal. It is a relatively high number compared with the number of dispute settlements and it showed the confidence of applicants in ECHA's Board of Appeal but caused an unexpected impact on ECHA resources.

A considerable number of guidance documents offer companies advice that enables them to conduct data-sharing negotiations with a reasonable effort.

In applying ECHA's policy to simplify and unify access to information on chemical substances from the different regulations (REACH, CLP, PIC and the BPR), the publicly available information on active substances and biocidal products was integrated into the infocards and brief profiles. This provides an overview of regulatory activities related to a substance.

ECHA was also able to contribute to the finalisation of the Commission's study on the review of the Fee Regulation and the assessment of the required resources for ECHA up to 2020. However, no decision has yet been taken on the review of the Fee Regulation.

An active approach to biocidal products authorisation

The authorisation of biocidal products by Member States or the Commission (for EU authorisation) follows a thorough assessment of the risks to humans, animals and the environment and the efficacy of the proposed products. Furthermore, for a biocidal product to be authorised, all the active substances in it have to first be approved. Only active substances that present an acceptable risk to human health and the environment can be approved.

However, the procedure to authorise products containing active substances that were used in biocidal products already present on the European market in May 2000 is different. Those biocidal products can remain on the EU market without being authorised until the end of the evaluation of the contained active substances. These active substances are called "existing active substances".

ECHA coordinates the evaluation of the active substances and the BPC adopts an opinion, which may or may not support the approval of a given active substance, as the final step in this evaluation process. For an EU authorisation of a biocidal product, ECHA also plays a coordinating role for the evaluation of the safety and efficacy and the BPC adopts an opinion, which may or may not support, the authorisation of the product under consideration.

The year in numbers

7967

export notifications for 2016

562

helpdesk questions from companies answered

-1 800

scientific/technical questions answered

PIC

International trade in hazardous chemicals has become more transparent

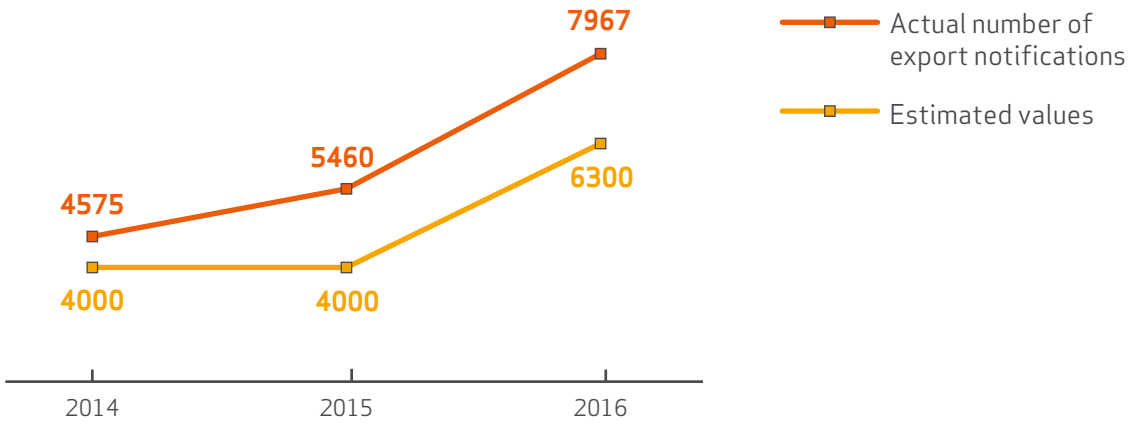
The EU can show a high level of compliance with the Rotterdam Convention to the global community as the processes under the PIC Regulation have matured. Non-EU countries (third countries and economies in transition) now receive a lot more information on chemicals that have been banned/severely restricted in the EU. This includes details on potential imports and sellers. The information helps countries to prevent the import of unwanted chemicals.

Main achievements

Although no new substances were added to the Prior Informed Consent (PIC) Regulation in 2016, it seems that interest in trading PIC-relevant substances has increased as the number of notifications received by ECHA was 30 % higher than in 2015, and 26 % higher than anticipated in the planning.

Nevertheless, pending the receiving country's consent, EU companies get swift access to the non-EU market for these substances since, in 2016, ECHA processed the export notifications efficiently and improved collaboration with non-EU countries.

FIGURE 11: Export notifications for exports in 2014-2016



Efficiency gains resulted from improvements to the ePIC submission tool, whereby certain tasks for the designated national authorities were automated in October.

Upon request, ECHA provided scientific support to the Commission by drafting notifications for final regulatory action for bitertanol (CAS 55179-31-2) and fenbutatin oxide (CAS 13356-08-6).

Overall, transparency of the international trade on hazardous substances is increasing as ECHA is publishing reports based on information submitted to the Agency due to the PIC Regulation. Authorities in both the EU and third countries, stakeholders and European citizens will soon be able to scrutinise information exchanged under PIC in 2014-2015, as ECHA will make the first biannual two reports publicly available on its website in May 2017.

> *I am happy to see that our data intelligence efforts are beginning to bear fruit and we can combine information from different processes, such as registration and PIC, to find cases where authorities' intervention will really make a difference.*
>
> **Christel Musset, Director of Registration**

INTERNATIONAL TRADE: A SHARED RESPONSIBILITY

The PIC Regulation (EU) 649/2012 administers the export and import of certain hazardous chemicals and places obligations on companies wishing to export these chemicals to non-EU countries.

It aims to promote shared responsibility and cooperation in the international trade of hazardous chemicals, and to protect human health and the environment by providing developing countries with information on how to store, transport, use and dispose of hazardous chemicals safely.

Within the EU, this regulation implements the Rotterdam Convention on the PIC procedure for certain hazardous chemicals and pesticides in international trade.

ECHA is responsible for certain administrative and technical tasks. It also provides assistance as well as technical and scientific guidance to industry, the designated national authorities (DNAs) both from the EU and from developing countries and countries with economies in transition, and the Commission.

Data management and dissemination

The year in numbers

Information

5 494

registration dossiers added to the dissemination website

ca. 1 million

views of infocards

49

data and service requests from external parties

ECHA's databases contribute to an improved regulatory strategy and better information to the public

ECHA continued to develop novel means to integrate the information generated by industry on chemicals on a central platform. The platform enables the effective use of data-mining and analysis methods and has led to significant steps in providing information to the general public and authorities. For the first time, the prioritisation of substances was conducted in a truly integrated manner and fed into the development of a common screening strategy covering all REACH and CLP processes.

Main achievements

In 2016, the multi-annual investment in a data-integration platform reached an important milestone. REACH and CLP data sourced from the IUCLID dossiers, the registration process, submissions and several ECHA regulatory processes (e.g. risk management processes, compliance checks) are integrated around chemical substances and used to give information to the general public, provide data to national authorities and carry out regular business reporting (e.g. to manage workload and processes).

In the process, ECHA built a corporate data model and a central regulatory master list of substances representing a master list to which any kind of information on substances can be linked, as well as, potentially, data from external sources. Both components represent building blocks for further enhancing ECHA's data management capabilities.

Thanks to this groundwork and the further development of data analysis tools, REACH and CLP screening activities were further integrated in 2016. In collaboration with the MSCAs, a common screening for all processes was used for setting the priorities. This involved deciding which substances warrant specific regulatory attention with a view to improving human health or the state of the environment, and deciding the best regulatory instrument to address the concern.

To stabilise the regulatory environment for all actors, screening will be done using the same triggers once a year, and early warnings to industry on regulatory actions will be published on ECHA's website. On 27 January 2016, the list of substances shortlisted for regulatory

actions was published for the first time.

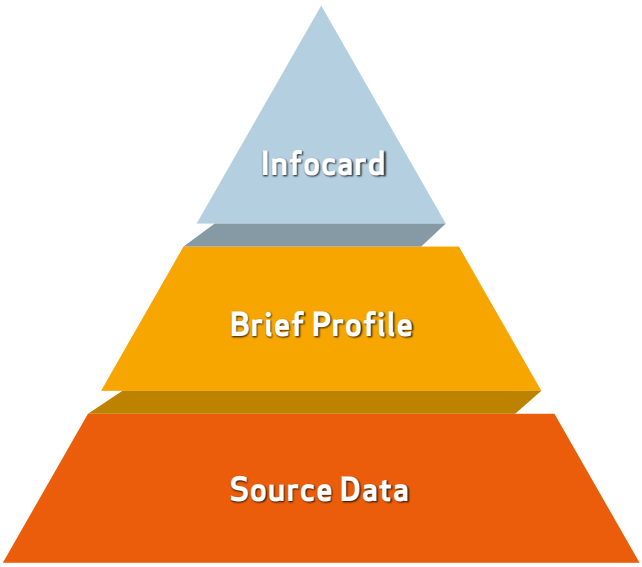
To enhance the possibilities of the Commission and the national authorities to use the data in ECHA's databases efficiently in their day-to-day regulatory activities, easier access to these data was granted along with support for the analysis methods developed by ECHA. For example, ECHA provided support for the 10-year update of the REACH baseline study of the Commission in the context of the REACH review 2017.

Furthermore, to support the work of national enforcement authorities, ECHA released new versions of ePIC and the Portal Dashboard for enforcement authorities, thereby granting access to more data and better functionalities.

Besides the authorities, other stakeholders and the general public also now have tailored access to the information on substances. The revamped dissemination website, launched in January 2016, totally changed the way in which chemical information is displayed by providing three different views of increasing complexity on the information on chemicals held by ECHA.

The **infocard**, which was introduced to serve non-expert audiences, summarises the key information on a chemical substance in plain English. Users can read about the chemicals they are exposed to, where they are commonly used, whether they are hazardous and the precautions they might need to take. In addition, information on whether a chemical substance is regulated, e.g. subject to authorisation or restriction or is classified, is now clearly displayed for all substances.

FIGURE 12: Three different views of increasing complexity on the information on chemicals held by ECHA



Well-managed data on chemicals benefit all ECHA stakeholders

Companies submit data on the hazards and safe use of chemicals to ECHA under REACH, CLP, BPR and PIC. In order to efficiently manage such a database and to produce information of added value from it, ECHA has put in place data-management processes and systems. These include processes for modelling, integrating, disseminating and analysing data. In this respect, the Agency's data-integration architecture is based on a substance-centric model.

The vast majority of the data ECHA holds is disseminated to the general public on its website. This is done at three levels of increasing complexity, to serve different audiences.

ECHA makes the data available to the Commission and Member State authorities by giving remote access to a Portal Dashboard for MSCAs and to repositories of submitted data in the IUCLID format. At the same time, ECHA protects the confidentiality of some of the data that it holds and ensures that data security is of the highest standard.

Finally, the Agency screens the database in an integrated way to support the efficient implementation of ECHA's regulatory strategy.

> *It is our mission towards the European citizens to make the most out of the wealth of information on chemicals submitted by companies. This can be achieved by carefully designing our systems so that the data from various sources can be pooled and analysed as a whole.*
>
> Luisa Consolini, Director of Information Systems

The **brief profile** goes deeper into the environmental, human health and physico-chemical properties of the chemical. It provides a user-friendly overview of the information collected for each substance under the different chemical regulations, which will be most useful for employers, workers, academics and regulators.

The third level, **source data**, includes the raw data submitted by companies to ECHA in REACH registration dossiers and notifications to the classification and labelling inventory. The dissemination portal was further enhanced in December 2016, to include information for which a confidentiality claim had been refused and the C&L inventory refactoring.

To make it easier for SME registrants of low-volume substances to decide what information is required from them, in May, ECHA published an inventory of substances for which the indications are that they are hazardous either to human health or to the environment. For these substances, unless the registrant can argue otherwise in the registration dossier, a full set of details listed in standard information requirements for substances manufactured or imported in quantities of one tonne or more13 is required. For substances not matching any of these Annex III criteria14, and registered at 1-10 tonnes/year, the physico-chemical information is adequate to satisfy the information requirements. The inventory was complemented with guidelines and illustrative examples.

Finally, to provide early support for companies dealing with toxic substances which have to submit notifications to the national poison centres, a new web section was launched in April 2016. The new notification obligations under the CLP Regulation will apply from January 2020 onwards. Efficiencies are created as companies, although notifying their respective poison centres, have one location where they can find information on their obligations and can familiarise themselves with the relevant tools that are the same for everyone. Furthermore, early publication enables companies to prepare and plan the work well ahead of the first deadline.

13 Annex VII to the REACH Regulation
14 i.e. i) substances predicted to be CMR 1A or 1B, PBT or vPvB; ii) substances with wide-dispersive use or diffuse use and hazardous as defined by the CLP Regulation

EXAMPLE OF AN INFOCARD AND INFORMATION IT CONTAINS

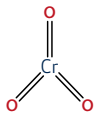
The infocard has an ambitious goal: to make the data on hazards and safe use of chemicals in Europe useful for different stakeholders: industry, non-governmental organisation and citizens. For this, it is essential to summarise the complex technical information submitted by industry on a given substance in plain English. The infocard concept became possible because ECHA developed suitable data management tools such as a central platform and algorithms for integrating and aggregating data from different sources (information submitted by industry for different regulations and information created by ECHA's regulatory work).

Chromium trioxide

Other names: IUPAC names [18] Regulatory processes names [3] Trade names [5] Groups:

Substance identity

EC no: 215-607-8
CAS no: 1333-82-0
Mol. formula: CrO3



Hazard classification & labelling

Danger! According to the Harmonised Classification and Labelling approved by the European Union, this is fatal if inhaled, is very toxic to aquatic life with long lasting effects, causes damage to organs through prolonged or repeated exposure, is very toxic to aquatic life, may cause cancer, causes severe skin burns and eye damage, may cause genetic defects, is toxic if swallowed, is toxic in contact with skin, may cause fire or explosion (strong oxidiser), is suspected of damaging fertility, may cause allergy or asthma symptoms or breathing difficulties if inhaled and may cause an allergic skin reaction.

Additionally, the classification provided by companies to ECHA in REACH registrations identifies that this substance is fatal in contact with skin and is very toxic to aquatic life.

Properties of Concern

C M S

Important to know

- Substance of very high concern (SVHC) and included in the candidate list for authorisation.
- Substance of very high concern requiring authorisation before it is used (Annex XIV of REACH).

About this substance

This substance is manufactured and/or imported in the European Economic Area in 10 000 - 100 000 tonnes per year.

This substance is used in the following products: metal surface treatment products, non-metal-surface treatment products, pH regulators and water treatment products, adsorbents and laboratory chemicals. This substance has an industrial use resulting in manufacture of another substance (use of intermediates).

This substance is used for the manufacture of: chemicals, plastic products and fabricated metal products.

Release to the environment of this substance is likely to occur from industrial use: as an intermediate step in further manufacturing of another substance (use of intermediates), formulation of mixtures, formulation in materials, as processing aid, manufacturing of the substance and in the production of articles. Other release to the environment of this substance is likely to occur from: indoor use as reactive substance.

ECHA has no registered data indicating the type of article into which the substance has been processed.

How to use it safely

- Precautionary measures suggested by manufacturers and importers of this substance.
- Guidance on the safe use of the substance provided by manufacturers and importers.

INFOCARD - last updated: 10/02/2016

GOVERNANCE AND SUPPORT

Management of ECHA bodies and networks

The committees – Member State Committee (MSC), Committee for Risk Assessment (RAC), Committee for Socio-economic Analysis (SEAC) and the Biocidal Products Committee (BPC) – form an integral part of ECHA. They play a crucial role by providing independent scientific and technical advice (i.e. agreements and opinions) for ECHA and Commission decision-making.

The Forum for Exchange of Information on Enforcement provides a network of Member State authorities responsible for the enforcement of the REACH, CLP and PIC regulations, with the aim of harmonising their approach to enforcement.

The HelpNet is a network made up of the ECHA and national BPR, CLP and REACH helpdesks. The HelpNet is governed by the HelpNet Steering Group comprising ECHA, the national helpdesks, the Commission and observers from candidate countries and/or stakeholder organisations.

The Security Officers' Network (SON) is a network of experts from MSCAs, mandated national institutions, the Commission and Cefic, and provides advice to ECHA on issues related to the secure access to ECHA's IT systems.

The Board of Appeal was established by the REACH Regulation to provide interested parties with the possibility of legal redress.

It should be noted that to achieve all the operational activities' objectives, other informal bodies and expert groups function alongside those mentioned above.

The year in numbers

26

plenary meetings in total (all Committees)

99 %

unanimous MSC decisions

97 %

RAC and SEAC opinion adopted by consensus

Committees

Committees' decisions feed into work on chemical safety

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 valuable opinions and agreements to support ECHA and the European Commission's decisions. The commitment of the RAC and SEAC's regular and co-opted members was essential in handling a heavy workload. At the end of the year, there were no backlogs and all processes were carried over smoothly into 2017.

Main achievements

RAC and SEAC successfully managed the high workload caused by a peak in applications for authorisation, with over 60 combined opinions on authorisations agreed or adopted. In fact, a record number of committee meetings were held in 2016 with four RAC meetings, two SEAC meetings, and one MSC meeting being extended into a second week to deal with the extra work. The active involvement of the stakeholders helped to ensure high quality outputs and promoted the transparency of the committees.

Committee members and experts contributed extensively to the evaluation of the safe use of chemicals from different processes within REACH, CLP and the BPR, channelled through their plenary meetings and decision-making structures.

ECHA managed the committees' memberships including the correct implementation of ECHA's Conflict of Interest policy and timely renewal of memberships, and encouraged the competent authorities to ensure adequate capacity for the committees. Furthermore, in 2016, eight co-opted members were fully operational in assessing applications for authorisation.

RAC members	SEAC members	MSC members	BPC members
53 (incl. 4 co-opted members)	43 (incl. 4 co-opted members)	28 members and 24 alternates	28 members and 27 alternates

ECHA also organised a broad range of other smaller-scale meetings, including working groups and preparatory meetings, to facilitate the assessment work entrusted to the committees, the drafting of opinions and other preparatory work to build consensus on important issues. Written consultations and procedures were used to achieve the necessary efficiency, together with continued improvement in the integration of IT tools and platforms.

All these measures allowed the committees to dedicate all available discussion time to the most challenging topics during their meetings, and to deliver high-quality outcomes and opinions with a sound scientific basis.

In 2016, the above resulted in nearly **100** opinions in RAC (99 opinions and two agreements on the DNEL setting within applications for authorisation), 65 opinions in SEAC and 128 agreements and 6 opinions in the MSC.

In total, the BPC adopted 53 opinions in 2016. The opinion-forming activities are covered under the Operations section.

Cooperation with another EU scientific body to resolve scientific conflicts and diverging methodologies related to exposure of chemicals at the workplace

As part of a second Article 95 request, received from the Commission in 2015, the ECHA Secretariat allocated resources to create and support a joint RAC-SCOEL Task Force on the scientific aspects and methodologies related to the exposure of chemicals in the workplace. The first Article 95 request from the Commission to resolve the differences in the case of 1-methyl-2-pyrrolidone (NMP) between the occupational exposure limits (OEL) developed by the SCOEL and the derived no effect level (DNEL) developed by RAC in its restriction opinion on this substance was finalised in 2016 but no agreement was found.

FIGURE 14: RAC plenary meetings in 2016

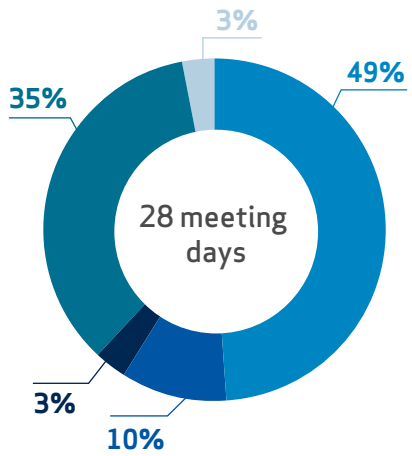


FIGURE 15: SEAC plenary meetings in 2016

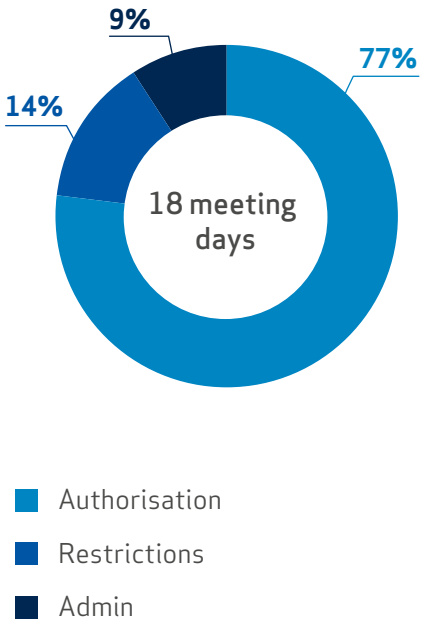


FIGURE 16: MSC plenary meetings in 2016

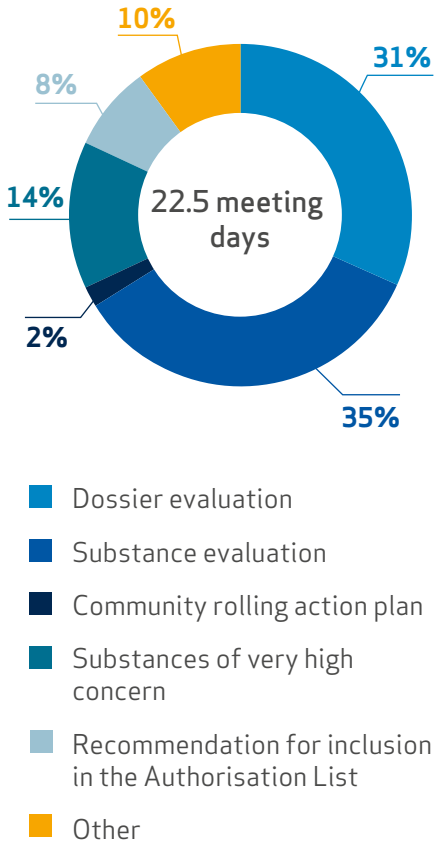
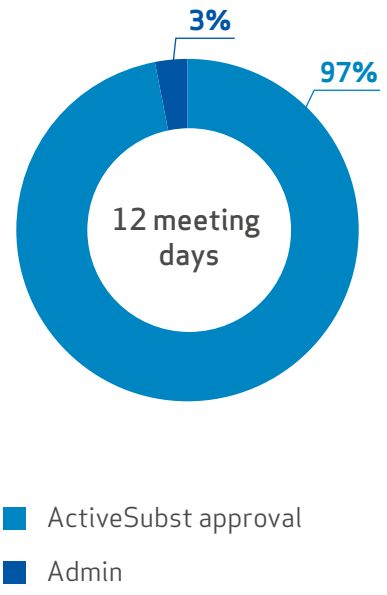


FIGURE 17: BPC plenary meetings in 2016



Forum

A steady output of joint enforcement projects achieved

Seamless collaboration with national authorities underpinned the enforcement measures taken during the year. The Forum's reports on the outcome of three pilot projects revealed that some inspected companies were lax in complying with their obligations.

Main achievements

The seamless collaboration between all actors involved in the Forum's work as well as the experience of the Forum Secretariat in designing, preparing and simultaneously executing a multitude of joint enforcement projects testified to the maturity of ECHA Forum's operations. This collaboration comprises Forum members, national enforcement authorities, MSCAs, the Commission's services, and ECHA's regulatory operations.

This maturity not only underpinned a fluid throughput of such projects, but also resulted in ECHA's decision to entrust a dedicated Forum sub-group to pursue a coordinated approach to enforcing the BPR. That decision was made after close consultation with the Commission and the Member State authorities, especially the Biocides Enforcement Group (BEG) that held three meetings under the auspices of the Commission during 2016.

During 2016, inspectors engaged in two ongoing REF (REACH Enforcement) projects on restrictions and exposure scenarios, respectively. The Forum also focused on enforcing CLP by launching its REF-6 project on compliance with classification and labelling obligations for mixtures and relevant parts of the safety data sheet (SDS). Whilst REF projects regularly involve the national enforcement authorities of all Member States, the Forum's practices also include pilot projects that are targeted at more specific situations affecting some Member States or at trying out new enforcement approaches.

The Forum's reports published by ECHA on the outcome of three concluded pilot projects revealed a varied picture of compliance by inspected companies. Their results unearthed a somewhat worrying lack of safety-consciousness by a significant segment of companies putting containers of hazardous substances on the market with inadequate child-resistant fastenings.

At the other end of the spectrum, interested audiences could take comfort from the highly satisfactory outcome of the first pilot project

The year in numbers

3
pilot projects closed

2
REF projects ongoing

1
REF project selected

128
inspectors trained

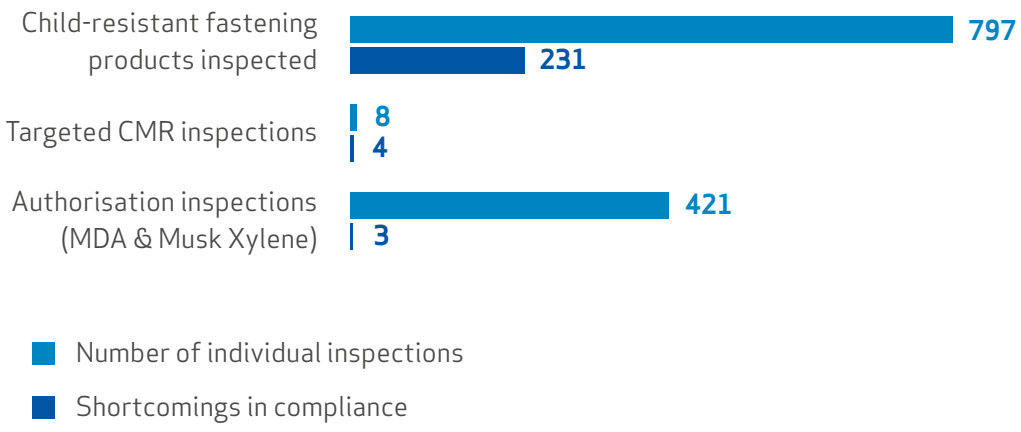
18
active working groups

on authorisation-related obligations for 4,4'-methylenedianiline (MDA) and musk xylene. Inspections revealed that these substances were hardly present on the EU's internal market. Furthermore, they found inspected companies had only breached their REACH authorisation obligations in three instances. A small project on CMRs and skin sensitisers confirmed how ECHA and national inspectorates are able to cooperate smoothly in targeting and enforcing very specific aspects of non-compliance with CLP duties.

From early in the year onwards, REACH and CLP inspectors benefited from the use of a new IT tool, the Portal Dashboard for national enforcement authorities, for which ECHA provided additional features to replace the previous RIPE tool. This aid allows enforcers in the field to have real-time access to relevant substance-related data filtered from ECHA's databases to suit enforcement needs. In preparation for an analogous tool for BPR inspectors, the BEG developed specifications for data and features required by inspectors for the enforcement of the BPR.

Drawing on its experience, the Forum contributed to the design of various tools and procedural mechanisms to enhance the efficiency and effectiveness of inspections. In this respect, examples in 2016 include the finalisation of a compendium of analytical methods for checking compliance with restrictions under REACH as well as an 'Interlinks Guide'. This guide details the modalities according to which ECHA and the national enforcement authorities cooperate in numerous specific scenarios such as enforcing ECHA's regulatory decisions at the national level.

FIGURE 18: Outcomes of the national enforcement actions in 2016



HelpNet and Security Officers Network

Services in place to assist companies and protect IT systems

The HelpNet is well positioned to face the expected demand for its members' services from companies preparing to submit dossiers before the 2018 REACH registration deadline. The approach to security was revised to meet more sophisticated threats to IT systems.

Main achievements

HelpNet

Having gathered experience over nearly a decade since its predecessor (the REHCORN – REACH Helpdesk Correspondents' Network) started work in February 2007, the HelpNet and national helpdesk correspondents have continued to mature their skills.

By 2016, this put them in an adequately robust position to face the particular demands of the 2018 REACH registration deadline, although subject to national resourcing and continued preparatory training over the months to come.

Companies preparing to submit dossiers for the 2018 deadline could benefit significantly from the roll-out, by national REACH helpdesks, of the six comprehensive information packages compiled, with their input and support, within the framework of the REACH 2018 Roadmap. Furthermore, HelpNet correspondents provided their knowledge and insights to the REACH 2018 Communicators' Network, sharing best practice in reaching out to enterprises and in responding to their queries.

The HelpNet workshops held in 2016 separately for REACH, CLP and BPR, for correspondents from 31 national and observer helpdesks focused on keeping them abreast of new information material as well as use of the newly released IT tools (IUCLID 6, REACH-IT and Chesar), not least by providing hands-on training.

'HelpNet Updates', a newsletter provided six times a year by the HelpNet Secretariat for all correspondents, served the same purpose. National helpdesks consistently reused this information material, adapted to their purposes, and provided it in their national languages to convey the contents to their audiences in industry.

The year in numbers

6

HelpNet Updates sent to HelpNet correspondents

6

workshops for REACH, CLP and the BPR

'HOT TOPICS' from national helpdesks:

REACH

Import
Registration
Roles and obligations under REACH
Safety data sheets
Substances in articles

CLP

Classification
Classification and labelling of mixtures
Labelling

BPR

Authorisation
Fees
General obligations under BPR
National procedures

Collaboration within the HelpNet benefited from ECHA's efforts to make efficient use of the WebEx technology when conducting virtual HelpNet workshops. For the first time, a BPR workshop took place remotely, focusing on the interaction of Commission services with national helpdesks, thereby addressing scoping issues.

Security Officers Network

The Security Officers' Network provided advice to ECHA on security issues related to the secure exchange of information pertaining to the REACH, CLP, PIC and Biocidal Products regulations, between ECHA, MSCAs, mandated national institutions and the Commission. In 2016, they reflected critically on the security model, mirroring the experience they had gained over the last five years. The revised model aims to embrace new ways of working, in view of more sophisticated security threats targeting IT systems as well as the availability of more innovative IT solutions.

In May, 34 security officers representing 37 national authorities in EU/EEA Member States gathered in ECHA for their 13th meeting. In their role of safeguarding industry data on chemicals, they focused on the security model and analysed it in depth. The model encompasses standard security requirements for accessing and exchanging information between national authorities, the Commission and ECHA.

They critically considered new security threats and risks along with modern security solutions implemented by the national authorities. They reflected upon modern technology and new ways of working alongside business needs. Even though the network members did not raise compelling reasons for significantly modifying the security model, they decided to revise certain areas and to demonstrate better integration among security elements.

The network appointed a task force group with the aim of having the new security model in place in 2017.

Board of Appeal

New decisions on key rules give companies clarity

In 2016, the Board of Appeal dealt with appeals requiring important aspects of REACH to be interpreted. For example, the Board clarified the joint submission obligation (the 'one substance, one registration' principle), the definition of intermediates, the scope of environmental risk assessment, the requirements for read-across, the definition of nanomaterials, and several aspects of the substance evaluation process.

Main achievements

The Board of Appeal adopted 24 final decisions in 2016 (nine more than forecast); 14 new appeals were received during this period and 19 cases were pending at 31 December 2016. The Registry processed over 1 000 procedural documents. All decisions in closed appeal cases were published online in a searchable database, developing a body of decisional practice and ensuring transparency.

Appeal cases continued to involve highly complex issues. Several appeals concerned the issue of whether or not ECHA exercised its discretion correctly during substance and dossier evaluation. The Board of Appeal examined amongst others the requirements for a read-across justification, and under what circumstances ECHA is entitled to reject such a proposal[15]. It also clarified some of the registrants' procedural rights under the evaluation procedures[16], and in which circumstances companies that register a substance during an ongoing substance evaluation should be included in the procedure[17].

The Board of Appeal further clarified a number of important aspects in the REACH Regulation. These included, for example, provisions concerning the definition of intermediates, the scope of the obligation to perform an environmental risk assessment[18], and the meaning of 'data obtained under relevant conditions' for PBT assessment .It also confirmed that the principle of 'one substance, one registration' ('OSOR') is a fundamental pillar of the REACH Regulation, and that ECHA must apply that principle by rejecting separate registrations submitted outside an existing joint submission. It further confirmed that ECHA can take remedial action for separate registrations which were accepted in the past[19].

15 For example, Case A-004-2015
16 Cases A-009-2014, A-004-2015
17 Case A-013-2014
18 Cases A-010-2014, A-015-2014 and A-018-2014, respectively
19 Case A-022-2013

The year in numbers

24
final decisions

14
new appeals

FIGURE 19: Appeals in 2016

In addition, in several cases the Board of Appeal highlighted the need for ECHA decisions to be clear with regard to their content. For example, in four cases concerning nanomaterials, the Board insisted on a clear definition of terms for reasons of legal certainty[20]. It also stressed the importance of clearly identifying the concerns underlying a request for further information in the context of substance evaluation[21].

In 2016, the Board of Appeal put further emphasis on procedural efficiency. Despite temporarily reduced resources and the complexity of cases, appeals continued to be processed at a satisfactory rate (18-month average duration, excluding withdrawn cases). In particular, following the Commission's amendment of the Rules of Procedure, the Board of Appeal thoroughly reviewed its practice directions to parties (published in February 2017). The review of internal working practices also resulted in simplified procedures.

20 Cases A-008 to A-011-2015
21 For example, Cases A-009-2014, A-018-2014

Management

Long-term perspective for effective management

The past year was a time for taking stock, both in terms of the operations of REACH and CLP and making progress on the 2020 goals of the World Summit on Sustainable Development. In parallel, 2016 also marked the start of a strategic long-term planning exercise, with management focusing on making ECHA's functioning more effective, efficient and transparent.

Main achievements

The World Summit on Sustainable Development (WSSD) in 2002 saw a global political commitment made to sound chemicals management by 2020 by minimising the harmful effects of hazardous chemicals. This has sparked a fundamental change in the EU's chemicals policy.

REACH and ECHA are central players in this overhaul, and with a limited time remaining to complete the goals set by the World Summit, the wide consultative process led by ECHA in 2016 highlighted that the authorities in charge of REACH and CLP, and ECHA in particular, have made considerable progress towards the achievement of the 2020 targets.

In addition, the Agency has supported the efforts of the EU candidate countries and potential candidates by various capacity building activities towards this goal. To have clear and tangible criteria that allow ECHA and the relevant stakeholders to successfully make REACH and CLP deliver on its World Summit 2020 ambitions, ECHA adopted a strategic approach and initiated a set of consultative steps, which allowed a common understanding to be fostered among all stakeholders on the success factors and measures needed to achieve them.

The Agency has also made further progress towards its vision of being the world-leading agency in chemicals management. During the year, this was demonstrated by peers in Australia turning to ECHA for support in implementing IUCLID, Canada and the USA for data on chemicals and authorities in Korea, New Zealand and Taiwan for best practice in the EU chemicals management.

The publication of ECHA's second five-year report on the operation of REACH/CLP in 2016 provided all stakeholders with an in-depth view of the regulatory achievements of these regulations and their impact. The report highlights the wealth of information on chemicals that is now freely available on ECHA's website and points out that

The year in numbers

102

accredited stakeholder organisations

1 501

general enquiries

46

decisions on access to document requests

'HOT TOPICS' in the media:

- Classification of glyphosate
- Safety of rubber crumb used in artificial turf in sports fields
- Safety of tattooing inks
- Authorisations of numerous uses of chromium VI
- REACH 2018 preparations, in particular support needed and provided for SMEs
- Endocrine-disrupting chemicals

increased knowledge of chemical properties leads to improved chemicals management, to safer products and to the phasing out of the most dangerous substances.

Nevertheless, the report includes recommendations for improvement, such as the need for improved quality of data on chemicals, more effective communication in the supply chain, the need to further harmonise the classification of substances at EU level and the need to provide more information to consumers on SVHCs in products. As required by the legislation, key EU institutions and the Member States, as well as ECHA's accredited stakeholders received targeted and relevant information on ECHA's findings, which will enable them to use the information in the report for their future policy-related, regulatory or business decisions.

Facilitated by the Secretariat, ECHA's Management Board was actively engaged in designing the Agency's next strategic plan in 2016, with contributions gathered from ECHA's key stakeholders, its staff and the MSCAs. An important milestone, reached at the end of the year, was the definition of ECHA's ambition towards 2025. This work will continue in a similarly inclusive spirit in 2017. As a next step, ECHA will define its strategic priorities for 2019-2023, followed by a public consultation on a draft strategic plan in 2018.

Where requested, ECHA has contributed to the ongoing REACH evaluation carried out by the Commission. This process is likely to have an impact on ECHA's long-term priorities, which will be reflected to a significant extent in ECHA's next multi-annual strategic plan.

The effective, efficient and transparent functioning of ECHA has been a prerequisite for past achievements and is absolutely essential for forward-planning.

ECHA's stakeholders expect the efficient use of the Agency's resources, compliance with the laws, and traceable and effective operations and decision-making. These requirements are being fulfilled thanks to the continued investment in improving the Agency's Integrated Quality Management System (IQMS).

ECHA's certification according to the most recent standard ISO 9001:2015 was confirmed in 2016 and its scope was extended to include processes under the BPR. ECHA's efforts to become an environmentally friendly workplace will bring benefits to the ecological environment, stakeholders and staff. ECHA received the certification for its environmental management system according to ISO 14001:2015.

In 2016, the focus of coordinated process improvements continued in areas such as evaluation, applications for authorisation, corporate planning and monitoring and the helpdesk. The projects, supported

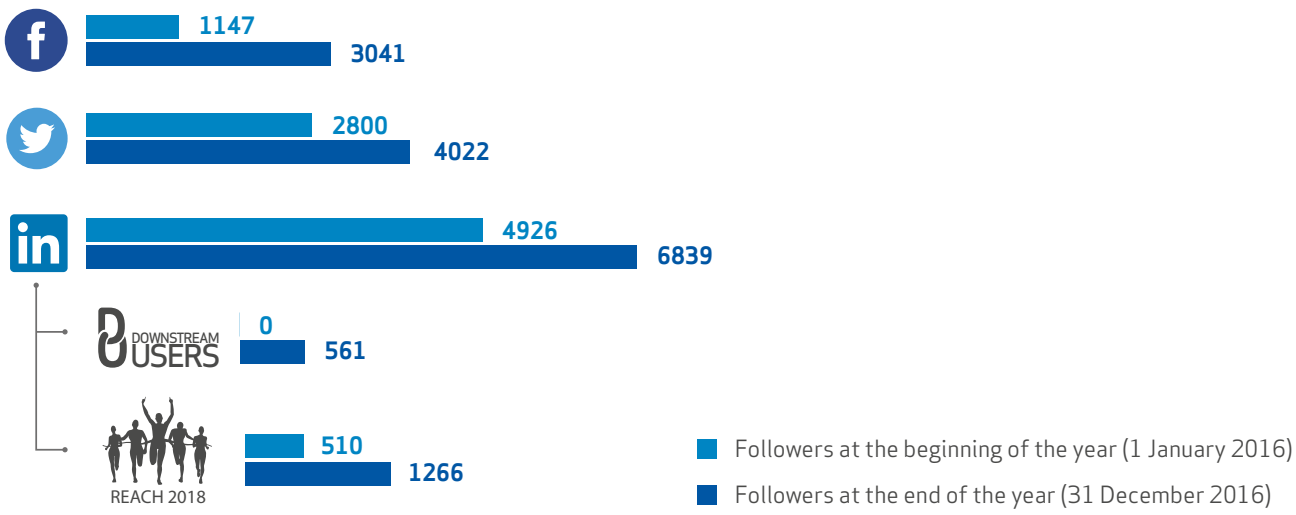
by communications and human resource development activities, facilitated changes in processes, organisation (such as the merging of the info desk and mail registry) and staff capabilities. Investment in efficiency through ICT automation also continued, in parallel with process improvements. New initiatives aimed at supporting further improvements have been started in areas such as committees, meeting organisation and biocides.

The accreditation system of representative organisations continued to underpin the Agency's reputation as an open and transparent public authority. Journalists and others recognised ECHA as a reliable source of information, such as on the classification of glyphosate or the authorisation of certain uses of chromium VI that were hot issues during 2016.

The need to reach out to smaller companies and to the interested citizen led ECHA to widen its communications toolkit and to upgrade its website. Expanding the use of social media to draw additional audiences' attention to the ECHA website showed a remarkable, even exponential increase during the course of the years.

Involving communications officers of key stakeholders in a REACH Communications Network and becoming an Associate Member of the European Enterprise Network (EEN) increased the Agency's potential to spread information to relevant audiences.

FIGURE 20: Uptake of ECHA's content through social media



Resources

Finance, Human Resources, Corporate Services, Communications and Information Communications Technology (ICT) functions are needed for an organisation with stable and reliable funding, services, competences and place of work.

Financial resources

Challenges met with improved efficiency and sound management

Managing the annual budget was more challenging than in previous years due to the mixed funding regime, and the amount and timing of fee income. ECHA responded by focusing on improving efficiency and simplifying processes while maintaining high standards of sound financial governance.

Main achievements

The magnitude and timing of the fee-based financing was difficult to predict, particularly for operations relating to biocides and REACH. This was primarily due to insufficient advance market information that could indicate industry's intentions, especially in relation to the upcoming registration deadline in 2018. As a result, a considerable amount of the EU subsidy financing initially foreseen was unnecessary due to more favourable fee-income receipts and a slightly downward revision in expenditure.

The Agency's total budget remained largely at the 2015 level. In 2016, the fees and charges collected covered 46 % of ECHA's expenditure. In the absence of any reserves, the financial management environment was characterised by a high degree of uncertainty concerning the magnitude and timing of fee income.

The audits carried out by ECHA's external auditor (European Court of Auditors) during 2016 resulted in no findings, which once again served as a proof of sound financial governance. While maintaining high standards of income and expenditure monitoring and compliance, the Agency also paid greater attention to the effectiveness of the measures in place by simplifying processes where possible.

The total revenue received under ECHA's REACH/CLP Regulation amounted to EUR 104.2 million and 4.8 million will be returned to the Commission. The fees and charges increased slightly from the previous year to EUR 33.4 million. The majority of the fee income continued to originate from the registrations of substances in the highest tonnage band, above 1 000 tonnes. During the year, the fee income estimates were adjusted upwards by EUR 7 million and the reserve was increased by EUR 3.3 million due to the previous year's positive outturn. At the same time, the net expenditure was increased by EUR 2 million (mainly due to IT development of the cloud services for SMEs). Consequently, the Agency was able to reduce the subsidy request by EUR 8.3 million compared to the subsidies approved by the Management Board for the financial year 2016.

The year in numbers

> EUR 33.4 M
in REACH/CLP fees

> EUR 7.6 M
in BPR fees

~ EUR 110 M
trainings organised

570
SMEs checkes

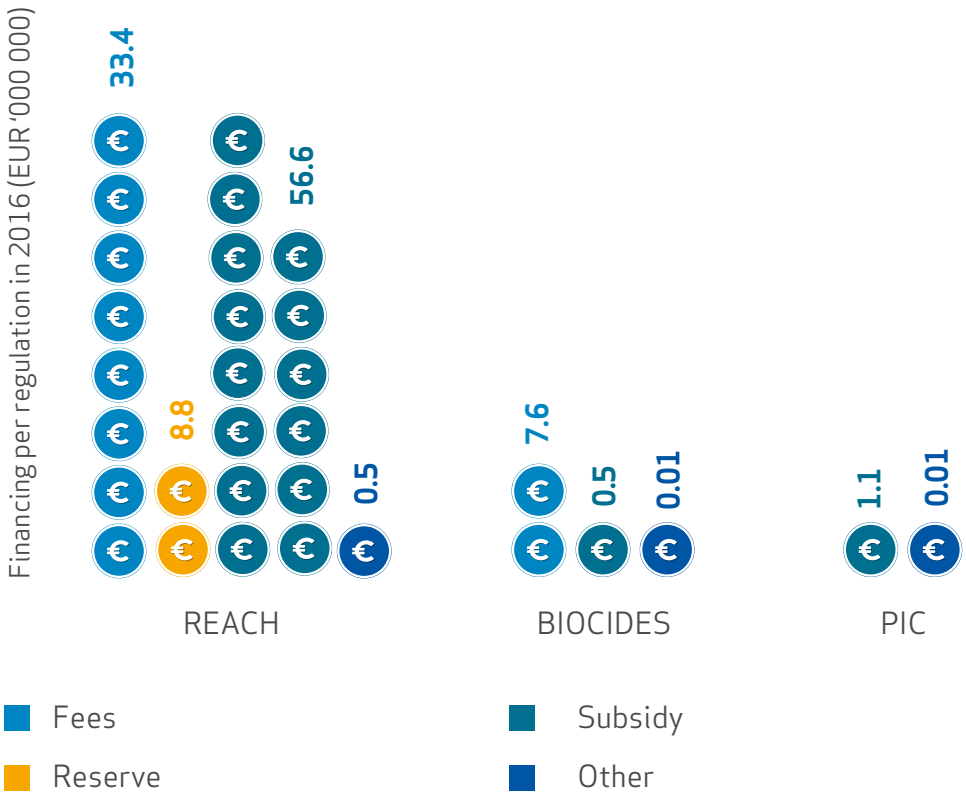
The total revenue received under the Biocidal Products Regulation amounted to EUR 8.6 million and 0.5 million will be returned to the Commission. This sum included the biocidal fee revenue of EUR 7.6 million which was significantly higher than planned but was only received in the last quarter of the year. This was due to the higher than expected number of applications for approval of active substances related to the September 2016 deadline. As a result, EUR 2.8 million of the balancing subsidies initially foreseen for 2016 was not required.

ECHA received a contribution of EUR 1.2 million from the EU for the PIC Regulation and 0.1 million will be returned to the Commission.

The overall budget implementation at the Agency level exceeded the annual targets for both the commitment and payment rates (key performance indicators).

The Agency continued its systematic verification of the status of companies that had registered as SMEs and had consequently

FIGURE 21: Financing of the expenditure in 2016

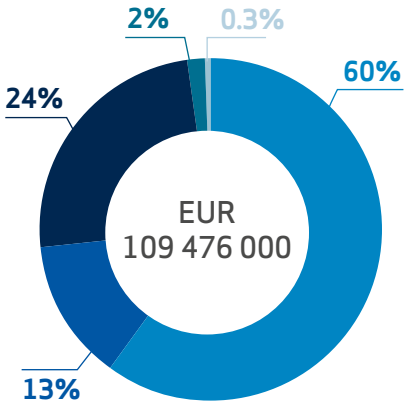


benefited from SME reductions. As a result of increased efforts, a total of 570 companies which had registered under the REACH/CLP regulation were verified, bringing a total of EUR 3.3 million in fees and charges collected. In addition, five companies were verified among the applicants for authorisation, while the *ex-ante* verification of company size was also completed for 25 companies under the Biocidal Products Regulation. The results achieved for the number of companies checked exceeded the annual target by 14 %.

In 2016, the Agency opted for several measures to improve efficiency. For example, verification of SME size will, in future, focus primarily on cases where the financial impact of a wrong declaration is highest. In addition, official communication with the registrants was streamlined. The Agency also conducted an *ex-post* evaluation of a major operational programme (chemical safety assessment) to assess its costs and benefits and draw lessons for the future.

ECHA took on-board tools that make its procurement operations more cost-effective, and further developed its processes and simplified its financial workflows to achieve greater efficiency.

FIGURE 22: Expenditure committed in 2016



- Staff
- Building equipment & miscell. operational expenditure
- Operating expenditure (REACH/CLP)
- Operating expenditure (BIOCIDES)
- Operating expenditure (PIC)

The year in numbers

564

staff in payroll

98 %

establishment plan posts filled

309

trainings organised

Human resources

HR planning and recruitment in a demanding environment

By maintaining a proactive approach to human resources management, HR was able to fill all of ECHA's available 'establishment plan' posts for REACH/CLP, the BPR and PIC in 2016. In addition, the turnover rate of statutory staff continued to fall. Together with a balanced learning and development plan that combined directorate, unit and individual learning needs, HR contributed to ensuring that the Agency has the necessary number of motivated and skilled staff at its disposal.

Main achievements

The Agency's recruitment target was achieved with 98 % of posts filled at the end of the year for REACH/CLP, PIC and the BPR. This percentage of posts required is aligned with the 2017 establishment plan (as of 1 January 2017) – i.e. 10 fewer posts (-2 %) for REACH/CLP. Hence, practically all available posts were filled in 2016.

Overall, ECHA's staff planning exercise is becoming increasingly demanding due to the ongoing need to take into account the number of post cuts being imposed on the Agency, and the uncertainty in the level of activity and related funding in the biocides area.

ECHA has fully implemented the reductions foreseen in 2016 for authorised staff numbers in REACH/CLP. As the Agency's workload did not decrease during 2016, ECHA continued to achieve the agreed cuts by placing a stronger focus on workload prioritisation (and related staff allocation) and efficiency gains. Finally, the performance management and contract renewal processes were more closely aligned with the general requirement to deliver all of the Agency's tasks and objectives by using fewer human resources.

Achieving the same with fewer resources requires highly motivated and committed staff members able to demonstrate efficiency and initiative in their respective roles within the Agency. Hence, in career development, a new streamlined reclassification process was designed and executed in 2016 to value excellence in performance over seniority at ECHA.

Following the staff engagement survey in 2015, a number of actions were implemented in 2016 to address the developmental areas identified, including the adoption and implementation of a health

and well-being action plan for 2016-2017. This plan aims to maintain a healthy work environment and high level of staff motivation, while keeping the time off for sick leave at a low level.

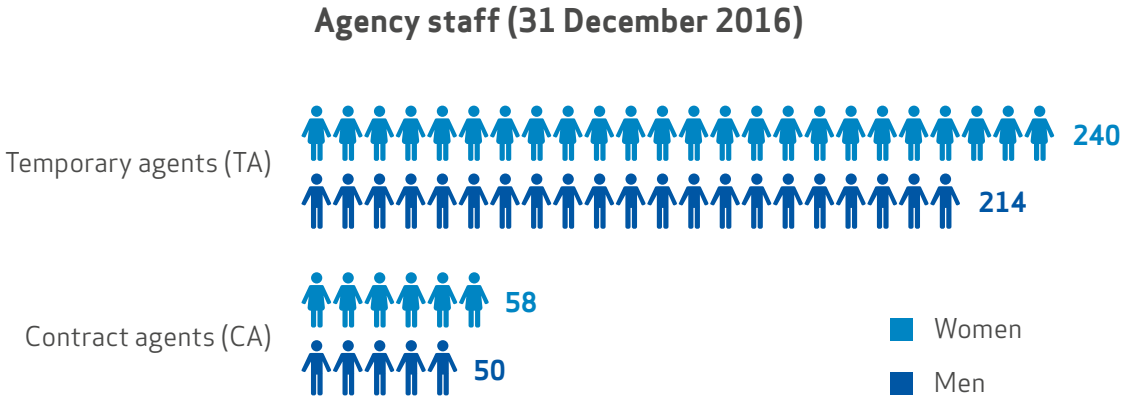
In 2016, three more modules of the new IT tool, the HR portal, were rolled out to staff in the areas of learning and development, performance management, and selections and recruitment. The aim of the tool is to integrate the different HR procedures in one tool while improving the efficiency of the underlying processes.

Finally, in 2016, ECHA started to implement decision-making related to staff entitlements upon recruitment and during their service at the Agency. This has led to a number of gains in both efficiency and savings for the organisation.

The screening/benchmarking exercise was conducted at the end of 2016 and revealed an increase percentage in operational staff, while the number of staff working on horizontal activities fell further.

Finally, HR participated in the Agency's preparatory group for the 2018 registration deadline and designed a staffing plan for the temporary additional workforce requirements.

FIGURE 23: Agency staff in 2016



Corporate Services

The year in numbers

1580

meetings held at ECHA conference centre

650

work stations maintained

Demand for services increases

The unit met the demands of a challenging year with increased activity in all areas of work. A significant organisational achievement was the key role the Corporate Services played in attaining the ISO 14001 environmental management certification. The unit also prepared the ground for ECHA's future relocation to a new building.

Main achievements

ECHA's conference and meetings facilities were used extensively, with 8 000 people attending virtual meetings organised by the Agency (up 33 % from 2015) and 9 560 external participants attending meetings hosted at ECHA's premises (up 4 % from 2015), which included 1 580 meetings hosted in its conference centre. In relation to this, the audio-visual infrastructure in ECHA's conference centre was significantly upgraded during 2016 to support the digital transmission of images and to give participants an enhanced viewing experience.

As ECHA's lease on its current premises expires at the end of 2019, a number of important preparatory activities relating to the selection of the Agency's future building were undertaken in 2016, including the definition of a future workplace concept (involving extensive consultation with staff) and the launch of a prospection of the local market and subsequent negotiated procedure, based on ECHA's specific requirements. It is anticipated that this ongoing process will lead to the identification of a preferred option in 2017.

The Corporate Services team also initiated preparatory activities related to the 2018 registration deadline, by kicking off the installation of the movable wall system in the existing conference centre area.

During 2016, the same team addressed a number of air-quality issues with the landlord; new framework contracts for the provision of catering, security and reception services were established; the project to install ergonomic electric work desks progressed; and a crisis management exercise for ECHA's strategic and operational groups was organised.

Finally, the project concerning the introduction of a new event logistics management tool began in 2016. This aims to improve

ECHA's approach to the organisation of meetings and events through more automation, to facilitate better reporting and, in general, to streamline the process.

ICT

Greater efficiency and cost savings achieved

During 2016, ECHA completed a major upgrade to its ICT infrastructure and services. The transition from 'owned infrastructure' to 'Infrastructure as a Service' (IaaS) began and was completed in the first quarter of 2016. ECHA infrastructure services are now provided according to a private cloud model by an outsourcer in a more cost-effective manner, thereby providing Agency stakeholders with a higher quality of service.

To increase its overall efficiency, ECHA has been pioneering the roll-out of a new generation of IT facilities for the workplace: mobility, teleworking, web-meetings and instant messaging have now been enabled for all staff to support collaborative and dynamic ways of working.

Main achievements

ECHA has completed the implementation of two different identity and access management (IAM) portals. The first solution serves the external competent authority users and the second is for internal users.

The new-generation IAM service has resulted in greater compliance, increased security and cost savings while maintaining a high quality of service. The external user administrators have also been empowered to perform all the administration, user and access management tasks.

Thanks to several automated workflows, those responsible for granting access to ECHA IT systems – both internally and externally – spend very little effort on previously time-consuming tasks.

ECHA has promoted new ways of working to 'free staff from their desks', by providing them with lightweight devices (tablet/laptop) able to connect wirelessly from anywhere in the premises. Consequently, a variety of new work practices have sprung up across the Agency, increasing its efficiency.

Mobile smart phones were provided for all staff and the old telephone system was decommissioned. Wireless networks were extended from meeting rooms to cover the entire building.

Application management services for ECHA's website, dissemination,

eChemPortal and Portal Dashboard have been fully outsourced to a new framework contract that ensures collaboration between development and operations staff throughout all stages of the development life cycle.

During the course of the year, migration was completed to a new IaaS owned and managed by the provider. New capacity management practices have been established to take advantage of server-infrastructure as a commodity.

Building on practices developed for the new-generation go-live during the summer, a release manager was appointed to improve the orchestration of complex changes in IT. Thus, a higher quality of service was achieved in a more cost-effective way, driven by a progressive shift of ECHA IT staff from purely technical tasks to service management and integration and capacity management.

Good progress was made in creating further synergies between the REACH/CLP and BPR processes. The work on IUCLID for the BPR, industry support, MSCA's support, internal IT tools used by biocides staff are embedded in the same teams working for REACH and CLP, although the time spent is accounted for by legislation; analogically for the horizontal work on ICT infrastructure and IT operations services, procurement, end user ICT helpdesk, security as well as IT management functions. All the BPR activities could leverage such rich and high performing IT foundations.

Agency risks

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

An annual risk assessment exercise was conducted in 2015 to identify, assess and manage potential events that could put achievement of the objectives defined in Work Programme 2016 at risk. This exercise is an integral part of the Work Programme preparations.

Based on this assessment, ECHA's management identified six main risks which were included in the corporate Risk Register. The management also agreed that all these risks should be reduced through specific actions described in the Risk Register action plan.

Senior management followed up on the implementation of the risk mitigation measures and reviewed their effectiveness twice in 2016 on a four-monthly basis, in May and September. The final review of the Risk Register is usually performed at the end of the year and the analysis of the risks and mitigation measures taken is included in the Agency's Consolidated Annual Activity Report for that year.

In the last follow-up, which was done at the beginning of 2017, the management concluded that the actions taken to mitigate the risks had been implemented according to the plan, had proven to be effective and had not led to any major secondary risks.

One of the risks with the highest impact, which materialised as of 31 December 2016, was related to achieving the Biocides Review Programme target, set at 50 opinions per year. Even though ECHA was undertaking mitigating actions, such as creating guiding templates, supporting the quality of the assessment reports and using scenario planning to enable response to different market situations, the Review Programme's target was not met (41 of the 50 opinions foreseen were adopted in 2016). This may influence chances of reaching the BPR objectives to ensure a high level protection of human health and the environment. This was mainly due to a number of deliverables (CARs) being postponed by the MSCAs because of insufficient resources on their part and the fact that it is not possible for ECHA to substitute the MSCAs in their role.

The market risk for the authorisation applications related to a potential peak in applications (more than 40) also materialised in 2016. 77 applications for authorisation covering 112 uses were received providing a very high workload for the committees. The risk was effectively managed through flexible redeployment of REACH staff, increased mobilisation of RAC and SEAC members as rapporteurs and the introduction of co-opted members, as well as by making the process more efficient (processing time reduced by 15 %).

None of the other risks had an impact on execution of the Work Programme for 2016, although most of them will continue to be relevant in the future.

The risk concerning the peak in biocides applications relating to insufficient resources to handle them did not materialise, but will remain high in the years to come. It is currently being tackled through scenario planning and fall-back plans. On the other hand, thanks to the higher than foreseen income received in 2016, ECHA was able to cover its expenditure and avoid the financial risk materialising in 2016.

Clear scope and programme management have been effective in procuring and releasing most of the IT solutions

planned for the year, thereby avoiding any major delays in implementation.

The risk of not meeting all the objectives of the Efficiency Programme was also managed effectively through timely management support, empowering staff by delegating decisions to lower levels where the risk was assessed to be low, raising more awareness among staff and recruiting more volunteers to the programme. The score for Strategic Objective 4, which increased by 2.3 % compared to 2015, also shows that the Agency has achieved a greater output (+1 %) with fewer resources (-1.7 %).

ECHA's Strategic Objectives 2014-2018 – Results 2016

ECHA's four strategic objectives have been defined in the Multi-Annual Work Programme (MAWP) 2014–2018 adopted by the Management Board on 26 September 2013. ECHA has developed measurements to monitor the progress towards these objectives. The results achieved during 2016 are presented below:

1. Maximise the availability of high quality data to enable the safe manufacture and use of chemicals

The extent to which the first strategic objective (SO1) is achieved is measured by four indicators introduced in 2014. These indicators cover different parts of the registration dossier and diverse aspects of quality: shortcomings in substance identification, inconsistencies in the reported uses for substances registered as intermediate, the level of incompliance with harmonised classification and deficiencies identified in the data on physico-chemical, environmental and human health hazards.

They are not a direct measure of the compliance with information requirements; they are rather measurements of certain identified anomalies or inconsistencies in the data provided by REACH registrants that are checked by IT screening. Each result expresses the percentage of dossiers which successfully passed the automated screening.

In 2016, ECHA released its new generation of registration tools (IUCLID 6, REACH-IT) and revised its completeness check process. The IUCLID 6 format for reporting the data requirements was revised with the aim of providing registrants with a better understanding on how to submit a compliant dossier and to increase the inherent consistency of the data.

The completeness check process was adapted to the revised format and now includes a manual check for certain data elements that cannot be assessed automatically. These changes now directly address at submission time the findings that were only identified by IT screening after the registration process in the past.

With the launch of IUCLID 6, ECHA achieved the planned international harmonisation of templates in industry with regard to uses and exposures, which will make REACH implementation and dissemination more efficient. This will also assist companies and in particular SMEs in standardising communication in the supply chains and in identifying new opportunities for innovation.

This new situation is reflected in the calculation of the four indicators which are now partly based on the percentage of dossiers submitted as new or updates. Besides spontaneous updates from registrants, dossier updates are also stimulated by ECHA's regulatory activities such as evaluation, letter campaigns for substances shortlisted for manual scrutiny by authorities, and completeness checks applied retroactively on existing registrations that have not been updated yet.

Overall the quality (i.e. level of consistency and meaningfulness in the submitted information) of dossiers improved during 2016 compared to 2015 in the areas of substance identification (+3 %), hazard information (+3 %), use consistency with the intermediate status (+1 %). There was no change in the percentage of dossiers compliant with harmonised classification.

As for the substance identification, the value of this indicator is 71 % for 2016, calculated on the whole database (ca. 51 000 dossiers). The indicator on uses compatible with substances registered as intermediates is 92 % for all intermediate dossiers (ca. 10 000 dossiers). The hazard information indicator is up to 40 % for all lead and individual registration dossiers (ca. 8 500). Finally, the indicator on compliance with harmonised classification has remained steady at 96 %. These positive trends, although no large-scale letter campaign was done on those areas in 2016, clearly shows the impact of the strategy for raising data quality with the release of the new generation of registration tools, especially IUCLID 6 and the enhanced completeness check.

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

With regard to substance screening around 72 % of 182 substances that were picked up by the IT based mass-screening were found to require further follow-up actions. This number is slightly lower than last year, but, as already indicated in the 2015 report, this is linked to the fact that the same database is being searched for some years now with very similar scenarios (e.g. for CMR substances).

In addition, for several substances it was not possible to conclude the manual screening as work to clarify the hazardous properties is already ongoing under one of the REACH/CLP substances on a very similar substance. This clearly highlights the need to start working on groups of structurally similar substances rather than on single ones. In total, 22 Member States and EEA countries participated in the manual screening in 2016 which confirms the high interest from Member States in this activity.

It is still early to draw any conclusions on trends and effectiveness regarding substance evaluation as the process has not been completed for most of the substances, due to requests for further information. Between 2012 and 2016, 182 substances were evaluated and 49 (27 %) evaluations were concluded. Most of these conclusions were for substances for which no further information was requested. For 20 concluded cases, the evaluating Member State considered that further regulatory risk management may be needed.

In 2016 there was a slight reduction in the number of Member States (from 20 to 15) conducting a substance evaluation. This may be due to the fact that it has been challenging to find meaningful new CoRAP candidates and that Member States also need to conclude the cases they have started previously.

13 Member States submitted proposals for regulatory risk management measures under REACH or CLP which is slightly less than last year (this includes submission of proposals for harmonised classification and labelling of pesticides and biocides).

Only seven Member States submitted proposals for regulatory risk management measures under REACH. The extent to which the risk management options analysis (RMOA) conclusions received follow-up has however increased (84.8 %); SVHC identification and restriction proposals were followed-up in 87 % and 100 % of the cases, respectively, compared to the expected number of regulatory proposals. Two CLH proposals have also been followed up, which is a positive increase compared to last year.

The trend that most RMOA conclusions now receive follow-up clearly reflects that it simply takes time for Member States to turn a conclusion into actual follow-up action.

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

The aim of Strategic Objective 3 is to implement processes and actions in those areas which orientate

regulatory science activities to support the operational and strategic needs of ECHA. The activities focus on the implementation of ECHA's regulatory science strategy, on capacity building and on working as a hub in regulatory science.

ECHA has many topics to cover, many discussions to manage and manifold expectations to satisfy. This poses its own challenge, and 100 % satisfaction may not be possible. However, where ECHA could bundle its powers and take a leading role, success was rewarding all parties involved.

The 2016 Topical Science Workshop on New Approach Methodologies showed ECHA featuring as a hub of excellence in regulatory science, with a range of key experts contributing to the success of the workshop on the way to better toxicology with less animal testing. The active reflection of the impulse given by the TSWS 2016 in the form of internal trainings on new approach methodologies and pilot projects motivated staff to visionary thinking beyond their daily business. This will facilitate preparation for prospective scientific and regulatory development at an early stage, and sharpen the view of ECHA's needs in accordance with its mission and processes.

Beyond the organisation of workshops, targeted attendance of international conferences on regulatory science in accordance with its strategic priorities consolidated the Agency's embedment in its network of key partners in the EU and at global level. Based on an ECHA-wide analysis of capacity building and training needs, an action plan was set up, outlining capacity building needs in particular in human health exposure assessment and modelling as well as in regulatory impact assessment/socio-economic analysis. Relevant training is developed in cooperation with experts for 2017.

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

ECHA developed a composite score "Decisions and opinions equivalent" to measure its fourth strategic objective. It divides the total weighted decisions by the maximum annual staff capacity. The total weighted decisions represent the number of decisions and opinions produced in a given year, taking into account the whole process until a decision/opinion is issued, and weighted with the time required to process an average case.

The maximum annual staff capacity includes both operational and supporting personnel as well as consultants and operational interim personnel present over the whole year. The correlation between the weighted output of the Agency and the annual staff capacity gives an indication of an efficiency trend throughout the years, i.e. producing more weighted outputs with the same or less resources.

An analysis of the 2016 measurement shows that the "Decisions and opinions equivalent" continues to increase showing a positive trend in efficiency.

TABLE 1: Annual efficiency score

INDEX TREND	2014	2015	2016
TOTAL WEIGHTED DECISIONS	25 873	25 240	25 386
TOTAL STAFF	621	597	587
Decisions equivalent (No. of weighted decisions/opinions divided by the maximum annual staff ca-pacity)	55.6	56.4	57.7

TABLE 2: Trends in efficiency score between 2014 and 2016

% change	2014 -> 2015	2015 -> 2016
% change in TOTAL WEIGHTED DE-CISIONS	-2%	1%
% change in TOTAL STAFF	-4%	-1.70%
% change in Decisions equivalent	1.50%	2.30%

In 2016, biocides and evaluation generated lower regulatory output compared to 2015, while PIC and registration activities generated visibly higher output.

The total number of decisions and opinions produced in 2016 has increased by 33 % compared to 2015 (i.e. 17 595 vs 13 226). However, when weighted with the time needed to process an average decision or opinion, this value increased only by 1 % compared to 2015 as can be seen in Table 2 (i.e. under '% change in total weighted decisions'). This small increase is the result of the combined fluctuation of high and low-labour-intensive outputs compared to 2015.

Due to the inclusion of the new manual technical completeness check in the registration process and given that a higher percentage of complex dossiers started undergoing compliance check in line with the compliance check strategy, the time required to generate an average decision in those two processes had to be revised. Consequently, the provisional weighting factors established in 2014 for both registration and dossier evaluation processes were updated, leading to a more accurate measures of time spent per case.

Moreover, for the second year in a row the staff numbers slightly decreased in comparison with the previous year, which, combined with the slight increase in the total weighted decisions, resulted in an overall 2.3 % increase in the efficiency score compared to 2015 (see Table 2).

The trend of Strategic Objective 4 scores so far has shown that the Agency is able to produce a high number of regulatory outputs even when facing declining staff resources, which is a good indication of efficiency. It also satisfies ECHA's ambition to keep the steady increase of 2 % in its operational efficiency, as measured by this aggregated indicator.

ANNEXES

ANNEX 1: Achievements of Work Programme 2016

Overview of main actions and outputs specified in Work Programme 2016 with information on their achievement per activity

1.1.1 Registration dossier preparation	Achieved [Yes/No]	Additional information/explanation
Implement ECHA's REACH 2018 Roadmap, which outlines ECHA's plans for improving registration process, tools and support for the last registration deadline of phase-in substances, in dialogue with industry stakeholders, Commission and national authorities, and specifically:	**Yes**	
(1) Carry out the related coordinated communication activities through various networks (such as the REACH Communicators' Network), and using multiple communication channels (online, audio-visual, documentation, events and social media);	**Yes**	
(2) Conclude the support to industry sectors developing specific registration guidance (e.g. inorganic pigments, essential oils). This may be complemented by further communication on the methodology for determining substance sameness;	**Yes**	
(3) To provide stability to duty holders preparing for the 2018 REACH registration deadline, the Agency will apply a "Guidance moratorium" from 31 May 2016 onwards. Apart from exceptional updates in response to, for instance, changes to the legal texts or alignment of the guidance with updated tools or working procedures, ECHA will not publish registration-related guidance until after the registration deadline of 1 June 2018. For guidance documents, which eventually have not been finalised by the end of May 2016, ECHA will communicate by 1 June 2016 the nature of the changes proposed and a timeline for their publication;	**Yes**	
(4) Provide advice to SMEs for their negotiations in the SIEF to get access to data and the joint submission also taking into account the Commission's Implementing Regulation and ECHA's recommendations.	**Yes**	
Support the fulfilment of information requirements:	**Partly**	Wealth of material that supports fulfilling the information requirements was published over the year. For details, see the specific comments below.
(1) Develop CSR examples for a variety of typical assessment situations and provide training as well as webinars.	**Partly**	Publication of full CSR examples postponed to 2017 (de-prioritised in favour of supporting sector use maps; see 1.1.4). Webinars on CSA with Chesar held both for individual users and for trainers. Two-day Chesar training of trainers based on CSR examples.

(2) Amend the Read-Across Assessment Framework (RAAF) in particular to include environmental effects. Organise a topical scientific workshop on the use of new approach methodologies to generate human health hazard information.	**Yes**	
(3) Release a new version of the OECD QSAR Toolbox, which will include a streamlined approach to predict toxicity of endpoints related to low tonnage requirements, and further improve possibilities to build weight-of-evidence approaches for other endpoints (including *in vitro* methods/models, adverse outcome pathways, AoP).	**No**	Programming finalised and tested. Planned publication in April 2017.
(4) Publish an indicative list of substances for which there is evidence that one or more Annex III criteria are met and hence all information requirements according to Article 12(1)(a) should be provided, unless evidence to the contrary is included in the dossier.	**Yes**	
Publish update of the elements of the *Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA)* that relate to chemical safety assessment and exposure scenarios.	**Yes**	
Publish updates to guidance documents with regard to nanomaterials to also take any revisions of the REACH annexes into account.	**Partly**	Plan revised due to further delays in the publication of the new REACH annexes (publication still pending). Consultations on four documents relating to nanomaterial annexes initiated in May 2016. PEG meetings held September 2016. Final publication is scheduled for 2017 according to the revised plan.
Publish updates to *Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA)* e.g. relating to possible data waiving option for acute oral toxicity by weight of evidence, and for skin sensitisation by integrated approach for testing and assessment (IATA).	**Yes**	
Publish updated/new chemical safety assessment (CSA) and exposure scenarios-related advisory documents under the CSR/ES Roadmap to reflect the latest developments for gathering and documenting use and conditions of use information from downstream users.	**Yes**	
Release the first version of the new generation of IT tools, IUCLID 6 and Chesar 3 with a focus on improving the reporting possibilities to improve dossier quality and compliance and restructuring of the architecture for more effective maintainability; simplification of IUCLID for the user will be pursued. Release the IUCLID Validation Assistant with enhanced and upgraded rules for verifying data completeness and quality before submission to ECHA. Refine further release of Chesar towards the end of 2016 without disrupting the preparatory work for registrants towards the 2018 deadline.	**Yes**	
Subject to budget availability and the decision of the Management Board on the basis of the results of the feasibility study conducted in 2015, start the implementation of a centrally hosted IUCLID platform for industry to be made available online as a service; this new delivery model would ensure that the latest version of IUCLID and the IUCLID datasets created by users would always and securely be available online making access to IUCLID simpler and more cost effective for industry, particularly SMEs.	**Yes**	
Provide specific support to duty holders and national helpdesks during the roll-out of the new generation of IT tools through workshops or webinars, as necessary.	**Yes**	

1.1.2 Registration and dossier submission	Achieved [Yes/No]	Additional information/explanation
Release the new generation of REACH-IT so that registrants can start submitting their dossiers for the 2018 deadline with an improved and user friendly system. This also includes the changes on the completeness check process and the reinforcement of the "one substance – one registration" (OSOR) principle agreed in 2015 as well as a revised technical architecture, and a much improved user interface, especially for registrants submitting member dossiers. In addition, it includes an online help available in 23 languages, and integration with the ECHA Identity and Access Management services, which will allow better management of the companies legal entity data and simplified authentication for those who use more than one submission system of ECHA. Duty holders and national helpdesks will be informed through workshops or webinars, as necessary.	**Yes**	
Process an increasing number of registrations with the likely arrival of the first wave of registrations submitted by the large companies for the 2018 deadline (preliminary estimates up to ca. 4 000 new registrations and 6 000 updates). ECHA will also start to manually verify certain key points of the dossiers. A registration peak may also occur in the months preceding the release of the new IT tools. This may impact the follow-up activities such as assessment of confidentiality requests and verifying SME status.	**Yes**	
As part of implementing ECHA's compliance check strategy agreed in 2014, continue to stimulate dossier updates by publishing a list of substances to be potentially addressed under compliance check, targeted letter campaigns and other complementary measures so that the quality of information registration is further enhanced.	**Yes**	

1.1.3 Evaluation	Achieved [Yes/No]	Additional information/explanation
Continue to address relevant higher tier hazard endpoints for substances of potential concern through compliance checks on over 1 000 tonne dossiers and 100-1000 tonne dossiers, in line with the compliance check strategy set in 2014, and based on the implementing and priority setting approaches elaborated further in 2015. The selection of dossiers for compliance check will be based on the common screening also serving regulatory risk management and further manual screening to focus on the priority dossiers over 100 tonnes.	**Yes**	*NOTE: Detailed information on evaluation outputs and conclusions is provided in the annual Evaluation Report on ECHA's website.*
Start to provide more visibility to the content and outcome of compliance checks through the dissemination platform and the improved annual Evaluation Report (Article 54) as an important part of implementation of the compliance check strategy.	**No**	Dissemination of evaluation lifecycle postponed till late 2017. Improved reporting in Article 54 report and cumulative report on dossier evaluation outcomes was provided in the Article 117(2) report.
Conclude the remaining testing proposals from the 2013 registration deadline up to a draft decision, before the set legal deadline on 1 June 2016. It also aims to finalise the decision making on 80 % of all 2013 testing proposal cases processed by the end of 2015.	**Yes**	

Re-assess approximately 200 testing proposals submitted by registrants on reproduction toxicity and referred to the Commission for decision during 2011-2014, which are anticipated to be re-submitted to ECHA due to the amendment of the REACH standard information requirements. These will need to be re-examined and concluded with draft decisions; cases will be grouped and prioritised with the aim of efficient and effective handling of them. This includes considering how to apply Article 40(3)(c) of the REACH Regulation, based on which ECHA may request one or more additional tests in cases of non-compliance of the testing proposal with Annexes IX-XI.	**No**	All 216 cases are still pending the Commission's decision and have not yet been re-submitted. Consequently, ECHA did not re-assess any such testing proposals in 2016. This is also the major reason why the number of concluded testing proposals was lower than originally estimated in the Work Programme.
Continue to ensure that based on the experience gained in 2015 together with the Commission and the Member States, in the most efficient and effective manner, registrants comply with their obligations to conduct vertebrate animal testing only as a last resort. ECHA will also continue reporting on its actions in this regard.	**Yes**	
Together with Member States, make sure that substance evaluation supports and contributes to the regulatory risk management processes in an effective and efficient manner based on the conclusions achieved in 2015. It will include 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**	
Continue addressing the lack of information for the safe use of substances in nanoforms under both dossier and substance evaluation.	**Yes**	
Replace the IT-tools supporting dossier evaluation workflow (i.e. DEP by Dynamic Case) to harmonise case management throughout the REACH and CLP processes. Based on the outcome of the feasibility study mid-2015, the IT-tool supporting scientific assessment under dossier evaluation is integrated with other ECHA data/workflow systems.	**Yes**	

1.1.4 Communication of risk management advice through the supply chain	Achieved [Yes/No]	Additional information/explanation
Provide input to 2018 Roadmap actions to ensure that registrants have a solid information basis for their chemical safety assessment, in particular in relation to use description and potentially demonstrating negligible exposure.	**Yes**	
Hold targeted workshops with downstream user sectors to make use of the tools available for input to registrants (e.g. use maps) and biannual meetings of the Exposure Scenario Network (ENES).	**Yes**	
Develop further examples of exposure scenarios for communication (covering different kinds of hazards).	**No**	Update to CSR illustrative example postponed to 2017 to give priority to development of sector use maps. Model exposure scenarios for communication generated to support the Forum REF-5 enforcement project. They can be used by site inspectors in 2017.
Review the methodologies that have been used in different sectors for converging substance-related exposure scenario information into advice on safe use of mixtures.	**Yes**	

Broaden the exemplification of REACH information useful/needed to comply with other legislation.	**No**	Due to reduced availability of resources, limited action was taken: downstream user web page was refreshed and existing case study translated.
Continue to support enforcement authorities through the annual training event for inspectors and trainers who train inspectors on the national level.	**Yes**	

1.2.1 Identifying needs for regulatory risk management	Achieved [Yes/No]	Additional information/explanation
Further develop the common screening approach and in particular expand it to cover compliance check needs. This approach provides a basis for improved integration of further information generation through evaluation processes for the authorities to initiate, where relevant, further regulatory risk management under REACH and CLP.	**Yes**	
Continue preparation of RMOAs, upon request of the Commission, and provide coordination and support to Member States in their preparation. In general, it is expected that the number of these RMOAs will rise as a result of the work done in previous years under the common screening approaches as well as through the assessment work under the persistent, bioaccumulative and toxic/endocrine disruptor (PBT/ED) expert groups and substance evaluation.	**Yes**	
Maintain high levels of effort for cooperation and coordination with all authorities of the SVHC Roadmap implementation work, including RiME and the carcinogenic, mutagenic or toxic to reproduction (CMR) and sensitiser coordination groups. The work on petroleum and coal stream substances will reach the same implementation level as the other substance groups set up under the SVHC Roadmap.	**Yes**	
Develop the second SVHC Roadmap progress report and identify actions for further improvement.	**Yes**	
Generate increased information on ECHA's website on screening and assessments providing industry with better predictability of which substances will be under authorities' attention and consequently more time to plan for substitution and improving safety.	**Yes**	

1.2.2 Authorisation	Achieved [Yes/No]	Additional information/explanation
ECHA expects some increase in the number of SVHC dossiers. In addition, the overall workload will increase since most dossiers will relate to PBTs, EDs or other substances of equivalent concern and hence may require specific effort and involvement from the respective expert groups, including from the MSC.	**Yes**	
ECHA will have implemented a further streamlined and focused application process taking account of the experience gained with the first applications, including the "Lessons Learned Conference" held in February 2015 as well as the recommendations of the "Task Force on Applications for Authorisation" that are planned to be delivered in mid-2016.	**Yes**	

ECHA will have made IT tools fully operational including the notification register for companies covered by the authorisation to notify their uses and for helping authorities to enforce authorisation.	**Yes**	
ECHA will further improve and adapt communication through the web to facilitate the preparation of "fit for purpose" applications for authorisation.	**Yes**	
ECHA anticipates that some 100 applications, mostly relating to the use of chromium compounds, are likely to be submitted in the latter part of 2015 and early 2016. This increase in activity will provide a specific challenge for ECHA including for RAC and SEAC. To this end, the ECHA Secretariat and MSCAs will need to make specific efforts to ensure adequate capacity of RAC and SEAC to appoint rapporteurs for all applications and implement further measures to improve the committees' efficiency.	**Yes**	
Organise specific awareness-raising activities related to substances in articles for one or more priority article or material types.	**No**	Due to limited resources and priority given to the other substances in articles-related activities, in particular, the update of the Guidance document (see next row) but also the development of a proposal for an enforcement (pilot) project by Forum, ECHA has not proactively organised article or material-specific awareness raising activities. ECHA has, however, participated in selected awareness-raising support activities organised by stakeholders, such as conferences (within the EU and in the USA) or workshops/working groups (CEN working group on chemicals in product standards, EEA workshop on chemicals and circular economy).
Initiate the review of the *Guidance on Substances in Articles* to adapt it to experiences obtained and the outcome of the court case on the 0.1 % limit and, where possible, increase its practicability for industry.	**Yes**	
Support further method development to quantify the human health impacts through willingness-to-pay or quality-adjusted life years approaches.	**Yes**	
Support further development of methodology for carrying out socio-economic analysis for PBTs and PBT-like substances including both costs and benefits estimations.	**Yes**	

Publish the Forum's report on inspections and enforcement action undertaken under its first pilot project on authorisation-related obligations (regarding MDA and musk xylene) and first results of the second pilot project (substances with a sunset date in 2015).	**Partly**	Report on the first pilot project on authorisation-related obligations (regarding MDA and musk xylene) was published in early 2016. The first results of the second pilot project were not published as the project plan was changed by the Forum in March 2016. The operational phase of the project was prolonged by four months to allow more time for inspections. Consequently, the deadline for national authorities to report results to ECHA was deferred to November 2016 and the publication of results was postponed to 2017.

1.2.3 Restrictions	Achieved [Yes/No]	Additional information/explanation
Implement the recommendations of the Restriction Efficiency Task Force to improve the efficiency of the dossier preparation and opinion-forming processes. ECHA will provide support to the Member States during their preparation of restriction dossiers.	**Yes**	
Develop examples of the article service-life exposure assessment, identify the main gaps in approaches and further develop priority aspects of the assessment methods to serve development and evaluation of restriction dossiers.	**No**	This was not achieved in 2016 due to other priorities.
Forum will oversee the implementation of the operational phase of the fourth Forum coordinated enforcement project (REF-4) focused on the enforcement of restrictions.	**Yes**	

1.2.4 Classification and labelling	Achieved [Yes/No]	Additional information/explanation
ECHA will further align the respective regulatory processes for harmonised classification and labelling (CLH) for active substances in biocides and pesticides. About two thirds of the CLH opinions will concern these substances, whereas the total number of RAC opinions is expected to remain at the same level as in previous years.	**Yes**	
Continue screening in cooperation with Member States; industrial chemicals are preferably selected from priorities resulting from this common screening approach.	**Yes**	
Continued monitoring of convergence of self-classifications; where appropriate focused actions encouraging industry to agree on classifications and update notifications accordingly.	**Yes**	
Publish an update to the *Guidance on labelling and packaging in accordance with Regulation (EC) 1272/2008 (CLP)*.	**Yes**	
Support national helpdesks in their awareness-raising activities towards consumers in relation to the new CLP pictograms, which will be in full use for substances and mixtures newly placed on the market.	**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**	

Report of the Forum pilot project where national enforcement authorities follow up specific cases where ECHA has identified deficiencies in harmonised classification and labelling, focusing on substances with CMR or sensitising properties.	**Yes**	
Report of the Forum pilot project on child resistant fastenings.	**Yes**	

1.3 Biocides	Achieved [Yes/No]	Additional information/explanation
Implement further measures to increase the efficiency of the active substance approval process and the Review Programme based on the outcome of the workshop with Member States that took place in 2015.	**Yes**	
Support to the Member State competent authorities for preparing BPC opinions on active substances.	**Yes**	
Support for preparing the first BPC opinions on Union authorisation of biocidal products is expected to take place with a special emphasis on the efficiency of the opinion-forming process and the coordination between Member State competent authorities dealing with the high number of related applications that have been received in 2015.	**Yes**	
Continue evaluating new applications for inclusion in the Article 95 list beyond 1 September 2015 as later deadlines are applicable for products not considered as biocides under the former directive and for products containing *in situ* generated active substances not covered by the current entries in the Review Programme.	**Yes**	
Further develop the Register for Biocidal Products (R4BP 3, including the migration from the previous system) and the SPC editor, to progress towards the comprehensive implementation of the biocides legislation and in particular to address the request of the Commission to implement the meta-SPC concept for the authorisations of Biocidal Product Families (BPFs). Start of phase 2 of the further development of IT tools depends on further availability of additional resources.	**Yes**	
Publish updates to the *Guidance on the Biocidal Products Regulation: Volume IV Environment, Part B, Risk assessment* and *Volume V on micro-organisms* as well as new *Guidance on Volumes I, II, III & IV, Part C, Evaluation* (subject to available resource in 2015 and 2016).	**Partly**	For the following work items initiated but not yet completed: Written consultation initiated in December 2016 on the update for *BPR Volume IV Environment, Part B, Risk Assessment (active substances)* including new guidance for *biocidal products* and *Part C Evaluation*. Written consultation on *Volume V Guidance on Disinfection By-Products* initiated in April 2016 and *Volume II Efficacy Assessment and Evaluation (Parts B+C)* in August 2016. An update to *Volume III* to add *Part C, Evaluation* was initiated in November 2016.

Following the request made by the Commission in 2015, and within the limitations of available resources and also in light of other priorities within the activity, support the renewal process of anticoagulant rodenticide active substances carrying out coordination work during the evaluation phase, the BPC opinion-forming process and the European comparative assessment of biocidal products containing these active substances.	**Yes**	
Provide regulatory advice to stakeholders under the BPR replying to the questions they submit to ECHA.	**Yes**	

1.4 PIC	Achieved [Yes/No]	Additional information/explanation
Process a continuously increasing number of export notifications.	**Yes**	

1.5 Data management and dissemination	Achieved [Yes/No]	Additional information/explanation
Deploy and support the new Portal Dashboard for Enforcement developed in 2015 and replacing the RIPE system. The main focus for its further development will be the dissemination of biocidal information and authorisation notifications.	**Yes**	
Integrate all REACH and CLP screening activities in support of working on substances that matter.	**Yes**	
Adapt the new Dissemination platform to the IUCLID 6 format. This platform will be extended to become the single source of disseminated content, either coming from industry dossiers or produced by the Agency or MSCAs, notably the status of substances and dossiers under evaluation. External audiences will easily find relevant information on the chemical substances disseminated under REACH, CLP, BPR and PIC in the new ECHA Dissemination web pages on chemicals.	**Partly**	The new Dissemination platform was adapted to rely on IUCLID 6 and also further developed. The implied major technical adaptation of the platform was published in December 2016. Further integration of other sources progressed with the publication of an inventory of substances likely to meet REACH Annex III criteria, and thus requiring full Annex VII information for registration. Dissemination of the substance and dossier evaluation status was not achieved, see previous "No" on dissemination of the life cycle of decisions.
Continue disseminating information on substances in nanoform, taking into account information from other relevant sources, and also taking into account different audiences, such as specialists and the general public.	**Yes**	
Consolidate the case management system used in all REACH and CLP regulatory processes (Dynamic Case) to support further efficiency making and extend support to new use cases in the administrative and biocides processes.	**Yes**	
Pending confirmation of resources by the European Commission, contribute to the European Commission's development of tools to facilitate data provision by companies to national poison centres under Article 45 of the CLP Regulation. Explore further options to support companies and Member States.	**Yes**	

Pending availability of funds, perform a feasibility study to expand the scope of dissemination to related EU legislations.	**No**	Delegation agreement signed only on 23 December 2016. Procurement was done in 2016 and the study will start in Q1/2017.

2.1.1 Committees	Achieved [Yes/No]	Additional information/explanation
Manage memberships of each committee (renewals and new appointments/nominations), with a specific focus on ensuring adequate capacity of RAC and SEAC.	**Yes**	
Implement efficiency improvements continuously in all committees also by analysing the opportunities offered by further IT support and better integration of IT tools.	**Yes**	
Prepare, run and follow-up of plenary meetings for the MSC (6), BPC (5), RAC (8) and SEAC (6).	**Yes**	
Cooperate with the scientific committee on occupational exposure limits (SCOEL) concerning scientific aspects and methodologies related to exposure to chemicals at the workplace with a view to their harmonisation.	**Yes**	

2.1.2 Forum	Achieved [Yes/No]	Additional information / Explanation
Support the harmonisation of national enforcement authorities' approaches to enforcement through three Forum plenary meetings, methodological tools and the sharing of information.	**Yes**	
Prepare the Manual for the fifth Forum-coordinated enforcement project (REF-5) focusing on obligations related to extended safety data sheets (e-SDSs), exposure scenarios, risk management measures and operational conditions, and select the subject of the sixth Forum project (REF-6). Continue establishing best practice in enforcement and testing enforcement approaches by running pilot enforcement projects.	**Yes**	

2.1.3 HelpNet and Security Officers Network	Achieved [Yes/No]	Additional information/explanation
Draft and discuss frequently asked questions (FAQs) and their respective answers through the HelpNet, including their publication on ECHA's website.	**Yes**	
Organise at least one HelpNet Steering Group meeting.	**Yes**	
Organise at least one SON meeting.	**Yes**	

2.1.4 Board of Appeal	Achieved [Yes/No]	Additional information/explanation
Process incoming appeals which are expected in particular in relation to substance evaluation decisions and compliance checks.	**Yes**	
Adopt up to 15 final appeal decisions.	**Yes**	
Adopt procedural decisions, as needed.	**Yes**	
Publish a robust body of high-quality decisions online.	**Yes**	
Ensure effective (i.e. clear, accurate and timely) communication with the (potential) parties in relation to appeal proceedings.	**Yes**	

2.2 Management	Achieved [Yes/No]	Additional information/explanation
Maintain and further improve stakeholder relations using dedicated accredited stakeholder organisation communication activities, joint projects and events, interactions with Member States and EU partners to ensure efficient communication with a wide range of audiences throughout Europe.	**Yes**	
Prepare and publish ECHA's second report on REACH and CLP operations under Article 117(2) of REACH.	**Yes**	
Provide support to registrants and downstream users through the Agency's SME Ambassador, in view of the expectation that companies will take their business decisions on continuing to place specific phase-in substances due for registration in 2018 onto the market only during 2017.	**Yes**	
Implement the corporate wide efficiency development programme with new pilot projects, competency development, communication and performance management.	**Yes**	
Optimise the existing Integrated Quality Management and Internal Control System further towards the 2016 surveillance audits.	**Yes**	
Perform audit and consultancy activities in line with the annual audit plan.	**Yes**	
Respond to enquiries (ca. 600) from the general public about ECHA and its activities.	**Yes**	
Develop ECHA's electronic content management system (e.g. Dynamic Case) further in support of house-wide efficiency gains in regulatory and administrative processes.	**Yes**	
Continue streamlining of ECHA's planning and reporting activities with a leaner process and improved and integrated IT solution supporting multiple dimensions of the planning cycle.	**Yes**	
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**	
Benefit from an updated internal website and new internal communication tools.	**Yes**	

2.3.1 Financial resources	Achieved [Yes/No]	Additional information/explanation
Progressively extend the support for standardised finance systems, following the architectural and functional choices made in 2015.	**Yes**	
Continuously ensure correctness of the SME fee reductions claimed by registrants with a focus on examining registrations from the 2013 deadline. Support the verification process with a case management system, including further measures to facilitate correct declarations of company size.	**Yes**	
Implement further efficiency measures, including automation and streamlining of financial processes.	**Yes**	

Progressively extend the use of the European Commission's financial and accounting system used by ECHA (ABAC) for procurement and contract management workflows.	**Partly**	Commission's e-tendering was in full use and a contract for a cost-efficient, non-Commission, electronic procurement system (Cloudia) was established to be used for low-value procurements. ECHA was informed that the Commission will phase out the ABAC contracts application and will replace it with a new contract module (LCK) in the ABAC Workflow.

2.3.2 Human resources	Achieved [Yes/No]	Additional information/explanation
Conduct of the job screening exercise (as part of a wider inter-Agency benchmarking exercise initiated by the European Commission).	**Yes**	
Implement capacity-building actions identified under Strategic Objective 3.	**Yes**	
Implement a general competency exercise for non-scientific staff.	**Yes**	
Complete implementation of the HR Management System (with the addition of the Recruitment site).	**Yes**	
Roll-out change management initiatives.	**Yes**	

2.3.3 Corporate services	Achieved [Yes/No]	Additional information/explanation
Develop a vision and implementation plan for the Agency's future workplace (including a market survey of the local real estate market to determine options for ECHA's decision on its future building).	**Yes**	
Complete the refurbishment plan of ECHA's present building.	**Yes**	
Analyse possible efficiency increases by automation of the management of events (meetings, workshops etc. hosted by ECHA).	**Yes**	
Implement a new framework contract for security and reception services.	**Yes**	
Implement a new A/V signal distribution system in ECHA's Conference Centre.	**Yes**	

2.3.4 ICT	Achieved [Yes/No]	Additional information / Explanation
Adequately support the delivery of the new generation of business information systems to secure the Agency's upgrade milestones in 2016.	**Yes**	
Increasingly use the centralised integrated access management service launched in 2015 by a significant additional number of IT systems.	**Yes**	
Ensure that maintenance releases of all the IT tools used for the administration of the Agency are in production.	**Yes**	

Working in conjunction with the building project, deliver the upgrade of the ICT facilities available at the workplace to align with the evolution of IT technology and enhance flexibility and mobility of the workforce.	**Yes**	
Carry out a major upgrade of the ICT infrastructure and services to support the performance of the data management IT solutions which are particularly demanding in terms of computational and storage capacity. In this context, a new sourcing approach for ICT infrastructure capacity and for application management services will become effective, also to optimise resources and control of costs. ECHA's IT services will become even more of a multi-provider environment whilst ECHA IT staff will focus on service management, service integration and capacity management. The internal processes will be adapted accordingly.	**Yes**	

ANNEX 2: Workload drivers and performance indicators

Workload drivers and baseline numbers	2016 estimate	2016 actual
1.1.1 Registration dossier preparation		
Helpdesk questions	3 0003F	3 298
HelpNet Steering Group meetings	1	1
Inquiries concluded	1 600	1 235
Data-sharing disputes	20	23
Decisions on data-sharing disputes	16	7
Access to data older than 12 years	320	167
Appeals on data-sharing decisions	1	4
1.1.2 Registration and dossier submission		
Registration dossiers (including updates)	10 000	11 357
Confidentiality requests	390	187
PPORD notifications (including requests for extension)	300	212
Helpdesk questions	3 500	2 292
Decisions on completeness check (negative)	100	89
Decisions on confidentiality requests (negative)	50	24
Decisions on PPORD	50	44
Appeals submitted	2	5
1.1.3 Evaluation		
Testing proposals	220	245
Draft decisions on testing proposals	300	133[22]
Final decisions on testing proposals	250	116[23]
Compliance checks concluded, at least 75 % of which address the relevant higher tier hazard endpoints	200 (150)	184 (156)
Final decisions on compliance checks	180	132[24]
Follow-up evaluations on dossier evaluation decisions concluded	350	355
Final decisions or conclusions on substance evaluation	45	47
Appeals submitted	23	8
Helpdesk questions	150	801[25]

[22] Deviation from estimation explained by the delay in receiving resubmitted testing proposals on reproduction toxicity, pending the Commission's decision.

[23] See footnote 22.

[24] Deviation from estimation explained mainly by incorrect estimation but also, to an extent, by a higher than expected number of cases terminated after cease of manufacture or tonnage downgrade.

[25] Reporting of helpdesk questions per activity was introduced in 2016. Due to the lack of historical data, the 2016 estimates were based only on the regulatory questions received in the past, whereas the actual volumes reported above also include a portion of IT-related questions submitted by industry and national authorities.

Workload drivers and baseline numbers	2016 estimate	2016 actual
Substances on the CoRAP to be evaluated by Member States	39	39
Updates of the CoRAP for substances subject to substance evaluation	1	1
1.1.4 Communication of risk management advice through the supply chain		
Helpdesk questions	100	173
1.2.1 Identifying needs for regulatory risk management		
Upon request by the Commission, support provided for the development of RMO analyses and/or SVHC dossiers.	5	0
1.2.2 Authorisation		
Number of proposals for identifying SVHCs	201[26]	10
Recommendation for inclusion of substances in the authorisation list.	1	1
Applications for authorisation (number of uses)	60	112
RAC & SEAC opinions on applications for authorisation	60	63
Helpdesk questions	300	843[27]
1.2.3 Restrictions		
Annex XV restriction dossiers prepared on request by the Commission	2	1
Restriction proposals (Annex XV)	10	2
RAC & SEAC opinions on restriction proposals	7	2
Helpdesk questions	100	847[28]
Restriction proposals (or reports) developed under Article 69(2)	2	2
1.2.4 Classification and labelling		
Proposals for harmonised classification and labelling	60	45
RAC opinions on proposals for harmonised classification and labelling	55	35
Alternative name requests	100	33
Helpdesk questions	250	261
1.3 Biocides		
Number of active substance/product type combinations to be assessed under the Review Programme	50	41
Biocides inquiries	50	56
Biocides data-sharing disputes	5	4
Applications for new active substance approval	23	42
Applications for renewal or review of active substances	0	0
Applications for Union authorisation for biocidal products	8	24
Applications for active substance suppliers (Article 95)	35	54
Applications for technical equivalence	30	21

[26] The expected number of proposals for identification of SVHCs stems from the extrapolation of yearly consultation with the Member State competent authorities on their plans for developing such dossiers and adjusted by intelligence from the processes.

[27] See footnote 25.

[28] See footnote 25.

Workload drivers and baseline numbers	2016 estimate	2016 actual
Applications for chemical similarity	0	1
Submissions to Member States	3 000	1 368
Appeals	1	4
Helpdesk questions	400	2 790 [29]
BPC meetings	5	5
1.4 PIC		
Export notifications	6 300	9 733
Helpdesk questions	150	536[30]
New TA posts to be filled for PIC	0	0
2.1.1 Committees		
MSC meetings	6	7
RAC meetings	8	8
SEAC meetings	6	6
2.1.2 Forum		
Forum meetings	3	3
2.1.4 Board of Appeal		
Appeals submitted	26	28
Cases closed	15	24
2.2 Management		
Resolved general enquiries	600	1 501
Management Board meetings	4	4
2.3.1 Financial resources		
SME status checks for REACH/CLP[31]	500	570
2.3.3 Corporate services		
Press enquiries and interviews	500	498

[29] See footnote 25.
[30] See footnote 25.
[31] SME status checks for the BPR will be performed on demand, according to the rules of the BPR.

Work Programme 2016 Performance Indicators	Target 2016	Result 2016
1.1 REACH dossier management and assessment		
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
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	High	High
Level of satisfaction of users with the quality of external users support service ECHA Helpdesk services	High	High
Level of satisfaction of MSCAs with ECHA's coordination and support to substance evaluation	High	High
Level of satisfaction of interested parties with dossier submission and dissemination activities of ECHA	High	High
Percentage of testing proposals from 2013 deadline concluded	100 %	100 %
Percentage of unanimous MSC agreements on evaluation decisions	80 %	99 %
Percentage of ECHA Helpdesk questions answered by the external users support service within the established timeframe (15 working days)	90 %	91 %
1.2 Risk management		
Level of satisfaction of the 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
Percentage of committee opinions adopted by consensus	80 %	97 %
1.3 Biocides		
Level of satisfaction of the members of the BPC (including its working groups), coordination group, the Commission, MSCAs and industry with the quality of the scientific, technical and regulatory support provided	High	High
1.4 PIC		
Percentage of export notifications processed within the legal timeframe	100 %	100 %
Level of satisfaction with the quality of scientific, technical, and administrative support provided to the Commission, Member State designated national authorities and industry	High	High
1.5 Data management and dissemination		
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
2. Governance and support		
Commitment rate (of commitment appropriations at the end of the year)	95 %	98 %
Payment rate (of payment appropriations at the end of the year)	80 %	86 %
Carryover rate (% of committed funds carried over into 2016)	< 20 %	13 %
Level of satisfaction of the committee, Forum and MB members with the functioning of the conference centre	High	High
Percentage of establishment plan posts filled	95 %	98 %
Turnover of TAs	< 5 %	2 %

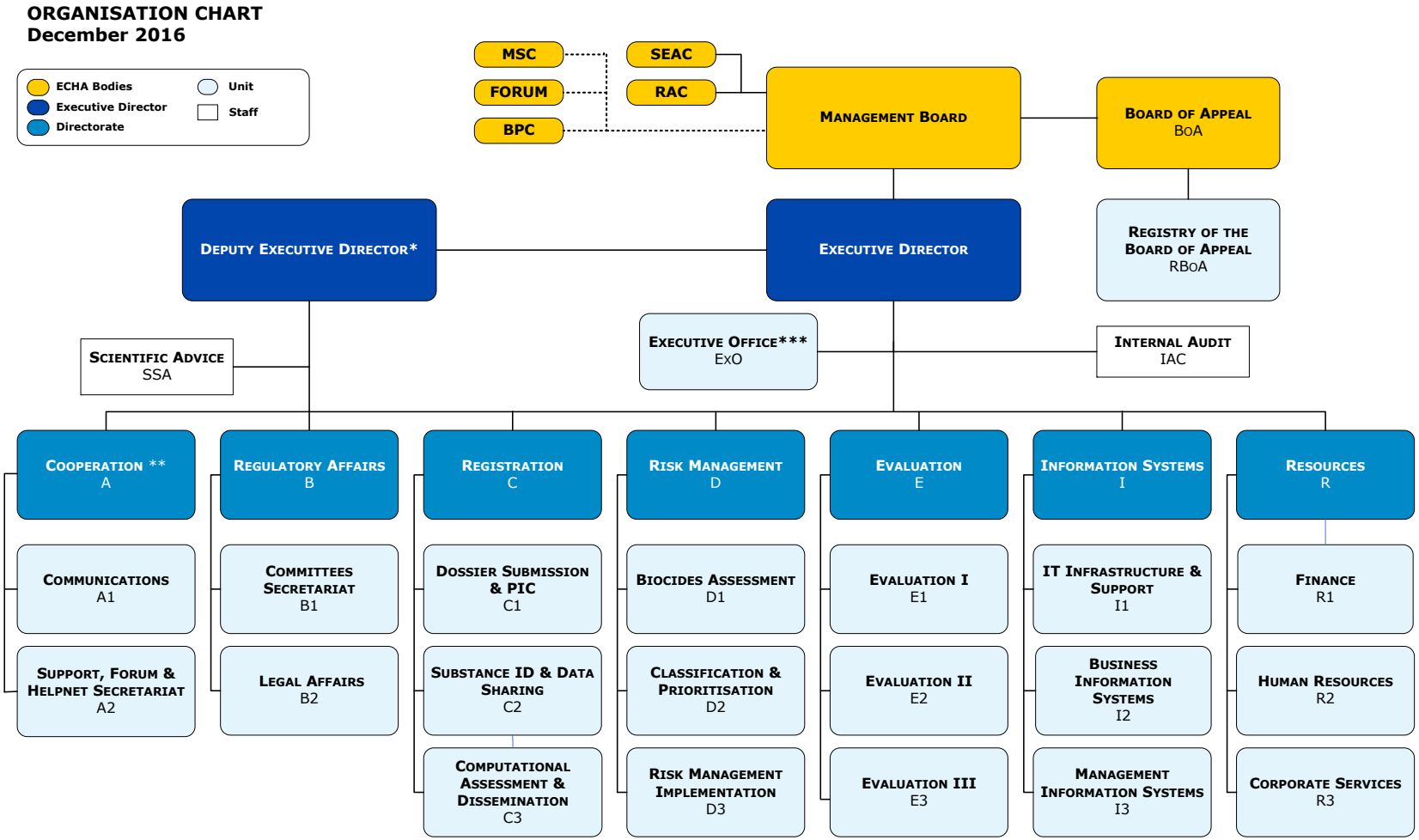
Work Programme 2016 Performance Indicators	Target 2016	Result 2016
Turnover of CAs (excluding short-term CAs)	< 10 %	7 %
Availability of mission-critical systems for externally used IT systems (i.e. uptime during service hours)	On average 98 %	99.8 %
Level of users satisfaction with IT services	High	High
Percentage of very important audit recommendations implemented within the deadline (IAS)	100 %	100 %
Percentage of final Board of Appeal decisions made within 90 working days of the closure of the written or oral procedure	90 %	79 %
Decisions equivalent (no. of weighted decisions/opinions divided by the maximum annual staff capacity)	2 % increase over 2015 value	2.3 % increase over 2015 value

ANNEX 3: Resources 2016

WP 2016 Activity The numbering below refers to the WP 2016, not to the numbering in the budget	Staff Resources 2016		Expenditure 2016 (Commitments made)	
	Planned FTEs **	Actual FTEs*	Planned**	Actuals*
1.1.1 Registration dossier preparation	48	45	11 736 098	13 443 371
1.1.2 Registration and dossier submission	43	39	9 256 352	9 856 308
1.1.3 Evaluation	106	106	18 947 311	18 503 168
1.1.4 Communication of risk management advice through the supply chain	17	15	2 996 515	3 098 187
1.2.1 Identifying needs for Regulatory Risk Management	17	18	2 961 639	2 926 922
1.2.2 Authorisation	33	35	5 830 893	5 715 551
1.2.3 Restrictions	17	17	3 274 879	3 306 157
1.2.4 Classification and Labelling	23	24	4 071 679	4 272 487
1.3 Biocides	53	50	7 865 000	8 207 359
1.4 PIC	7	7	1 151 000	1 082 842
1.5 Data management and dissemination	37	38	10 097 385	11 163 016
2.1.1 Committees	17	17	3 705 446	3 581 580
2.1.2 Forum	8	8	1 702 050	1 646 407
2.1.3 HelpNet and Security Officers Network	2	2	300 561	295 458
2.1.4 Board of Appeal	11	11	1 680 880	1 622 936
2.2 Management	42	42	7 711 311	6 731 601
2.3.1 Financial resources	27	25	3 959 909	3 850 643
2.3.2 Human resources	27	24	3 645 030	3 814 363
2.3.3 Corporate services	23	20	3 308 612	3 249 273
2.3.4 ICT	22	26	3 164 759	3 108 000
Total	**580**	**569**	**107 367 309**	**109 475 628**

*11 vacancies (TA+CA) at 31 December 2016 out of which 7 under recruitment
** 2 additional CA posts since June MB, not included in the 2016 planned figure

ANNEX 4: ECHA Organisation 2016



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

Members of the Management Board on 31 December 2016

Chair: Sharon McGUINNESS

Member

Thomas JAKL	Austria
Anne-France RIHOUX	Belgium
Parvoleta LULEVA	Bulgaria
Bojan VIDOVIĆ	Croatia
Anastassios YIANNAKI	Cyprus
Karel BLAHA	Czech Republic
Henrik Søren LARSEN	Denmark
Aive TELLING	Estonia
Pirkko KIVELÄ	Finland
Catherine MIR	France
Jörg LEBSANFT	Germany
Kassandra DIMITRIOU	Greece
Krisztina BIRÓ	Hungary
Sharon McGUINNESS	Ireland
Antonello LAPALORCIA	Italy
Judite DIPĀNE	Latvia
Marija TERIOSINA	Lithuania
Paul RASQUÉ	Luxembourg
Edward XUEREB	Malta
Hans MEIJER	Netherlands
Lidia WASOWICZ	Poland
Ana Lilia MARTINS	Portugal
Luminița TÎRCHILĂ	Romania
Miroslava BAJANIKOVA	Slovakia
Simona FAJFAR	Slovenia
Ana FRESNO RUIZ	Spain
Nina CROMNIER	Sweden
Keith BAILEY	United Kingdom

Independent persons appointed by the European Parliament

Christina RUDEN	

Member

Anne LAPERROUZE	
Representatives appointed by the European Commission	
Antti PELTOMÄKI	Directorate General for Enterprise and Industry
Kestutis SADAUSKAS	Directorate General for Environment
Sabine JÜLICHER	Directorate General for Health and Food Safety
Stefan SCHEUER	European Environmental Bureau / European Consumer Organisation
Peter SMITH	European Chemical Industry Council
Esther LYNCH	European Trade Union Confederation
Observers from EEA/EFTA and other countries	
Sigurbjörg SÆMUNDSDÓTTIR	Iceland
Sverre Thomas JAHRE	Norway

MEMBERS OF ECHA COMMITTEES AND FORUM ON 31 DECEMBER 2016

Nominating state	MSC – Member State Committee Chair: Watze DE WOLF	RAC - Committee for Risk Assessment Chair: Tim BOWMER	SEAC - Committee for Socio-economic Analysis Chair: Tomas ÖBERG	BPC – Biocidal Products Committee Chair: Erik VAN DE PLASSCHE	Forum for Exchange of Information on Enforcement Chair: Szilvia DEIM
Austria	Helmut STESSEL	Christine HÖLZL, Sonja KAPELARI	Simone FANKHAUSER, Georg KNOFLACH	Nina SPATNY	Eugen ANWANDER
Belgium	Kelly VANDERSTEEN	Hélène LECLOUX	Simon COGEN, Benjamin DELCOURT	Boris VAN BERLO	Paul CUYPERS
Bulgaria	Tsvetanka DIMCHEVA	Stephka CHANKOVA-PETROVA	Elina Velinova STOYANOVA-LAZAROVA	-	Elena ZIDAROVA
Croatia	Dubravka Marija KREKOVIĆ	Veda Marija VARNAI	Silva KAJIĆ	Ivana VRHOVAC FILIPOVIC	Dubravka Marija KREKOVIC
Cyprus	Maria PALEOMILITOU	Kostas ANDREOU	Leandros NICOLAIDES	Andreas HADJIGEORGIOU	Tasoula KYPRIANIDOU-LEONTIDOU
Czech Republic	Pavlina KULHANKOVA	Marian RUCKI, Michal MARTINEK	Martina PÍŠKOVÁ	Tomáš VACEK	Oldřich JAROLÍM
Denmark	Henrik TYLE	Lea Stine TOBIASSEN, Peter Hammer SØRENSEN	Lars FOCK	Jørgen LARSEN	Birte Nielsen BØRGLUM
Estonia	Enda VESKIMÄE	Urs SCHLÜTER	Andreas LÜDEKE	Anu MERISTE	Aljona HONGA
Finland	Susan LONDESBOROUGH	Riitta LEINONEN, Tiina SANTONEN	Johanna KIISKI	Sanna KOIVISTO	Marilla LAHTINEN
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Germany	Helene FINDENEGG	Norbert RUPPRICH, Ralf STAHLMANN	Karen THIELE, Klaus URBAN	Stefanie JÄGER	Katja VOM HOFE
Greece	Aglaia KOUTSODIMOU	Nikolaos SPETSERIS, Christina TSITSIMPIKOU	Ionna ALEXANDROPOULOU, Alexandra MEXA	Athanassios ZOUNOS	Eleni FOUFA
Hungary	Szilvia DEIM	Anna BIRO, Katalin GRUIZ	Endre SCHUCHTÁR	Emese SZÁNTÓ	Szilvia DEIM
Iceland	-	Stine HUSA	-	-	Ísak Sigurjón BRAGASON
Ireland	Majella COSGRAVE	Brendan MURRAY, Yvonne MULLOOLY	-	Finbar BROWN	Sinead MCMICKAN
Italy	Pietro PISTOLESE	Paola DI PROSPERO FANGHELLA, Pietro PARIS	Stefano CASTELLI, Luisa CAVALIERI	Maristella RUBBIANI	Mariano ALESSI

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Latvia	Anta JANTONE	Normunds KADIKIS, Jolanta STASKO	Ivars BERGS, Jānis LOČS	Julija BROVKINA	Kristine KAZEROVSKA
Liechtenstein	-	-	-	-	Manfred FRICK
Lithuania	Lina DUNAUSKINE	Lina DUNAUSKIENE, Žilvinas UŽOMECKAS	Ilona GOLOVACIOVA, Tomas SMILGIUS	-	Otilija GRINCEVIČIŪTĖ
Luxembourg	Alex WAGENER	Ruth MOELLER, Michael NEUMANN	-	Jeff ZIGRAND	Kim ENGELS
Malta	Ingrid BORG	-	-	Wayne GIORDMAINA	Michael CASSAR
Netherlands	Jan WIJMENGA	Betty HAKKERT, Marja PRONK	Richard LUIT, Cees LUTTIKHUIZEN	Corine KOMEN	Jos VAN DEN BERG
Norway	Linda REIERSON	Christine BJØRGE	Thea Marcelia SLETTEN	Suzanne Collet GORDON	Gro HAGEN
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Slovenia	Tatjana HUMAR-JURIČ	Anja MENARD SRPČIČ, Agnes SCHULTE	Janez FURLAN, Karmen KRAJNC	Petra ČEBAŠEK	Vesna NOVAK
Spain	Esther MARTÍN	Miguel SOGORB, Ignacio de la FLOR TEJERO	Adolfo NARROS	Covadonga CABALLO DIÉGUEZ	Pablo SÁNCHEZ-PEÑA
Sweden	Ivar LUNDBERGH	Anne-Lee GUSTAFSON, Bert-Ove LUND	Maria NORING, Åsa THORS	Edda HAHLBECK	Henrik HEDLUND
Switzerland	-	-	-	Manuel RUSCONI	-
United Kingdom	Amanda COCKSHOTT	Stephen DUNGEY, Andrew SMITH	Gary DOUGHERTY, Stavros GEORGIOU	Michael COSTIGAN	Appointment pending
n/a (Co-opted)		Elena-Ruxandra CHIURTU	Lars DRAKE		

MEMBERS OF ECHA COMMITTEES AND FORUM ON 31 DECEMBER 2016

Nominating state	MSC – Member State Committee Chair: Watze DE WOLF	RAC - Committee for Risk Assessment Chair: Tim BOWMER	SEAC - Committee for Socio-economic Analysis Chair: Tomas ÖBERG	BPC – Biocidal Products Committee Chair: Erik VAN DE PLASSCHE	Forum for Exchange of Information on Enforcement Chair: Szilvia DEIM
n/a (Co-opted)		Elzbieta JANKOWSKA	Robert CSERGO		
n/a (Co-opted)		Rudolf van der HAAR	Derrick JONES		
n/a (Co-opted)		Susana VIEGAS			

ANNEX 5: Candidate List of substances of very high concern (SVHCs)

Substances added to the Candidate List in 2016 and January 2017

Substance name	EC number	CAS number	Date of inclusion on Candidate List	Reason for inclusion	Candidate List Decision	Submitted by
4,4'-isopropylidenedi-phenol (Bisphenol A, BPA)	201-245-8	80-05-7	12/01/2017	Toxic for reproduction (Article 57c)	ED/01/2017	France
4-heptylphenol, branched and linear [substances with a linear and/or branched alkyl chain with a carbon number of 7 covalently bound predominantly in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof]	-	-	12/01/2017	Equivalent level of concern having probable serious effects to environment (Article 57 f)	ED/01/2017	Austria
Nonadecafluoro-decanoic acid (PFDA) and its sodium and ammonium salts	206-400-3, -, 221-470-5	335-76-2, 3830-45-3, 3108-42-7	12/01/2017	Toxic for reproduction (Article 57c), PBT (Article 57 d)	ED/01/2017	Sweden
p-(1,1-dimethylpropyl) phenol	201-280-9	80-46-6	12/01/2017	Equivalent level of concern having probable serious effects to environment (Article 57 f)	ED/01/2017	Germany
Benzo[def]chrysene (Benzo[a]pyrene)	200-028-5	50-32-8	20/06/2016	Carcinogenic (Article 57a), Mutagenic (Article 57b), Toxic for reproduction (Article 57c), PBT (Article 57 d), vPvB (Article 57 e)	ED/21/2016	Germany

ANNEX 6: Management Board Assessment of the Consolidated Annual Activity Report for 2016

MB/3/2017 FINAL

30/03/2017

ASSESSMENT OF THE CONSOLIDATED ANNUAL ACTIVITY REPORT OF THE AUTHORISING OFFICER FOR THE YEAR 2016

In assessing the Consolidated Annual Activity Report 2016, the Management Board made the following observations[32]:

1. The Report provides a detailed account of the activities carried out by ECHA in 2016, a comprehensive overview of activities, financial information, the risks related to organisational 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. The Management Board notes with satisfaction that ECHA could increase the output in spite of staff reductions.
3. The Management Board welcomes that ECHA implemented the nine recommendations of last year's Management Board assessment, noting that some of these recommendations are of ongoing nature.

The Management Board notes/welcomes in particular the following achievements:

1. Out of the 27 performance targets set in the Work Programme 2016, ECHA achieved 18 performance targets, exceeded 8 and missed only one by a small margin. Stakeholder satisfaction was high in all of the 14 areas measured.
2. Compared to the year 2015, the number of opinions or agreements was significantly increased from 260 to 351. The Committee for Risk Assessment (RAC) adopted 99 opinions, the Committee for Socio-economic Analysis (SEAC) 65 opinions, the Member State Committee (MSC) adopted 6 opinions and reached 128 agreements and the Biocidal Products Committee adopted 53 opinions.
3. Enhanced support was provided to small and medium sized enterprises (SME), including SME targeted guidance and more user-friendly versions of IT tools used to prepare the registration dossiers. Furthermore, the development of cloud service for the registration of dossiers has been launched.
4. The dissemination portal was tailored to various audiences' needs and structured in three layers (Infocard, Brief Profile and Source Data), thus making the information of up to 120 000 chemicals publicly available in a user-friendly format.
5. The examination of completeness of REACH registration dossiers was enhanced focusing on the description of the substance identity and on data waivers for hazard data that had not been substantiated by justifications.
6. Read-across has been extensively used by registrants to avoid animal testing under REACH. The framework for

[32] Assessment pursuant to Article 47 of the Agency's Financial Regulation

the assessment of the applicability of read-across was further developed to include environmental endpoints.

7. The further progress made in implementing task under the newer EU Regulations (BPR, PIC), the successful start of the new task on poison centers and the delegation agreement signed with the Commission on the EU Observatory for nanomaterials and the EU Chemicals Legislation Finder.
8. The high degree of budget execution and low degree of vacancies, the collection of higher than estimated volumes of fees and charges under the different regulations and the adequate follow up of audit recommendations.
9. The adequate management of risks, the progress made on transparency, prevention of conflict of interest, data protection, security and business continuity, higher compliance with the integrated management standards and the efforts undertaken to improve economy and efficiency in all activities.

The Management Board recommends for 2017 to:

1. Continue implementing the Agency's Integrated Regulatory Strategy for achieving the commitments made at the World Sustainable Development Summit 2002 for 2020, and further focus on grouping when addressing substances for further regulatory action, including through a collaborative approach between European and national authorities. Evaluate options for increasing the efficiency of the evaluation process, e.g. by aiming at avoiding multiple evaluations for the same substance.
2. Provide adequate follow-up to relevant findings and recommendations of the European Commission's REACH Refit Evaluation whilst involving transparently and inclusively ECHA's stakeholders.
3. Continue to provide dedicated SME services for substance suppliers and downstream users, based on relevant tools, guidance and multilingual communication.
4. Further follow-up on the concerns expressed by the European Parliament in its resolution of 25 November 2015 as regards the process for authorisation applications under REACH, and further focus on simplification and harmonisation of the authorisation and restriction processes. Continued particular attention should be given to gathering information on alternatives to chemicals subject to the authorisation requirement.
5. Further improve the forecasting of the income from fees and charges, while acknowledging the constraints and the efforts deployed by ECHA. Further efforts are still necessary to reduce the gap between the balancing subsidy requested and the amount consumed at the end of the year. The Management Board should revise the subsidy estimate in its June meeting to allow the redeployment of unused appropriation by the Commission.
6. Support Member States and encourage them to take up their roles under the legislations and provide adequate resources and expertise.
7. Continue with the preparation for the new tasks on endocrine disruptors, in particular the establishment of guidance on the hazard identification.
8. Encourage and support Member States to carry out their roles and tasks under the review programme on existing biocidal active substances in order the timelines in the programme will be respected.
9. Continue the implementation of the efficiency programme and explore further synergies between the different pieces of legislation entrusted to ECHA. Report on the synergies in the next consolidated annual activity report and on the tools and mechanisms that ensure the segregation of expenditure incurred for the various pieces of legislation.

For the Management Board

The Chair

Sharon McGuinness

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