ECHA
EUROPEAN CHEMICALS AGENCY

General Report 2015

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General Report 2015

Helsinki, March 2016
Doc: MB/02/2016 final adopted 17.03.2016

Reference: ECHA-16-A-02-EN
Cat. number: ED-AG-16-001-EN-N
ISBN: 978-92-9247-836-0
ISSN: 1831-712X
Publ. date: April 2016
Language: EN

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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
CG	Coordination Group
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
IPA	Instrument for Pre-Accession Assistance
IQMS	Integrated Quality Management System
ISO	International Organisation for Standardization
ICT	Information Communications Technology
IR	Information requirements
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

NeRSAP	Network of REACH SEA and Analysis of Alternatives Practitioners
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	Risk Assessment Committee
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REACH-IT	REACH-IT is the central IT system providing support for REACH
RIPE	REACH Information Portal for Enforcement
RMO	Risk management option
RMOA	Risk management options analysis
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
WP	Work Programme

FOREWORD BY THE EXECUTIVE DIRECTOR

"The year of Integrated Regulatory Strategy "

This report covers ECHA's activities in 2015. Looking back, the focus of the year has been on reorienting our regulatory work to achieve maximum impact on human health and the environment. Once again, ECHA delivered well last year, achieving almost all the performance indicators in the Work Programme, and receiving excellent feedback from the various stakeholders.

REACH, CLP, Biocides and PIC share the common aim of protecting human health and the environment from the most hazardous chemicals. In 2015, we developed a **new integrated regulatory strategy** which brings all our processes together to reach the aims of these regulations, as well as the 2020 goals of the World Summit on Sustainable Development. Together with the Member States we further developed the common screening process which identifies substances that have the greatest potential for negative impact on human health and the environment. Based on the common screening we conclude which substances need further compliance check and/or substance evaluation and which substances can be directly earmarked for the EU risk management measures. Depending on the evaluation results we will be able to conclude whether a substance is of concern or not. Also industry can contribute by proactively updating their dossiers when informed of the results of the common screening and by providing better use and exposure information. This level of coordination will also be instrumental in making sure that all relevant currently known substances of very high concern (SVHC) are on the Candidate List by 2020 with the best risk management options identified.

REACH enables companies to request **authorisation** to continue using an SVHC until an alternative can be developed. This process is reaching maturity and peak activity. Many applications arrived towards the end of last year and more are expected in early 2016. To prepare for the high workload, new co-opted members of the scientific committees were nominated in 2015. Stakeholders have concluded in a workshop last year that the authorisation process is working: it leads to improved risk management; involves third parties and observers; and is transparent, affordable and predictable. Notwithstanding, further improvements can still be made and the Commission is planning an implementing regulation to cover some of these.

2015 was an important year in preparing for the **2018 REACH registration deadline**: the biggest in terms of dossiers, substances, and the participation of inexperienced and smaller companies. Work began in 2015 to improve all our IT systems and materials for registrants. Related to that, we radically improved the way in which **information on chemicals** is presented on our website – helping companies and consumers to make more use of it.

Finally, the implementation of the **Biocides** regulation resulted in unexpectedly high activity. That is welcome – it shows that companies are becoming familiar with the changes and the opportunities offered by Union Authorisation – however, with a frozen staff level on Biocides, it presented quite a challenge.

I must close by paying tribute to my colleagues in ECHA and to the wider group of professionals working on chemical safety in the Member States, the European Commission, stakeholder organisations and companies throughout Europe. I am proud to work with such motivated and committed people for the noble objectives of these laws that are so important to Europe's citizens, businesses and our collective future.

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".

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

<table>
<tr><th>Mission</th><th>Values</th></tr>
<tr><td>ECHA is the driving force among regulatory authorities in implementing the EU's groundbreaking 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.</td><td rowspan="3">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.</td></tr>
<tr><th>Vision</th></tr>
<tr><td>ECHA aspires to become the world's leading regulatory authority on the safety of chemicals.</td></tr>
</table>

Highlights - Summary

In 2015 ECHA continued its pursuit of the four strategic objectives by concentrating the efforts to:

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

2015 was a year of preparation for the 2018 REACH registration deadline. It was notable that the number of registration dossiers received, especially new registrations, was much higher than expected. This suggests that companies have already started to submit their registrations for the last registration deadline. However, only 17% of all registrations came from SMEs. Compared to the forecasted 30% it underlines the fact that awareness of SMEs on their registration obligations remains a major concern.

In this respect ECHA started implementing actions under REACH 2018 Roadmap and publishing the first two phases of new SME friendly multilingual support material accessible via dedicated web pages. In addition, the Agency started preparing to release the next generation of dossier preparation and submission tools which will be much more user friendly. To better understand the needs of SMEs in these regards, ECHA launched a specific SME visits programme with targeted visits to SMEs from certain sectors and countries.

Also the Chemical Safety Assessment programme included actions targeting SMEs via short explanation videos, webinars and presentations. Overall improvements in communication in the supply chain under the Chemical Safety Report / Exposure Scenario Roadmap will result in more relevant information communicated in a standardised way to downstream users. Altogether, these actions help SMEs without registration obligations to better understand the impact REACH has on their business and how to comply with their downstream user obligations.

ECHA started implementing the compliance check strategy established in 2014 with over half of all performed compliance checks addressing substances of high relevance for risk management. Selection and priority setting of the dossiers was based on the integrated IT and manual screening as well as previous assessments. In 2015 ECHA changed also its approach towards dossier updates, promoting pro-active dossier improvements by publishing lists of substances which may potentially be selected for future compliance check.

Reaching a major planning milestone, ECHA completed by year end, the work that allows all EU citizens to access summary safety information on up to 120 000 chemicals directly on the Agency's website. The collected extraordinary amount of data is tailored to various audiences' needs and structured in three layers: 'Infocard', 'Brief Profile' and 'Source data'. This new way of disseminating information allows the interested stakeholders to scrutinise the information on substances of their interest while helping companies to become more aware of the quality of their dossiers and eventually giving an incentive for further improvements. It also benefits the SMEs as they can identify if their substance has already been registered or check information from their suppliers. The official launch of the new platform was, for promotion reasons, postponed to January 2016.

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

2015 was a second year of implementation of 'The EU Roadmap for SVHC identification and implementation of REACH risk management measures to 2020' which resulted in

further development of the common screening approach, integrating all processes, defining screening scenarios and focusing on the substances that matter the most for human health and environment safety. An increasing number of Member States participated in the manual screening that followed the IT screening.

The Member States Compethent Authorities continued to evaluate substances listed on the updated Community Rolling Action Plan. As a result further information was proposed to be requested for 39 substances while conclusions were reached for 11 substances, of which majority showed no further concern. ECHA supported the evaluating Member States by providing consistency screening and assisting in finalisation of the draft decisions. To improve the substance evaluation process, ECHA launched a review which identified several areas for improvement. This was further strengthened by the feedback received from the first decisions of the Board of Appeal on the process and substance evaluation decisions. The proportion of substance evaluation decisions which have been appealed remained relatively high (over 20%).

In terms of identifying substances of concern, 7 new SVHCs were added to the Candidate List in 2015 based on member states proposals and Commission's request. Although less than expected, it brings the total number of identified SVHCs to 168 by the end of 2015. Moreover, ECHA provided its sixth recommendation for inclusion of 15 more priority substances in the Authorisation List to the Commission and developed its draft seventh recommendation. As a direct result of the SVHC Roadmap implementation ECHA published on its website conclusions on 24 Risk Management option analyses, 21 of which identified a need for further regulatory action.

ECHA continued raising awareness on the authorisation requirements by means of pre-submission information sessions, publication of clear and well-structured examples of authorisation applications evaluated by RAC and SEAC and SME-friendly web guide to authorisation. Moreover, the application process was simplified to render it more fit-for-purpose. Also the Implementing Regulation establishing simplified rules for special cases advanced well and is awaiting the Commission adoption.

During the year, ECHA received 7 new applications for authorisation covering 13 different uses, while RAC and SEAC adopted 25 opinions on applications submitted mostly in 2014. In addition, ECHA's Committees adopted opinions on restriction reports submitted by Member States (ammonium salts, cadmium in artists paints, perfluorooctanoic acid and its salts, Bisphenol-A) and by ECHA (Asbestos and Decabromodiphenylether).

Finally, RAC adopted 38 opinions on harmonised classification and labelling proposals on substances in consumer products, in wide industrial uses and several plant protection and biocidal products, reaching the milestone of 200 such opinions since it started its work.

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

In 2015 ECHA continued implementing the Science Strategy defined in 2014. This was achieved through its contributions to the OECD Test Guidelines and Guidance Documents on the priority endpoint areas of skin sensitisation, genotoxicity, endocrine disrupters and aquatic and terrestrial ecotoxicity. Furthermore ECHA co-organised a Topical Scientific Workshop on Soil Risk Assessment and designed training programmes to strengthen the competences in the relevant priority areas.

ECHA promoted a dialogue between authorities and researchers on scientific issues, especially to promote alternatives to animal testing. Further scientific advice was

provided to authorities and registrants through publishing the Read-Across Assessment Framework on how to build and assess read-across justifications for human health information requirements.

Significant work has also been dedicated to 'nanomaterials', with ECHA continuous chairmanship of the OECD steering group for testing and assessment under the Working Party on Manufactured Nanomaterials and especially with the view to an expected, although postponed, revision of REACH Annexes to explicitly include the 'nanoforms' of substances.

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

Throughout the year ECHA paid special attention to the ways its work is organised to further strengthen the effectiveness and efficiency of the REACH and CLP processes. Furthermore ECHA continued to strengthen its processes through the integrated regulatory strategy which shall overall increase effectiveness and coherence of all operations ECHA and its partners have at their disposal to ensure improved dossier compliance and safe use of substances. A number of initiatives including a wide-scope efficiency programme and introduction of change management to work leaner helped the Agency to mitigate the regulatory staff reductions. The achievement of the Work Programme targets was to a large degree possible thanks to the smooth functioning or upgrading of many of the administrative and scientific IT workflow systems.

In preparation for an expected peak in workload on authorisation applications, the Management Board concurred with the Secretariat on the need to encourage the nomination of more regular committee members and nine co-opted members were consequently appointed to the two committees (RAC and SEAC).

Despite the significant financial and human resources constraints under Biocides Regulation ECHA managed to meet and exceed its targets for the Biocides, keep the Registry for Biocidal Products (R4BP 3) up-to-date and hold a workshop with the national authorities to review the active substance approval process and explore possible ways of increasing further its effectiveness and efficiency.

In 2015 ECHA achieved also a cruising speed in handling PIC notifications, which increased by 19% compared to 2014. ECHA managed to effectively co-ordinate gathering of information for the yearly report on realised imports and exports.

ECHA's Strategic Objectives 2014-2018 – Results

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 2015 are presented below:

1. Maximise the availability of high quality data to enable the safe manufacture and use of chemicals (SO1)

In 2014, ECHA established four indicators to measure progress towards its first Strategic Objective (SO1), i.e. maximise the availability of high quality data to enable the safe manufacture and use of chemicals. The indicators 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 via IT Tools. Each result expresses the percentage of dossiers which successfully passed the automated screening.

Overall, the quality of dossiers improved during 2015 compared to 2014 in the areas of substance identification (+3%), and uses in intermediate dossiers (+2%). There were no changes in the percentage of dossiers having issues on hazard information, and a slight decrease in the compliance with harmonised classifications (-1%).

As for the substance identification indicator, the value of this indicator is 68% for 2015, calculated on the whole database (42.000 dossiers). This shows an improvement of +3% compared to 2014, +6% compared to the baseline measured in 2013 and +13% compared to 2010. When considering only the registrations submitted in 2015, the quality raises to 79%. These positive results show that registrants respond to ECHA's efforts to stimulate improvements in the quality of substance identification in the registration dossiers.

As for the indicator on uses incompatible with substances registered as intermediates, the value arrives to 91% for all intermediate dossiers (9000 dossiers) in 2015 (+2% compared to 2014, +3% to 2013, and +33% to 2010). When considering only intermediate registrations submitted in 2015, the value raises to 96%. The constant improvement recorded since ECHA's letter campaign on this area in 2012[1] shows that such actions bring benefit also in the long term as industry remains aware of the identified problems subject to the campaign and also apply it to their future registrations.

As for the indicator on compliance with harmonised classification, the value reached 96% in 2015 for the whole database (42.000 dossiers). Since 2010, every year the indicator had been steady at a value of 97%. In 2015, ECHA included in the search the new harmonised classifications from the 6th Adaptation to Technical Progress (ATP) to the CLP Regulation. The analysis of the detailed results has shown that the classification of some substances with a high number of registrations has been updated following this ATP, but some of the existing registrations still report the older classification. Therefore the 1% decrease of the indicator is associated to this update.

As for the hazard information indicator, this remained at the same level of 2014, i.e. 37% (+1% compared to 2013, +9% to 2010), based on 4.500 lead and individual dossiers screened. The methodology used to measure this indicator relied on the compliance check strategy implemented before 2013. ECHA's strategy is now to focus on

[1] Intermediates letter campaign: http://echa.europa.eu/view-article/-/journal_content/0d1a14fe-9c63-4807-a3de-380c0dbffdf5

substances and endpoints that matter[2], so the indicators on this area will no longer be maintained.

Table 1. Results of SO1 indicators for 2015, showing the % of registrations that pass successfully the automated screening.

Area	Result
Substance identification	68% (79%)
Classification	96% (96%)
Uses (in intermediate dossiers)	91% (96%)
Hazard	37% (38%)

For each area, the value of the indicator for the whole database (i.e. for dossiers submitted since 2008) is given first. The number in brackets indicates the value registered when considering only registrations submitted in 2015.

2. Mobilise authorities to use data intelligently in order to identify and address chemicals of concern (SO2)

From all substances that were identified by IT-based mass-screening, 76% were found to require further follow-up actions. This number is slightly lower than last year but is linked to the fact that the same database is being searched for some years now with very similar scenarios (e.g. for carcinogenic, mutagenic or toxic to reproduction substances). Further improvements of the screening and identification of substances of potential concern are under development and should be reflected in the years to come. In total, 21 Member States and EEA countries participated in the manual screening in 2015 which is three more than last year indicating a clear interest from Member States in this activity.

It is still early to draw any conclusions on trends and effectiveness regarding substance evaluation as for most of the substances the process has not been completed, due to requests for further information. Between 2012 and 2014, 134 substances were evaluated and 29 (22%) evaluations concluded. Most of these conclusions were for substances for which no further information was requested. For 11 concluded cases (38% of all conclusions), the evaluating Member State considered that further regulatory risk management may be needed.

20 of the Member States/EEA countries were actively evaluating substances in 2015 (stable in comparison to 2014, with the same number of countries involved). This leaves still room for improvement for the future years.

16 Member States submitted proposals for regulatory risk management measures under the REACH or CLP which is a clear increase compared to last year (11). The extent to which the conclusions from the risk management options analysis (RMOA) received further follow-up has also increased (68% vs 17% in 2014). The SVHC identification and Restriction proposals were followed-up in 80% of the cases. On the contrary, none of the two substances for which CLH was concluded as the best RMO has yet been taken forward.

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 (SO3)

[2] Compliance check strategy: http://echa.europa.eu/documents/10162/13608/echa_cch_strategy_en.pdf

The aim of strategic objective 3 is to facilitate ECHA's activities under strategic objectives 1 and 2 (enabler function) while independent operative goals for strategic objective 3 have not been defined in the MAWP 2014-2018. Nevertheless, a broad range of work is outlined and can be sub-divided in three priority areas: regulatory science strategy, capacity building and working as a hub in regulatory science.

Selected activities that are considered to be especially important or representative for the relevant priority areas – the milestones – are mentioned in the MAWP Annex. Their completion is key for the specified priority areas as well as for ECHA's success in meeting the goals under this objective.This is done on one hand by enhancing the scientific competences of ECHA's own staff, and on the other hand in close cooperation with other actors within the concept of ECHA acting as a hub. Therefore, ECHA's corporate performance in relation to these milestones is measured. The overall implementation rate for the eight milestones in 2015 was high by measuring the achievement of their objectives within the planned timeframe.

ECHA's capacity to act as a hub of excellence in regulatory science was reflected by stakeholders who responded to corresponding questions in the 2015 stakeholder survey, with a high level satisfaction as the result[3], which is an increase from the medium level observed during the 2014 survey. The responses showed that ECHA is assessed to work on the most relevant topics of regulatory science, with some further topics suggested to be given priority as well. Stakeholders also appreciated that ECHA was taking part in the work of international bodies and networks. While ECHA's engagement in regulatory science development, cooperation and capacity building is overall acknowledged, sharpening of ECHA's role and input in relation to regulatory science should be in the focus when shaping future initiatives.

4. Embrace current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints (SO4)

ECHA developed a composite score "Decisions and opinions equivalent" to measure the 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 on whether the Agency is following an efficiency trend throughout the years, i.e. producing more weighted outputs with the same or less resources.

An analysis of the 2015 measurement shows that the "Decisions and opinions equivalent" continues to increase thus showing a positive trend in efficiency.

Table 2. Efficiency trend

INDEX TREND	2013	2014	2015
TOTAL WEIGHTED DECISIONS	24 323	25 873	25 240
TOTAL STAFF	592	621	597

[3] Measured via the standard methodology of ECHA's annual stakeholder satisfaction survey.

Decisions equivalent (No of weighted decisions/opinions divided by the maximum annual staff capacity)	54.8	55.6	56.4

Table 3. Efficiency score

% change	2013 -> 2014	2014 -> 2015
% change in TOTAL WEIGHTED DECISIONS	+6%	-2%
% change in TOTAL STAFF	+5%	-4%
% change in Decisions equivalent	+1.4%	+1.5%

In 2015, the evaluation, registration and CLP activities have generated lower regulatory output compared to 2014, while the Biocides, PIC and risk management activities have generated higher output. The total number of decisions and opinions produced in 2015 has increased by 13% compared to 2014 (i.e. 13 205 vs. 11 706). However when weighted with the time needed to process an average decision or opinion this value decreased by 2% compared to 2014 as can be seen in Table 3 (i.e. under '% change in total weighted decisions'). This small decrease is the net result of a combined fluctuation of different types of high- and low-labour-intensive outputs compared to 2014. Due to the increased maturity of Biocides processes and the development of the new Biocides staff model, the provisional weighting factors established in 2014 for Biocides processes have been updated, leading to more accurate measures. On the other hand, in 2015, for the first time compared to previous years there has been a decrease in the staff numbers. Proportionally this represented a higher decrease than the decrease in total weighted decisions, thus resulting in an overall 1.5% increase in the efficiency score compared to 2014.

The trend of SO4 so far has shown that the Agency is able to produce high number of regulatory outputs without increasing its total staff numbers proportionally, which is a good indication of efficiency.

1. Implementation of the Regulatory Processes

1.1. Registration, data sharing and dissemination (Activity 1)

Registration is one of the cornerstones of REACH, since it is the main step for companies for ensuring the safe manufacture or import and use of chemicals. Companies that manufacture or import a substance at or more than one tonne per year, need to document the properties and uses of their substances and demonstrate that the substances can be used safely in a registration dossier submitted to ECHA. Before assigning the registration number, ECHA verifies the completeness of the information and the payment of the registration fee. Most of the information is then disseminated to the public through ECHA's website.

Due to the registration process, ECHA holds a unique database on chemicals, which can be efficiently used in further regulatory processes, especially in 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 where they communicate the conditions of safe use further down the supply chain and make the safe use of chemicals a reality to tens of thousands of downstream users and their customers. It is, therefore, crucial that the registration information is of adequate quality to achieve the key objectives of REACH. In practice, this means that the information is compliant with the regulations, fit for purpose and easily accessible to all parties.

The Agency will continue actions towards raising dossier quality, and as a new emphasis, reorienting these actions on substances and dossiers that matter most for risk management purposes. This ensures integration of the objectives 'information quality' and 'intelligent use of this information' of ECHA's multi-annual strategy. Finally, ECHA will continue to find synergies so that biocides and PIC-related work can be efficiently integrated in its existing activities of dossier submission, data sharing and dissemination, without compromising the specific features of each regulation.

1. Main achievements in 2015

Registration and dossier submissions

Registration

Year 2015 had no deadline for phase-in substances. It is therefore a regular year for registration. In total ECHA received 8 200 registration dossiers, 50% more than predicted, of which 41% were new registrations. This was most likely due to two reasons: firstly, companies, especially big players,appear to have slowly but steadily started submitting their registrations for the last registration deadline of 2018 with a view to divide the work over several years. Secondly, the number of updates received remained at higher level than predicted.

The majority of the registration dossiers were updates as in 2014. However, the ratio of new registrations and updates changed compared to the previous year as the number of new registrations increased by 20%, and the number of updates decreased by 35%. This reflects the fact that no major letter campaigns to encourage registrants to scrutinise and update their dossiers were carried out in 2015 and illustrates the positive impact of complementary measures to raise the level of compliance of the registration dossiers. In terms of substances, 886 substances were registered for the first time under REACH, which is more than twice the number of first-time substances in 2014. Of these about

280 were non-phase-in substances, so majority of the increase appears to be due to activities related to the last registration deadline of phase-in substances.

Of all registrations received, only 17% came from SMEs, a bit less than in 2014, compared to the forecasted 30%. There are indications that companies have not started their registration preparations for the last deadline yet.[4] This underlines the fact that awareness of SMEs on their registration obligations remains a major concern for the 2018 registration deadline. Furthermore, what can be observed is the steady flow of registration dossiers for phase-in substances registered above 100 tonnes/year. This reflects the normal market behaviour where companies seize new opportunities and add and remove substances from their portfolio. As in the previous years, a clear majority of these registrations are for substances from outside the EU (i.e. registered either by an importer or an only representative).

In order to lower the barriers for inexperienced registrants, especially SMEs, for fulfilling their obligations, ECHA started to implement actions under ECHA's REACH 2018 Roadmap. In practice, the Agency developed new SME friendly multilingual support material for the first two phases of the Roadmap (Phase 1: Know your portfolio, Phase 2: Find your co-registrants), made it more accessible via the REACH 2018 web pages and delivered webinars where participants could ask questions related to the topics of the phase. The material has been well received, and ECHA will continue the implementation in 2016 for the four remaining phases of the Roadmap.

In the run up to the last registration deadline, ECHA also intensively continued the work towards releasing the next generation of dossier preparation and submission tools, IUCLID, Chesar and REACH-IT in 2016. As part of ECHA's commitment to make the tools more user-friendly, the review of all manuals started with the aim to release the IT tools with integrated help in 2016 in order to better support the registrants completing their dossiers. Importantly, the ongoing development of REACH-IT accommodates the Implementing Regulation on joint submission of data and data sharing[5] which clarifies that ECHA shall ensure that all registrants of the same substance are part of the joint registration submitted by the lead registrant. REACH-IT will prevent registrants from submitting an individual registration or creating a joint submission for a substance for which a joint submission already exists. Furthermore, the decision in ECHA's Management Board in summer 2015 to include a manual check of certain information in the completeness check process was taken into account in the tool. The changes forthcoming in 2016 were shared well in advance with the stakeholders during 2015 in an open seminar to allow duty holders to start preparing for them.

Activities related to chemical data management and data provision have continued to grow steadily in 2015 to serve both internal requests to support evaluation and risk management work as well as external requests stemming from the MSCAs, the European Commission and other EU institutions that use the REACH and CLP data to perform their day-to-day regulatory activities. In 2015 ECHA continued to develop its data screening methodologies for analysing the whole database of registration dossiers and the Classification and Labelling (C&L) inventory. This served multiple purposes one of which was to provide more targeted support to registrants on common issues found in their dossiers. Findings were further integrated in support material and the validation assistant tool so that registrants could get a better understanding on how to prepare their registrations.

Furthermore, ECHA continued to focus its attention on substance identity information (SID) provided in registration dossiers and utilise its data screening tools to detect

[4] Reference: p. 109 (footnote 83) of the COM Monitoring study.
[5] Commission Regulation (EU) 2016/9 of 5 January 2016, available in the Official Journal at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0009&from=EN.

potential shortcomings. The Agency will use the results in a pilot phase to detect and address severe deficiencies in substance identification before more resource demanding regulatory processes, such as dossier evaluation, are initiated.

In general, ECHA considers that informing registrants on dossier anomalies with the option to update the dossier on a voluntary basis is an efficient complementary measure towards better information on safe use of chemicals. To that end, the Agency also redesigned the information letters and the overall process between registrants and the Agency in order to send more informative letters and provide additional time to registrants to improve their dossiers.

In the area of substances registered as intermediates, following the successful information letter campaign on intermediate registrations of 2012, ECHA examined the quality of the use description information in intermediate dossiers in 2015 and found that the overall quality has increased to a sufficient extent that a second information letter campaign was not required at this stage. This demonstrates the far-reaching effects of a letter campaign. This enabled ECHA to focus its efforts on clarifying the intermediate status for priority substances, for example those listed in the candidate list (see Section 1.3).

ECHA has also supported several national initiatives related to screening by providing data analysis expertise and ensuring that the outcome of this work feeds back into the common screening. In total, 215 requests for data were handled by the Agency in 2015, of which 60 came from outside ECHA, especially from the Commission services in support of their policy activities, and 155 concerned internal requests supporting other REACH and CLP processes.

Other types of dossier submissions, including biocides dossiers and PIC notifications

REACH allows exemption from registration for substances used in product and process oriented research and development, if such activities are notified to ECHA (so called 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 Member State competent authorities.

In 2015 ECHA enhanced and streamlined the internal process and monitoring of PPORD notifications, and was able to process the notifications swiftly. Altogether 247 notifications were received, and consequently ECHA sent 40 PPORD Decisions to notifiers. Of these, 31 were requests for further information and 8 were decisions on extending the time for PPORD exemption and one was about imposing conditions.

Because of the awareness actions started in 2014, the PPORD assessment is now more familiar to stakeholders. ECHA noted that if, following a request for information, it is clear that conditions may be imposed by the Agency because they are needed to meet REACH requirements, companies often decide to withdraw the notification and proceed with a registration. In 2015 this happened in 13 out of 17 cases. In 2015 ECHA also revised the decisions on imposing conditions to make them more understandable. In addition, the Forum for Exchange of Information on Enforcement (Forum) provided recommendations how to adapt the decisions to allow better enforceability of them. Also on other issues pertaining to PPORD notifications, such as implementing it for substances in articles processes, active stakeholder discussions continued throughout 2015 and will continue in 2016.

As for dossiers received under the Biocidal Product Regulation, there were nearly 5200 incoming submissions of which 70% were transmitted to the Member States. Nearly 2000 submissions triggered significant processing work for the dossier submission team,

especially for handling the invoicing. In 2015 ECHA also continued the development of the next generation of the Biocidal Products Regulation (BPR) submission tool, R4BP.

Chemical Safety Assessment (CSA) Programme

The CSA Programme continued its work in 2015 by cooperating intensively with stakeholders via the CSR/ES Roadmap working groups and the broader community in ECHA-Stakeholder Exchange Network on Exposure Scenarios (ENES) meetings.

One of the core activities in 2015 was the further development and testing of the ***use maps*** templates to be published in early 2016. They are meant to support the description of typical uses in given downstream sector, and as integral elements, they contain inputs for the registrant's exposure assessment related to workers, consumers and the environment. Clearer and more complete information on existing situation provided to registrants aim to result in clearer and more practically useful advice on conditions of safe use communicated from registrants down the chain. In this context, ECHA also contributed to industries work on their exposure assessment inputs, i.e. SWEDs (sector-specific worker exposure description), SpERCs (Specific Environmental Release Categories) and SCEDs (Specific Consumer Exposure Determinants). It is foreseen that some downstream user associations will start populating their sector use maps and making this information available for registrants in 2016.

To better support the efficient communication of safe use advice from registrants to downstream users, a major update (version 2.0) of the ESCom package was released in summer 2015; this consisted of an XML format for the electronic communication of exposure scenarios in the supply chain, and a catalogue of standard phrases.

Another core activity was the implementation of the ***assessment entity*** concept into IUCLID and Chesar. This new functionality supports chemical safety assessors in better documenting the assessment of substance with a complex behaviour. Examples are substances with significant differences among the contained constituents in terms of exposure behaviour, and substances which are known to have transformation products or form changes associated with changes in the hazard profile.

In order to support registrants in improving the ***safety assessment*** for the substances in ***articles*** ECHA published an illustrative example for such assessment. It illustrates the consumer exposure assessment for a substance used in construction (wood panels).

The work on enhancing the ***support for better use description*** was also continued. Examples of use description were integrated as much as possible in the updated Guidance on use description R.12 which was published in December. Further examples are foreseen to be published in the context of the use maps' development in 2016. In an effort to harmonise practices on a global level, ECHA started to work with the US Environmental Protection Agency to further develop internationally harmonised use codes, with the focus on the article categories and technical functions of substances. These codes are being discussed at OECD level in the context of the Task Force on Exposure Assessment and are expected to be finalised during 2016.

Finally, a broad range of activities were carried out throughout 2015 to ***support downstream users*** with the awareness and implementation of their obligations. ECHA published five editable presentations on downstream user relevant topics to help multipliers communicating the main messages, two short video tutorials for downstream users as well as a checklist for SDS verification and a new Practical Guide on the downstream user chemical safety report. ECHA tested a methodology developed by industry for identifying the lead component(s) in mixtures driving the risk management advice to be communicated to the end-user of the mixtures. Finally, with a view to effectively coordinating activities and information generated under EU chemicals

legislation and national obligations, ECHA arranged a workshop on the use of REACH/CLP information at industrial sites in April 2015. The workshop report was published and new content was added to the downstream user section of ECHA website to cover this area.

Substance identification and data sharing

Due to substance identification being such a crucial step for all subsequent regulatory processes under REACH and CLP, activities in this area continued intensively in 2015. ECHA cooperated closely with specific industry sectors (including the sector of natural complex substances, complex inorganic pigments and metal UVCB substances) in developing guidelines on substance identification and substance sameness. This work enabled the publication of "Guidelines on substance identification and sameness of natural complex substances (NCS) under REACH and CLP" by industry in August 2015. The work initiated with the other industry sectors will continue in 2016. ECHA was also actively involved in the development of guidelines for the identification of hydrocarbon solvents at the OECD level. The guidelines were published in January 2016. To improve the accessibility to these documents, ECHA has created a new section on its website where all sector specific guidelines can be found. Finally, ECHA followed closely the Commission contract on characterisation of UVCB substances. The contractor completed the analysis of selected complex substance registrations, but the publication of the final report was extended to 2016. The factsheets, which will offer a summary of specific substance type registrations analysed by the project team, are not yet available.

To support transparency in joint registrations, ECHA decided, after taking advice from its Management Board, to integrate the substance identity profile (SIP) concept into improvements of its registration tools. The concept was developed by Cefic in 2010 to aid registrants transparently document their sameness criteria in SIEF formation. New fields in REACH-IT and IUCLID will enable registrants to transparently report the scope of the registered substance in terms of boundary compositions that their hazard information (Annex VII-XI data) refers to. The proposed implementation was presented to CARACAL. The proposal was generally accepted and the view from the Member States was that the current legal text has sufficient basis for its implementation. The concept will be introduced in IUCLID 6.1 and REACH-IT 3.1 which will be released in 2016.

As for data-sharing, the activity on inquiries was approximately at the expected level with 906 new inquiry numbers assigned. ECHA received in total 1368 inquiries of which 69% were initial inquiries and the rest (31%) were resubmissions. In 2015 ECHA accepted more than 60% of the assessed inquiries which is 10% more than in 2014. This reflects a better understanding of industry of the improved guidance and advice on the substance identification. More than 20% of the new inquiries contained data requests, with nearly half of them concerning data older than 12 years and thus available free of charge. ECHA monitors the fate of substances inquired on a longer-term perspective. Based on data from 2011-2013, it seems that during the regular years up to 70% of substances inquired will be registered within two years from the inquiry. There is no information on the remaining 30%. Typically, half of the inquired substances are registered within six months, then an additional 10-15% within a year from inquiry after which a long tail of registration follows for the rest.

The pre-registration activity, reflecting companies coming to the market with phase-in substances, seemed to slightly slow down with little over 12 000 pre-registrations arriving in 2015. As for data-sharing disputes, the activity remained low under REACH – only five cases were submitted to ECHA, and apart from one they all concerned data-sharing in SIEFs. In contrast, there were nine data-sharing disputes submitted under BPR, twice the number of 2014 (for details, see Section 1.7).

Dissemination – electronic public access to information

ECHA's database is one of the biggest sources of regulatory information on chemicals in the world and forms a major EU contribution to the 2020 goal to make information on chemicals available to the public, introduced at the World Summit on Sustainable Development in 2002. The database integrates the information from REACH registrations and C&L notifications with substance evaluation and risk management processes, such as harmonised classification and labelling, authorisation and restriction. For biocides, ECHA publishes information on active substances, biocidal products as well as a list of active substance and product suppliers. Statistics on the export and import of hazardous substances that are regulated under the Prior Informed Consent Regulation (PIC) are also made available.

In 2015 ECHA completed the work that totally changed the way in which chemicals data is displayed on its website. Information on up to 120 000 chemicals is now tailored to various audiences' needs and structured in three layers: Infocard, Brief Profile and Source Data. The most accessible new feature is the Infocard, which offers a summary of the key information on a substance in plain English. It is foreseen that this new way of compiling information will benefit any EU citizen who is interested in chemicals. The second new feature, the Brief Profile, is targeted more to the experts from all stakeholders and it offers a more detailed summary of the dossier data, while the third layer – the source data - is formed by the information submitted by companies to ECHA and will interest also researchers. In order to achieve maximum impact by the promotion activities around the new portal, the launch was scheduled for January 2016.

The Brief Profile makes the discrepancies in the data submitted by different companies more visible, specifically with the different classifications and uses of the substance. Therefore the new way of disseminating information allows interested stakeholders to scrutinise the information on substances of their interest and with their observations contribute indirectly to the improvement of the data submitted by companies.

As of 19 January 2016, ECHA's dissemination database contains information on 13 428 unique registered substances from 51 629 dossiers and classification and labelling information for 122 726 substances notified under CLP.

Companies have the possibility to claim some of the data in their registration dossiers confidential. ECHA assesses the claims, and if they are accepted, the information is not disseminated. The level of this activity was low for the 2014 dossiers, so all requests introduced in 2014 (209 requests) were assessed. They concerned mostly the company name (28%), the IUPAC name of the substance (25%) and the company's tonnage band for the substance (17%). In 67% of cases, the request was accepted while further information was requested in 28% of cases leading to a final decision in 2016. In 5% of cases it concerned a confidentiality request on the IUPAC name of a substance which was already notified under the previous Directive 67/548, and the registrant was informed that confidentiality had expired. Altogether, ECHA assessed 319 confidentiality requests, including 110 cases where further information supporting the requests had been requested from the registrants in 2014. Of those where further information was demanded, 36% of the requests were accepted based on the additional information, 30% were rejected, and 34% were withdrawn by the registrant.

In 2015 ECHA implemented automated daily publication of the latest data on biocides. In addition, ECHA made available a summary overview of the active substance approval, showing details of the substances and the biocidal product types for which approval is sought at a glance. In terms of numbers, 147 approved active substances were published, and the identities of the other active substances for which approval was or is being sought, as well as 5 110 biocidal product authorisations published, including both

those now valid and those previously granted. Finally, the Article 95 list of active substance suppliers was published

On publishing information under the PIC Regulation, ECHA's dissemination pages have a dedicated section for PIC data which is used for publishing statistical information on the number of export and import notifications and on explicit consents as well as designated national authority (DNA) contact details. The published data is in-line with what was previously published by the European Commission, but is more easily searchable.

2. Objectives and indicators

Objectives

1. All REACH, CLP, biocides and PIC dossiers, inquiries and data sharing disputes undergo the required checks and the respective decisions are taken, and confidentiality claims assessed, according to the standard procedures, ensuring the timely identification of problematic dossiers to stimulate their updates and have an impact on the data quality, and within the legal deadlines or internal targets set.

2. Decisions are well justified and of a high technical and scientific quality.

3. Stakeholders and the public have easy access to information from all the dossiers of registered substances and Classification and Labelling (C&L) notifications, as well as from biocides dossiers within a reasonable time after the registration/submission of notifications.

4. ECHA, through the ENES network, provides industry with high quality scientific and technical support under the CSA programme to enable successful development of the chemical safety reports (CSRs) and adequate risk management advice through the supply chain in the exposure scenarios.

Performance indicators and targets

Indicator	Target in 2015	Result in 2015
Percentage of registrations and PPORD notifications processed within the legal timeframe.	100%	100%
Percentage of inquiries concluded within the internal timeframe (20 working days).	80%	92%
Percentage of data-sharing disputes concluded within the legal/internal timeframe.	100%	100%
Extent of publication of registration dossiers successfully submitted by the registration deadline of 31 May 2013.	100%	100%
Level of satisfaction of interested parties with dossier submission and dissemination activities of ECHA, as well as with ECHA's activities on improving the quality of CSRs and exposure scenarios for communication.	High	High

3. Main outputs

Registration and dossiers submissions (see the tables below also)

- Approximately 8200 registration dossiers and 247 PPORD notifications checked for completeness and assigned registration number or a PPORD notification number
- 40 decisions on PPORDs were taken
- 3631 biocides applications (applications for new active substances, renewals or review, Union authorisations of products) were processed and transmitted to the Member States.

2018 Registration roadmap and dossier quality

- Phase 1 and phase 2 related new support material published (new web pages and webinars)
- Strategy to support 2018 registrants in relation to REACH Annex III submitted to the CARACAL

CSA programme

- The CSR/ES Roadmap was reviewed and the second implementation plan of the CSR/ES Roadmap was revised
- Two ENES meetings with up to 120 participants (one in Helsinki, one in Brussels)
- Illustrative example for consumer exposure assessment regarding substance in article published
- Improved Guidance and examples for use description in REACH registration dossier published
- Further elements of ECHA's DU support package released
- Use maps concept, template and guidance tested and ready for use by DU sector organisations in 2016
- Assessment entity approach tested and incorporated in Chesar and IUCLID, ready for use by registrants from mid-2016

Substance identification and data sharing

- Five REACH data-sharing disputes resolved (one claim closed without decision)
- 906 inquiry numbers assigned. 12 116 pre-registrations received

Dissemination

- Altogether information from 51 629 REACH registration dossiers published as well as 147 approved active substances, 5 110 biocidal product authorisations published, and the Article 95 list of active substance suppliers under the BPR
- 250 confidentiality claims assessed

Table 4: Number of dossiers (including updates) submitted (input) in 2015 as compared to the workload estimates in the Work Programme 2015

Dossier type	Actual 2014	Actual 2015	WP 2015 estimates
Registrations	9 001	8 243	5 700
Full registrations	7 615	6 933	-
Transported Isolated Intermediates	990	962	-
Onsite Isolated Intermediates	396	348	-
Other types of dossiers			
PPORD notifications	234	247	400
Inquiries	1 488	1 368	1 400

Table 5: Dossier types of new registrations in 2014-15

	Total 2014	Non-phase-in 2014	Phase-in 2014	Total 2015	Non-phase-in 2015	Phase-in 2015
Registrations	2 088	387	1 701	2 468	337	2 131
Transported Isolated Intermediates	515	163	352	554	152	402
Onsite Isolated Intermediates	135	63	72	242	98	144
Total	2 738	613	2 125	3 264	587	2 677

Table 6: Company sizes of registrants submitting new registrations in 2014-2015

Year	Total	Large	Medium	Small	Micro
2014	2 738	80.60%	10.30%	5.70%	3.40%
2015	3 264	83.15%	7.81%	4.72%	4.32%

Table 7: Dossier types of registration updates in 2014-15

	Total 2014	Total 2015	Non-phase-in 2015	Phase-in 2015	NONS 2015
Full registrations	5 657	4 263	265	3 864	134
Transported Isolated Intermediates	484	391	77	300	14
Onsite Isolated Intermediates	256	83	25	56	2
Total	6 397	4 737	367	4 220	150

Table 8: Types of update of registration dossiers updated in 2014-15

	Total 2014	Total 2015	REACH 2015	NONS 2015
Updates following regulatory communication	510	449	434	15
Spontaneous updates	5 887	4 288	4 153	135
Total	6 397	4 737	4 587	150

Table 9: Main reasons identified for spontaneous updates in 2014-15

	REACH 2014	NONS 2014	REACH 2015	NONS 2015
Change in classification and labelling	5%	8%	9%	8%
Change in company role in the supply chain	1%	1%	1%	0%
Change in composition of the substance	7%	3%	4%	1%
Change in the access granted to information	0%	1%	0%	3%
Change in tonnage band	9%	37%	8%	40%
New identified uses	8%	5%	5%	11%
New knowledge of the risks for human health and/or environment	4%	5%	2%	2%
New or update of CSR and guidance on safe use	20%	12%	31%	14%
Others (e.g. substance identification campaign)	46%	28%	41%	22%

1.2. Evaluation (Activity 2)

Dossier evaluation comprises both the examination of testing proposals and compliance checks. The purpose of the compliance check is to examine whether registration dossiers are in compliance with the information requirements of the REACH Regulation, while the examination of testing proposals aims to make sure that the generation of information on a given substance is tailored to real information needs and that unnecessary animal testing is avoided.

Substance evaluation aims to verify whether a substance constitutes a risk for human health or the environment. Substance evaluation is performed by the Member State competent authorities (MSCAs) and involves an assessment of all available information. It may also lead to requests for further information from registrants, if appropriate. The starting point for substance evaluation is the Community rolling action plan (CoRAP) for substances subject to substance evaluation.

1. Main achievements in 2015

Dossier evaluation

Compliance check

Year 2015 was the first full year of implementation of the compliance check strategy established in 2014 and hence posed significant challenges. Before starting new scientific evaluations, two major aspects had to be further developed first: selection of dossiers on substances that matter and clarifying the scope of the evaluations. Selection and priority setting of dossiers was based on internal IT-screening, previous assessments and the manual screening of dossiers by MSCAs and ECHA. As a new element, the potential relevance of compliance check outcome for regulatory risk management measures was incorporated into the manual screening. The screening resulted in a dynamic list of priority cases that ensured that at least 50% of the checks were addressing dossiers on substances of high relevance for risk management.

The workshop on compliance check strategy implementation organised by ECHA in May 2015 was an important milestone for settling the details of the implementation, in particular aligning views of ECHA, MSCAs and the Commission services on the scope of the compliance check. The workshop was successful in confirming the intended focus on the higher tier human health and environment endpoints, whilst acknowledging the evident link with other endpoints and laying down conventions for when other information requirements, including substance identity and chemical safety report, would be important to be included in the scope of the checks. The workshop proceedings were published[6] and ECHA moved into practical implementation.

In parallel, ECHA developed further the plan for implementation of the compliance check strategy, which resulted in a document presented to the Management Board in December 2015[7]. This plan, covering years 2015-2018, laid down the objectives, milestones and overall ambition level for an integrated regulatory strategy utilising all the capabilities, regulatory processes and tools that ECHA together with its partners has at its disposal. This further development of the strategy has significantly advanced the integration of evaluation processes with the other REACH and CLP processes, expands on the use of complementary measures and seeks to mobilise MSCAs and other actors to ensure improved dossier compliance and safe use of substances.

Besides the implementation of the compliance check strategy and adapting to drivers for

[6] http://echa.europa.eu/documents/10162/13628/cch_workshop_2015_en.pdf
[7] http://echa.europa.eu/documents/10162/21961120/mb_59_2015_update_cch_en.pdf

changing certain aspects of the work, the efficiency of the dossier evaluation process was further improved, leading to measureable decrease of average time required to process a single case. As part of these efforts and to avoid multiple rounds of extensive scientific evaluation, ECHA changed its approach regarding dossier updates. After a compliance check draft decision is issued, normally no dossier updates are anymore taken into account during the decision making but only at the stage of the follow-up evaluation. To promote proactive dossier improvements, ECHA started to publish and regularly update a non-exhaustive list of substances that may potentially be selected for compliance check. ECHA also continued offering registrants a possibility to have a discussion to clarify the requests in the draft decision and subsequent steps in the process. In addition, several internal process improvements were introduced, including elimination of multiple verification steps and empowering scientific staff and teams to process cases more independently. Further development of scientific and administrative IT-tools continued to be a major enabler for increased efficiency and consistency.

On the other hand, the time needed for setting the details of the compliance check strategy implementation and other dossier evaluation priorities outweighed some of the above efficiency gains rendering the achievement of the originally intended number of compliance checks (200) very challenging. ECHA put in place necessary contingency measures and prioritised compliance checks over other dossier evaluation tasks to ensure that at least 100 new compliance checks on the high priority cases were concluded in 2015.

Text Box: Main outcomes of the compliance checks concluded in 2015

In line with the current compliance check strategy, ECHA reserved most of its evaluation capacity for compliance checks on registrations from lead and individual dossiers of chemicals produced in volumes over 100 tonnes per year that may require substance evaluation or risk management measures. Of the concluded cases in 2015, 107 (58%) were performed on the dossiers of high priority substances. This involved the evaluation of 853 higher tier human health and environment endpoints.

Higher tier human health and environment endpoints of concern addressed as an outcome of CCHs for prioritised substances of potential concern concluded in 2015

Endpoint	CCh outcome	
	Concluded with draft decision	Concluded without action
Repeated-dose toxicity	38	69
Mutagenicity/genotoxicity	42	65
Pre-natal developmental toxicity	62	45
Reproduction toxicity	47*	57
Carcinogenicity	1	106
Long-term aquatic toxicity	28	79
Biodegradation	33	74
Bioaccumulation	19	88
Total	270	583

* 22 of these were requests for Annex IX screening studies.

In 2015, a total of 183 compliance check evaluations were concluded by ECHA. Of these, 33 (18%) were concluded with no further action and 150 cases (82%) led to a draft decision. Since the selection criteria are intended to find cases with high potential for compliance issues and only a small portion are selected randomly, these figures cannot be taken to indicate the overall quality of the whole registration database.

Source: Evaluation Progress Report 2015[8]

[8] http://echa.europa.eu/documents/10162/13628/evaluation_report_2015_en.pdf

Testing proposal examination

The number of concluded testing proposals (184) was slightly below the original estimations (220). This was due to two factors: the number of incoming dossiers with new testing proposals was lower than estimated and the highest priority and resources had to be assigned to compliance check strategy implementation. Despite the lower output, the specific target for 2013 testing proposals was met and exceeded.

Decision making on dossier evaluation

A significant proportion of evaluation resources was assigned to the handling of registrants' comments, referrals to MSCAs and the Member State Committee and finalisation and publication of the decisions. As expected, ECHA issued a high number of final decisions on dossier evaluation in 2015, exceeding the original estimation.

Regarding compliance check cases at the decision-making phase, 59 were closed after the draft decision thus rendering the dossiers compliant. For 144 dossiers, ECHA took decisions under compliance check with non-compliances most commonly identified in substance identification and composition, Chemical Safety Report issues, pre-natal developmental toxicity and effects on terrestrial organisms.

In 2015, ECHA adopted 194 decisions under testing proposal examination and closed 14 cases after draft decision thus no longer requiring new animal tests. Detailed overview of the information requests in the decisions is provided in the Evaluation Progress Report 2015[9].

Follow-up to dossier evaluation

Follow-up of the dossier evaluation decisions continued at high rate in 2015. However, the decision of the Board of Appeal issued in 2015 on a case related to so called statement of non-compliance (A-019-2013) required ECHA to review its approach and consult the Member State authorities and the Commission (see Section 2.2). These discussions were still ongoing at the end of the year and ECHA hence had to withhold some of its follow-up evaluation conclusions. The overall target set for this activity was nevertheless clearly met.

Text Box: Main outcomes of the dossier evaluation follow-up in 2015

[9] http://echa.europa.eu/documents/10162/13628/evaluation_report_2015_en.pdf

ECHA provides enforcement authorities with its opinion in cases where the dossier evaluation decision was not complied with through statements of non-compliance following a dossier evaluation decision (SONCs). In 2015, ECHA conducted 300 follow-up evaluations. Majority of these (75%) lead to Article 42(2) notification completing the evaluation process and considering the dossier compliant, while 14% resulted in SONC, where the Article 42(2) notification is put on hold until all requested information has been received. Additional 11% follow up evaluations resulted in Article 42(2) notification after initially issuing a SONC.
Table below provides a summary of the outcome of the follow-up evaluations, performed in 2015, for each endpoint group. It is important to note that a follow-up evaluation outcome may contain both compliant and non-compliant endpoints.

Number and outcome of follow-up evaluations conducted in 2015, by endpoint group

Endpoint group	Outcome		
	Fully compliant	Compliant with deviations*	Non-compliant
Substance Identity	62	36	24
Physical/chemical properties	49	37	10
Environmental endpoints	100	38	4
Human Health endpoints	91	46	26
CSR	36	10	6
Total	338	167	70

*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 considered to fulfil the information requirement, which is the basis for the decision.

The outcome of the 2015 follow-up evaluations shows that 88 % (505) of the endpoints originally identified (by CCh or submission of a testing proposal) as non-compliant with the REACH information requirements, are now deemed compliant as a consequence of the dossier evaluation process. For the remaining 12 % (70) of endpoints deemed non-compliant, ECHA sent a SONC to the Member State authorities for consideration of enforcement actions.

Source: Evaluation Progress Report 2015[10]

In the context of the follow-up evaluation ECHA also draws conclusions on the need for further regulatory action (i.a. substance evaluation, harmonised classification and labelling, SVHC identification) and informs Member States and the Commission accordingly. In 2015, ECHA identified a potential need for harmonised classification and labelling in 17 cases and a need for substance evaluation in 3 cases.

Other dossier evaluation specific activities

Regarding scientific and regulatory challenges, ECHA continued addressing the compliance of dossiers covering different forms, including nano-forms, of a substance. ECHA published the document explaining its approach to assessing read-across arguments addressing human health information requirements in dossier evaluation and continued developing the corresponding framework for environmental endpoints.

The amendment of REACH Annexes VII-X regarding the information requirements for reproduction toxicity continued to require major input from experts to support the guidance update, to prepare ECHA's decisions on the issue and support the processing of the pending cases referred to the Commission. Due to the complexity of the assessments and the test guideline on extended one-generation reproduction toxicity study, ECHA

[10] http://echa.europa.eu/documents/10162/13628/evaluation_report_2015_en.pdf

established a specific advisory expert working group consisting of Member States experts. ECHA presented several model cases for discussion in the group, which allowed alignment of expert views and is expected to pave the way for future decision making. In the second half of 2015 ECHA started to issue testing proposal and compliance check draft decisions addressing the amended information requirements. The Commission concluded in 2015 on a general approach on how the 216 draft decisions referred to it would be addressed. The approach entails that for many of the cases a revised testing proposal is expected to be submitted. However, due to a delay at the Commission end, no such resubmitted testing proposals were received yet in 2015 but are expected to arrive in 2016-2017.

In addition to reproduction toxicity, specific effort by ECHA experts was made to clarify and align views on correct in vivo tests on mutagenicity.

To promote compliance with Good Laboratory Practice (GLP), ECHA reviewed its practice of requesting study audits from GLP monitoring authorities. In the course of the year ECHA requested nine study audits from the EU monitoring authorities.

In the course of the dossier evaluation work ECHA continued to pay specific attention to avoidance of unnecessary vertebrate animal testing and engaged Member States, the Commission and stakeholders in the refinement of its approach. Important new elements on this sensitive topic were brought up by the European Ombudsman. Based on a friendly solution, issued in December 2014, two first pilot compliance checks were concluded with draft decisions requesting the registrant to justify the use of animal tests whilst alternative methods would seemingly be available. Another friendly solution on testing proposals was accepted in autumn 2015 and was immediately followed up by ECHA by intermediate measures requesting registrants with new testing proposals on vertebrate animals to provide their considerations for alternative methods before launching the public consultation on the proposed animal test(s). Further measures are still in consultation with Member States, the Commission and the stakeholder organisations.

ECHA continued its efforts to improve dossier quality and utilise its dossier evaluation experience through giving feedback to industry and communicating on its findings. Specific attention was paid on the messages relevant to the registrants of lower tonnages and SMEs in general.

ECHA published the evaluation progress report 2014, with specific recommendations for registrants, in February 2015 and continued its efforts to improve the transparency of the dossier evaluation outcomes and reporting in view of the evaluation progress report 2015. Technical requirements for future dissemination of dossier evaluation outcomes were laid down and publication of final decisions was further automated.

Substance evaluation

Outcomes of substance evaluation

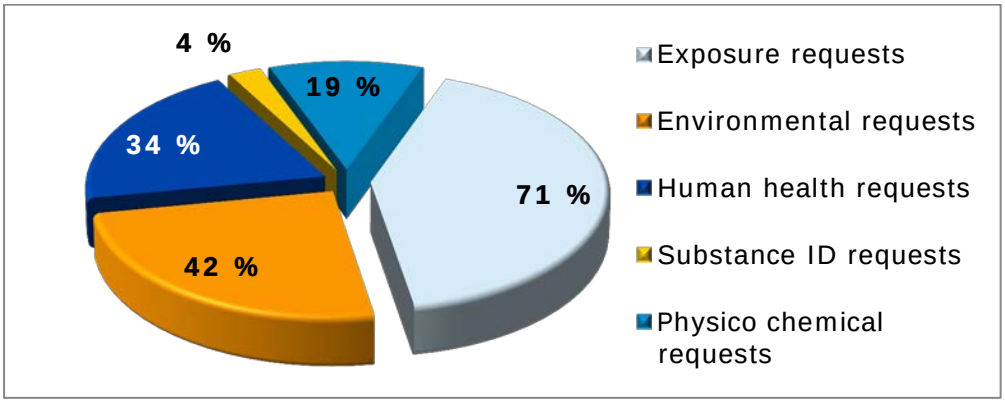
ECHA continued supporting the evaluating Member States by providing consistency screening and assisting in finalisation of the draft decisions. Furthermore, ECHA submitted its own proposals for amendments where this was regarded necessary to ensure the quality outcome of the decision. The increasing number of substance evaluation decisions and the complexity and sensitivity of the issues addressed in these decisions resulted in heavy workload both in the Member State Committee and the ECHA Secretariat. A relatively high proportion (over 20%) of substance evaluation decisions has been appealed. The reasons behind are assumed to include the relative novelty of the process and the interest to clarify the boundaries of what further information can be requested under substance evaluation. Furthermore, the costs linked to the generation

of the information requested in the decisions are sometimes substantial, going beyond those of the standard information requirements. In addition, many of the substance evaluations address complex and challenging scientific and technical questions (i.a. endocrine disruptors, nanomaterials), where views among authorities and registrants are not necessarily aligned.

The number of decisions issued and published was the highest so far since the process started but the evaluating Member States were not able to dissolve the backlog of draft decisions from the previous years and hence the number of decisions was less than originally estimated. ECHA made special efforts to speed up the finalisation of the decisions, including introduction of a fully IT-supported document management system . A specific project on efficiency improvements was launched in 2015 to further reduce process time and increase time available for more value added tasks such as expert input to the cases.

The below figure summarises the requests made within the decisions taken during 2015. In this general outline, requests made in relation to endocrine disruptor properties fall under human health or environmental requests.

Figure 1: Percentage of the 29 substance evaluation decisions adopted by ECHA in 2015 containing each type of request



Community rolling action plan

ECHA updated the Community rolling action plan (CoRAP) for years 2015-2017 and published it in March 2015. Altogether 48 substances were listed for year 2015. The three-year rolling plan includes altogether 134 substances, 66 of them being newly added. Similarities of the substances and efficient use of MSCAs resources were taken into account. The emphasis in selecting substances was on finding substances requiring clarification of relevant risks for human health or environment in order to decide on regulatory follow-up and where dossier evaluation was not regarded as sufficient.

The draft CoRAP update for years 2016-2018 was referred to the Member State Committee for its opinion and published in October, as planned.

Review of the process

After three years of experience in substance evaluation process, ECHA launched a review of the efficiency, effectiveness, transparency and workability of the substance evaluation process. An external contractor performed a survey with Member States, the Commission services, registrants and stakeholders seeking feedback on the process. The findings of the survey were discussed in the workshop organised by ECHA in November

2015[11]. It was acknowledged that the experience of the full process and its final outcomes is still limited and hence no firm conclusions could be made yet i.e. on the effectiveness of the process. However, several areas of improvement were identified and agreed to be implemented. In particular, the evaluation will be more targeted to the potential risk management outcomes and the synergy with compliance check will be further improved. Additionally, ECHA will enhance its support to the evaluating Member States in the decision making and drafting of the decisions.

In addition to the review of the process, first decisions by the Board of Appeal provided important feedback on the process and substance evaluation decisions. In particular, the decision A-005-2014 which annulled ECHA's decision on carbon tetrachloride, provides the basis for further clarifying and optimising the interplay of substance evaluation and compliance check and for ensuring the proper justification of information requests under substance evaluation (see Section 2.2).

2. Objectives and indicators

Objectives

1. Scientifically and legally sound draft and final decisions on dossier evaluation are prepared, in compliance with the legal requirements and in line with the compliance check strategy and multi-annual planning steered by ECHA's strategic approach.

2. The compliance with dossier evaluation decisions is followed up without undue delay after the deadline given in the decision has passed and the Member State authorities are informed about the outcome and cases requiring their action.

3. The CoRAP update is established in collaboration with Member States, with effective interlinks with other evaluation and regulatory risk management processes and according to the legal deadline.

4. All substance evaluations are prepared and processed with a high degree of scientific, technical and legal quality according to the agreed standard approaches and procedures and within the legal deadlines.

Performance indicators and targets

Indicator	Target in 2015	Result in 2015
Percentage of dossier evaluations treated within the legal timeframe.	100%	100%
Percentage of testing proposal examinations concluded for dossiers received by the 2013 deadline in order to reach the legal requirement to prepare a draft decision by the 1 June 2016 deadline.	75%	81%
Percentage of the follow-up evaluations, due in the given year, performed within six months after the deadline set in the final dossier evaluation decision.	75%	80%
Percentage of substance evaluations treated within the legal timeframe.	100%	100%

[11] http://echa.europa.eu/documents/10162/13628/sev_workshop_2015_en.pdf

Level of satisfaction of MSCAs with ECHA's support for substance evaluation.	High	High

3. Main outputs

Dossier evaluation

- 183 concluded (up to draft decision or conclusion) compliance checks, leading to 150 new draft decisions. 107 of the compliance checks addressed the higher tier human health and environment endpoints.
- 184 concluded (up to draft decision or termination) testing proposal examinations.
- 338 final decisions on dossier evaluations, of which 194 were on testing proposals and 144 were on compliance checks.
- 268 evaluations following up dossier evaluation decisions, 224 of them resulting directly in Article 42(2) notification completing the evaluation process and 44 in Statements of non-compliance following a dossier evaluation decision (SONC), where the Article 42(2) notification is put on hold until all requested information has been received. Additional 34 follow up evaluations resulted in Article 42(2) notification after initially issuing a SONC.
- Annual Evaluation Report and related communications, with specific emphasis on messages relevant for lower tonnage registrations and SMEs.
- Workshop on compliance check strategy implementation in May 2015 with published proceedings.
- Non-confidential versions of over 300 dossier evaluation decisions published on ECHA website.

Substance evaluation

- Consistency screening of majority of the draft decisions originating from the 2014 evaluations.
- Submission of draft decisions for comments to the 390 registrants of the 39 substances evaluated during 2014 and resulting in a draft decision.
- 29 substance evaluation decisions adopted and non-confidential versions published on ECHA website.
- 16 conclusion documents published for completed substance evaluation cases.
- Third update of the CoRAP adopted and published 17 March 2015, containing 134 substances, of which 48 were scheduled for evaluation in 2015. The list contained 66 newly selected substances and 68 substances carried over from the existing CoRAP.
- Fourth CoRAP update submitted to the Member State Committee for opinion in October 2015 and published on ECHA website. The draft list contained 138 substances, with 47 substances to be evaluated in 2016. The list contained 53 newly selected substances and 85 substances carried over from the existing CoRAP.
- Workshop on substance evaluation in November 2015 with published proceedings.
- Report on the substance evaluation process review[12].

[12] http://echa.europa.eu/documents/10162/13628/sev_survey_2015_en.pdf

1.3. Risk Management (Activity 3)

ECHA's tasks relating to risk management include updating the Candidate List of substances of very high concern (SVHCs), regularly preparing a recommendation to the Commission on substances from the Candidate List to be included in the Authorisation List – the list of substances subject to authorisation (Annex XIV to REACH) – and handling authorisation applications. Substances that pose unacceptable risks at EU level can be banned altogether or restricted for particular uses (Title VIII of REACH). ECHA can be requested by the Commission to prepare proposals for restrictions or review existing ones. Member States also submit proposals for restrictions, which are verified for accordance and forwarded to the Risk Assessment Committee (RAC) and Socio-Economic Analysis Committee (SEAC) for opinion making.

ECHA's strategic objective 2 calls for intelligent use of REACH and CLP data to ensure that authorities are able to timely and efficiently address the highest concerns. To this end, ECHA implements common screening approaches for all REACH and CLP processes to identify the substances and uses which matter the most. The risk management option analysis (RMOA) framework supports selection of the most appropriate regulatory risk management instrument(s) to address the identified concerns. The common screening approaches and RMOA together aim to ensure an efficient and integrated use of the REACH and CLP processes for clarifying, by further data generation where needed, and addressing the identified concerns.

1. Main achievements in 2015

Identifying needs for risk management

The implementation plan for 'The EU Roadmap for SVHC identification and implementation of REACH risk management measures to 2020', which was agreed in the Council in November 2013, provides the basis for ECHA's work in identifying relevant candidate substances for further regulatory action. The SVHC Roadmap Progress Report provides an overview of progress made towards achieving the objectives of the Roadmap[13].

Common screening serving REACH and CLP processes

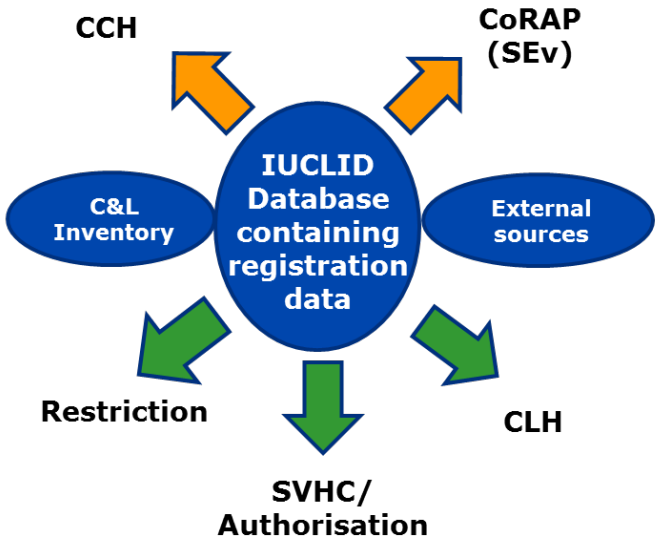
Common screening is a core ECHA activity with significant contribution towards efficient and effective substance prioritisation for all REACH and CLP processes. This year the compliance check was integrated to the common screening. Furthermore ECHA continued developing the hazard and exposure potential screening approaches (e.g. using predictive methodologies and external sources), and identifying structural similarities among substances to streamline MSCA's activities and future regulatory steps for substances that may require similar treatment. Common screening is carried out and further developed in close collaboration with Member States and the Commission.

The focus of the second annual round of common screening has been on identifying potential candidates for harmonised classification and labelling (CLH), either directly or after further information generated via evaluation processes, and on identifying potential endocrine disrupters. It identified around 200 substances for further scrutiny. Of those, Member States manually examined 165 and 76 % were found to require follow-up. 67 were proposed for substance evaluation (the majority are already included in 2016 draft CoRAP) and 36 for compliance check. 17 dossiers were proposed for harmonised classification and labelling and 6 for risk management option analysis. Additional 9 were

[13] http://echa.europa.eu/documents/10162/19126370/svhc_roadmap_2015_en.pdf

found to require further assessment due to PBT or ED properties or other actions. To better support the common screening ECHA started to investigate other ways of screening such as identifying applications where significant exposure to workers or releases to the environment can be expected.

Figure 2. Common screening approach



In 2015 all registrants of the shortlisted substances received a letter informing that their substances might be under scrutiny by Member States and were invited to review their dossiers with regard to the identified potential hazard(s) and use(s) and tonnage information. In addition to triggering updates of dossiers, the aim of this letter campaign was to increase transparency and predictability of the screening process.

Coordination and expert groups have provided input to the screening and supported the development of the screening scenarios. To avoid duplication of work by authorities, the timelines of the different processes have been aligned and templates streamlined. ECHA organised a workshop to reflect on the experiences so far obtained with the common screening and collect ideas for further improvements. This resulted in better alignment of authorities' views on the aims of the common screening and a number of recommendations, including strengthened feedback mechanisms from the follow-up steps back to common screening.

Assessment of hazard properties

The PBT and endocrine disruptor (ED) expert groups support the screening for and assessment of potential PBT and ED substances as well as the development of related methods.

The PBT expert group started in 2012 and currently supports ongoing assessments for around 100 substances. Of these, 50 in total were discussed in 2015 meetings. The majority of the ongoing assessments support further information generation via the substance evaluation. For six substances the assessment was finalised, all with conclusion "not PBT/vPvB". Additionally, several guidance development topics were elaborated in the group, e.g., UVCB assessment approaches.

The ED expert group started in 2014 and currently supports the assessment of approximately 30 substances. Two additional cases have been finalised in 2015 after expert group discussion by the assessing authorities (postponement of the assessment for one substance and ED conclusion for another).

ECHA continued to encourage the assessing authorities to refer all their ED or PBT assessment cases for discussion to the expert groups. The non-binding scientific advice

provided by these expert groups supports the Member States both in concluding whether or not certain substances have PBT or ED properties and in preparing good quality dossiers, which increases the efficiency of the subsequent formal decision-making under substance evaluation and/or SVHC identification.

Identification of most appropriate regulatory actions

ECHA continued to support the development and discussion on risk management option analyses (RMOAs) for identified substances. ECHA organised three risk management expert (RiME) meetings in cooperation with volunteering Member States. In addition, three workshops were organised for Member States who are less-experienced in carrying-out manual screening or risk management option analyses to benefit from the experience gained by ECHA and other Member States, on real-substance cases. In line with the Regulatory Strategy ECHA promoted the discussion between risk management experts on the integration and optimisation of the REACH and CLP processes, for instance substance evaluation and risk management option analysis activities, at general level (alignment of the templates, information sharing) and at substance and case level. Finally, ECHA facilitated the discussion at RiME on transversal topics, such as how to best address substances of potential concern due to their impurities.

In 2015, 24 RMOA conclusions were finalised and published with 21 of these suggesting a follow-up action, either under REACH or CLP (15) or under other EU legislation or of non-regulatory nature. The suggested follow-up action under REACH and CLP had already been initiated for two thirds of the cases by the end of 2015.

ECHA furthermore coordinated the regulatory work of several Member States and ECHA on per- and polyfluorinated substances. The very high number of these substances requires handling of substances group- and category wise.

Cooperation and communication

To further increase the transparency on the roadmap implementation, ECHA extended the scope of the so-called “public activities coordination tool (PACT)” to information on substances discussed by the ECHA PBT or ED Expert Groups. At the end of 2015, PACT included 319 entries, 179 of them relating to hazard assessment and 140 to RMOA activities on single or groups of substances.

The ECHA website on substances of potential concern was further developed and now includes more information on the common screening, including the description of screening scenarios and priorities for screening, with the aim to provide more transparency on this early step of authorities’ work and enabling stakeholders to predict what type of substances and cases authorities will work on. A graph with links to more information was developed to better clarify the interfaces between the different REACH and CLP processes.

ECHA set up a new dedicated group with representatives of Member States, stakeholders and the Commission to develop the approach on how to identify and address priority petroleum and coal stream substances (PETCO). Two meetings of the group were organised in 2015. In addition to developing the approach, the work concentrated on improving the understanding of the types and volumes of (non-fuel and non-intermediate) uses to ensure that the other activities related to substance identity and hazard properties can be targeted to the substances of high priority.

Authorisation

Identification of SVHCs and Annex XIV recommendations

Based on eight proposals submitted by Member States and one proposal by ECHA (at request of the Commission), in total seven substances of very high concern were added to the Candidate List in June and December 2015. Three substances were identified due to their toxicity to reproduction. One of these is in addition a PBT. A further three

substances were identified because they are vPvB (very persistent and very bioaccumulative) substances. One substance is identified due to its carcinogenicity. By the end of 2015, the total number of SVHC substances included in the Candidate List was 168. The number of SVHC dossiers has been relatively constant since 2012. Most of the new substances to be identified as SVHCs first required further information generation and either further assessment of the PBT or ED properties or harmonised classification. Therefore the total number of SVHC dossiers is lower than during the first years of the process

ECHA provided its sixth recommendation for inclusion of priority substances in the Authorisation List to the Commission in July. Inclusion of 15 substances and groups of substances from the Candidate List was recommended and suggestions for the application and sunset dates were made. ECHA's recommendation, the MSC opinion and all background documentation are publicly available on ECHA's website.

As already done for the sixth recommendation, ECHA developed its draft seventh recommendation using the agreed prioritisation approach which is based on the use of registration and other REACH/CLP data. At the start of the public consultation in November the priority ranking for all substances in the Candidate List, i.e. also for those substances which are currently not recommended, was made available on the website.

Similar to last year ECHA again facilitated a parallel call for information on the possible socio-economic consequences of the inclusion of substances in Annex XIV on behalf of the Commission.

ECHA informs all registrants and notifiers of substances subject to SVHC identification proposals and of substances included in the draft Annex XIV recommendation of the start of the public consultation. ECHA also recommends registrants and notifiers to inform their customers. This is to increase awareness of the public consultations and encourage industry to ensure that the registration and other REACH/CLP dossiers are up-to-date.

Authorisation applications

In 2015, the authorisation application process picked up with an increasing workload. ECHA continued to support industry by organising pre-submission information sessions (PSISs) which aim to provide future applicants with the opportunity to ask case-specific regulatory and technical questions. In total, 29 PSISs were held in 2015. ECHA has continued to receive very positive feedback on the usefulness of these sessions.

In 2015, ECHA received 7 applications for authorisation[14] for 13 different uses. ECHA successfully launched three public consultation rounds to collect information on alternative substances or technologies.

RAC and SEAC adopted 25 final opinions in 2015. This was less than projected in the 2015 Work Programme. The reason was that applicants actually submitted their applications later than they had announced. In other words, the work has shifted from 2015 to 2016[15]. On average, it has taken seven months for the committees to agree on the draft opinions, substantially less than the 10 months stipulated in the REACH Regulation.

[14] Lead chromate, Chromium trioxide, Sodium chromate, Sodium dichromate and 1,2-dichloroethane (EDC)
[15] For instance, on 10 February 2016, ECHA will launch simultaneously public consultations on 27 applications for 39 uses submitted in 2015 but processed up to the fee payment in early 2016.

Table 10: Key data on applications for authorisation for 2012-15

	Received notifications to submit	Pre-submission information sessions held	Received applications (applicants) [1]	Number of uses	RAC-SEAC opinions per use [2]	RAC-SEAC opinions per use and per applicant [3]	Commission decisions per use and per applicant [3]
2012	5	1	0 (0)	0	0	0	0
2013	11	9	8 (10)	17	1	1	0
2014	170	14	19 (33)	38	30	34	2
2015	72	29	7(19)	13	25	51	10
Total	**258**	**53**	**34 (62)**	**68**	**56**	**86**	**12**

[1] An application is received in terms of Article 64(1) of REACH when ECHA has received the application fee.
[2] One opinion refers to a compiled version of the final opinions of RAC and SEAC for each use.
[3] This is the total number of opinions and final decisions for each use and applicant. For instance, if one application has been submitted by three applicants for one substance and two uses there will be (3x1x2=) six RAC-SEAC opinions and Commission decisions. If another application is submitted by one applicant for one substance and three uses, there will be (1x1x3=) three RAC-SEAC opinions and Commission decisions. In total, there would be nine RAC-SEAC opinions and nine Commission decisions.

To further increase the awareness of the authorisation requirements, ECHA held a seminar for potential applicants in June 2015. ECHA continued to operate the *"Partners' service"* to help all potential applicants to know about each other in the supply chain. In February 2015 ECHA also organised together with the Commission a Conference on Lessons Learnt since the start of this process in 2013 and co-organised with the Commission a workshop on the Streamlining of Applications for Authorisations in November 2015. Some 200 representatives from Member States and key stakeholders participated concluding, amongst others, that the application system works well. The text Box below summarises the main conclusions of the workshops. It is also noted that the costs of applications have been reduced by almost a half from the beginning to about €120.000 per applicant per use.

Text Box: Main conclusions on applications for authorisation for 2015

- The Application for Authorisation system works
- It provides pressure on industry to substitute towards safer substances
  - Substitution can take time, even decades
- It leads to further improvement of Risk Management Measures
- Having DNELs and dose response function is almost a prerequisite
- Application effort and costs have reduced considerably
- It is transparent and predictable; companies that can demonstrate a well-documented business case will get an authorisation
- A further streamlined, and when appropriate, lighter process should be implemented
- The application fee structure should be adapted
- "Upstream" applications made by manufacturers are essential to keep the system manageable:
  - Increased incentive to control the risk or substitute
  - Increased information from downstream users; get the supply chain involved
  - Narrow use down to where no alternative exists
  - The representativeness of exposure data needs to be linked to a specific setting (e.g. technology, scale of operation)
- The Task Force on the workability of applications for authorisation needs to continue its work:
  - Additional advice and guidelines to build on experience and give practical examples

Sources: Conclusions of the Conference on the Lessons Learnt on Applications for Authorisation (10-11 February 2015) and the Workshop on Streamlining Applications for Authorisation (17 November 2015) organised by the European Commission and the European Chemicals Agency

ECHA also participated in several conferences, workshops and webinars organised by industry, Member States or NGOs to clarify different aspects of the authorisation process.

ECHA published on its website examples of clear and well-structured Analysis of Alternatives and Socio-economic Analysis submitted by applicants and evaluated by RAC and SEAC.

In 2015, ECHA carried out many internal and external steps to improve the efficiency of the application process, including use of the case management tool for applications. This allows effective communication with the Committees and has increased the efficiency and accuracy of the application process. Capacity building of RAC and SEAC, started in 2012, was continued in 2015. ECHA has also made internal arrangements for new staff and trained them to cope with the peak of Chromium VI applications that will be processed in 2016. ECHA, together with the Committees, developed 'opinion trees' and checklists to further streamline and enhance the consistency of the RAC and SEAC opinions. RAC has continued to derive dose-response relationships for substances included in the Authorisation List.

In 2015, ECHA continued to actively contribute to the work of the Task Force on simplified approach for special cases. As a result, the Commission intends to adopt in 2016 an Implementing Act to have the documentation on "low quantities" applications fit-for-purpose.

ECHA released the IT tools and instructions for downstream users who must notify to ECHA if they use the Annex XIV substance in accordance with the conditions of an authorisation granted to an actor up their supply chain. This notification is based on Article 66 of the REACH Regulation.

Restrictions

Following requests by the Commission, ECHA worked on the preparation of three review reports and is working on three guideline documents.

The Annex XV restriction report on cadmium in plastics was finalised and published on ECHA's website in 2015. No restriction was proposed due to the absence of sufficient information to demonstrate a risk that would justify an extension of the current restriction entry to cover all plastics.

Article 69(2) of REACH requires ECHA to consider whether or not to propose a restriction for substances included in Annex XIV of REACH for their use in articles after their sunset date has been reached. ECHA continued assessing the need for a restriction of the use of 4 phthalates (Bis(2-ethylhexyl) phthalate (DEHP), Benzylbutylphthalate (BBP), Di-n-butyl phthalate (DBP), and Diisobutyl Phthalate (DIBP)) in articles during 2015 under Article 69(2); the dossier is due for submission in early 2016. In addition, ECHA assessed the need for a restriction proposal for two further substances (Musk xylene, 4,4'- Diaminodiphenylmethane (MDA)) under Article 69(2) and proposed that no restriction was needed as there was no evidence that these substances are used in articles in the EU.

ECHA also continued to work on its assessment of various uses of five cobalt salts and this resulted in a report on dose-response that will be discussed in RAC during 2016.

The Commission requested ECHA, during 2014, to prepare an assessment of a potential restriction of lamp oils and grill lighter fluids labelled R65 or H304, intended for supply to

the general public (Annex XVII entry 3). The resulting report published in 2015 concluded that the current entry has had a clear positive effect and that there was no need to propose any changes.

In 2015, ECHA continued the close cooperation with the Commission to provide clarity for several restriction entries by developing several Questions and Answers on restriction entries. These Questions and Answers were published on ECHA's website in 2015.

In October 2014, the Commission requested ECHA to develop guidelines on three restriction entries (nickel, polycyclic organic hydrocarbons (PAHs) and lead) with the aim to clarify which articles and subtypes of articles fall under the scope of these entries. ECHA developed a draft guideline for lead of which the finalisation is expected in 2016. Targeted stakeholder consultations were carried out for PAHs and nickel and the draft guidelines were prepared and discussed with the Commission services. The work with these guidelines is postponed due to a need for a legal interpretation of the general scope of the PAHs restriction.

In addition, in 2015 ECHA received a request from the Commission to prepare three Annex XV restriction dossiers during 2016: Lead compounds as stabilisers in PVC, lead (metal) in shot and tattoo inks.

During 2015, the ECHA Secretariat gave administrative, technical and scientific support to process nine restrictions proposed by Member States and one restriction proposed by ECHA. ECHA received three new proposals for restrictions from Member States in 2015, which was less than planned (based on intitial estimates provided by Member States). The Committees carried out conformity checks on these proposals; 2 were agreed as being in conformity and one not in conformity[16]. In table 12 the work on restriction proposals from 2009–15 is summarised. The Committees and Forum section gives the details of these. Text Box summarises the implications ECHA's opinions made in 2015.

Table 11: Key data on restrictions for 2009-15

	Received intentions	Restriction dossiers submitted by Member States	Restrictions prepared by ECHA	RAC-SEAC opinions*	Commission decisions
2009	4				
2010	1	3	1		
2011	2	1		4	
2012	2	1	1	1	4
2013	7	3	1	2	
2014	4	4	2	5	3
2015	4	3	0	6	3
Total	**24**	**15**	**5**	**18**	**10****

*)A RAC-SEAC opinion means formally three opinions: one RAC opinion, one SEAC draft opinion and one SEAC opinion

**) In addition, Commission decisions on 2 further restriction proposals were made in January/February 2016

[16] The relevant MS has 60 days to resubmit the proposal and a further conformity check is foreseen for mid 2016.

Text Box: Implications of the restrictions that ECHA concluded on in 2015

In 2015 ECHA's Committees have adopted four opinions on restriction reports submitted by Member States (ammonium salts, cadmium in artists paints, Perfluorooctanoic acid (PFOA) and its salts, Bisphenol-A) and two opinions on restriction reports submitted by ECHA (Asbestos and Decabromodiphenylether (DecaBDE)); four of these opinions supported the restriction proposed, mostly with some adaptions, and one supported the proposal with some nuances. In addition, RAC adopted an opinion agreeing to amend the current entry on benzene in Annex XVII (entry 5). In 2015, the Commission adopted one restriction in Annex XVII as a result of previous Committee opinions (lead in consumer articles), adopted a Commission Communication for cadmium in artists paints where no restriction was proposed and amended the current entry on benzene in Annex XVII.

The impact of restrictions is manifold. For instance, if the restriction on PFOA and DecaBDE would be in place, about 5 tonnes of DecaBDE, 6 tonnes PFOA and 37 tonnes of PFOA-related substances would no longer be released to the European environment each year. In this manner there would be less persistent, bio-accumulative and toxic substances released in the EU. In addition, if a restriction was introduced for Bisphenol A (BPA) in thermal paper then the exposure to BPA to potentially several hundred thousand female cashiers of childbearing age would be avoided.

In order to support the stakeholders and the Member States, especially the enforcement authorities, work was carried out to provide further information on ECHA's website on the history of the existing restrictions. These improvements will be published in January 2016 when also searching of substances restricted under REACH will be improved.

One of the key priorities related to restrictions was to implement the total of 57 recommendations made by ECHA, the Commission and Member States in the Restriction Efficiency Task Force (RETF), to improve the efficiency of the restriction process. These were to a great extent implemented in 2015 with improvements made to Public Consultations on restrictions and relationships between the Committees and Dossier Submitters. In addition, ECHA published a new Annex XV restriction reporting format and updates to conformity check reports and opinion templates[17]. The framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals was also agreed with the two Committees. This describes how RAC and SEAC carry out conformity checks and evaluate Annex XV restriction proposals, implements certain RETF recommendations, provides consistency in opinion making and allows Dossier Submitters and stakeholders to understand how the Committees will treat restriction proposals. A workshop was held in May 2015 to discuss implementation of the recommendations for the Dossier Submitter and ECHA secretariat and the preparations were carried out in late 2015 a further workshop (held in January 2016) to discuss implementation of the recommendations for Committees. ECHA has continued to work with Member States, to better identify and develop EU-wide restrictions and to increase the capacities to monitor efficiency gains from the implemented recommendations. This will be a key objective to continue in 2016.

Despite all the above actions, the number of restrictions proposed by the Member States and the Commission remained below expectations and thus requires further attention and incentives at policy and technical level.

Other activities related to risk management

Socio-economic analysis

ECHA continued to support the practical application of socio-economic analysis by providing guidance to and building up capacity among submitters of restriction dossiers

[17] As a result of the recommendations of the Restrictions Efficiency Task Force

and authorisation applications. In 2015, ECHA published the results as well as a critical peer review of the estimated economic values for preventing a range of human health outcomes. It also published a review study of quality and disability adjusted life years associated with exposure to chemicals and continued to survey the efforts of preparing applications. In late 2015, ECHA prepared an international workshop which was held in January 2016 with academia on the valuation of health impacts related to chemicals. It also started the preparation for hosting an OECD workshop on socio-economic analysis related to chemicals (to be held in July 2016).

ECHA continued to develop the Network of REACH SEA and Analysis of Alternatives Practitioners (NeRSAP), an informal network of SEA practitioners to exchange experiences of methodological and practical issues and problems. Moreover, ECHA's staff collaborated with the Commission services in several studies including the benefits and the costs relating to chemicals regulation.

Substitution

Substitution is one of the key impacts of restrictions and authorisation processes as they lead often to an adoption of alternative substances or techniques by industry affected. When a substance is identified to be of very high concern, companies are given a strong signal to find substitutes. Substitution is one of the main aims of authorisation and all three steps of the authorisation process contribute to that aim. Obviously, if a particular use of a substance is restricted, the market needs to adopt an alternative.

There are some indications of substitutions taking place as a consequence of an authorisation requirement. Out of the 31 substances that have been placed on the Authorisation List, ECHA has received applications for authorisation for 12 substances. Nearly half of the applications for authorisation received so far have been submitted in order to be granted the necessary time to substitute the SVHC with a safer alternative. In other words, restriction and authorisation processes had an important impact on the substitution of hazardous chemicals in the EU in 2015.

ECHA, Member States and industry need to do more on substitution. In 2015, ECHA commissioned the University of Massachusetts Lowell to provide suggestions how to improve alternative assessment and the promotion of substitution in the EU, especially how Member States and industry can identify suitable alternatives. This work is carried out in collaboration with the Commission, Member States and stakeholders. The suggestions will be available in 2016.

ECHA launched in 2015 new web pages on substitution including a description of the main steps to follow, links to available tools and cases stories. This was followed by the first of a series of webinars organised with a group of accredited stakeholder organisations to inspire companies to substitute hazardous chemicals and explain how it can be done. ECHA is also participating in the work at the OECD level on substitution of hazardous chemicals.

Substances in articles

ECHA continued its efforts in awareness-raising on obligations related to the presence of Candidate List substances in articles, as well as on identifying possible actions to support importers (incl. distributors) and producers of articles, and consumers in identifying which Candidate List substances could potentially occur in articles. For that ECHA ran a pilot project on the consumer clothing sector. ECHA also conducted a study on the feasibility to establish a "Materials Information Platform (MIP)" to support duty-holders, and investigated other existing tools which could facilitate the communication on substances in articles in the supply chains. ECHA organised a workshop to discuss with representatives of various article importers/producers sectors its findings on the feasibility of a MIP concept, and other possible ways to support the objectives of REACH article 7(2) and 33(1).

2. Objectives and indicators

Objectives

1. All dossiers related to the authorisation and restriction processes are prepared and processed with a high degree of scientific, technical and regulatory quality according to the standard approaches and procedures adopted by ECHA and within the legal deadlines or targets set.

2. Industry, Member States and the Commission are provided with the best possible scientific and technical support and advice to identify substances that require further risk management and to define the best risk management approach.

Performance indicators and targets

Indicator	Target in 2015	Result in 2015
Percentage of SVHCs, restriction dossiers and applications for authorisation treated within the legal timeframe.	100%	100%
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.	High	High

3. Main outputs

- SVHC Roadmap progress report published
- Regular meetings of the expert and co-ordination groups and a dedicated workshop organised to promote common understanding of the priorities for authorities' work and efficient implementation of the REACH and CLP processes.
- A short list of about 200 substances of potential concern was provided to Member States
- 24 RMOA conclusions finalised and published
- Two updates of the Candidate List published
- 7 substances of very high concern added to the Candidate List
- The sixth Annex XIV recommendation submitted to the Commission and the draft seventh recommendation developed.
- Two Annex XV restriction review reports prepared and published.
- Two assessments under Article 69(2) published.
- Several questions and answers related to the restriction entries published.
- Efficiency in the restriction process improved after implementation of the recommendations of the restriction efficiency task force.
- New questions and answers and one frequently asked question on authorisations developed and web pages improved to enhance support to applicants.
- Three reference dose-response functions published on ECHA's website.

- Finalised the Report of the Task Force on the workability of Applications for Authorisation for 2014-15 and objectives for 2016-17 completed (to be published in 2016)
- Published the peer review and summary report of the willingness-to-pay for human health endpoints.
- Published the report on quality and disability adjusted life years.
- Preparations for a workshop on the valuation of health impacts of chemicals regulation completed (workshop held in January 2016).
- REACH Up Conference: Presentation of ECHA's new integrated regulatory strategy to stakeholders
- Preparations for a workshop on strengthening the implementation of REACH and CLP processes in contribution to the WSSD2020 (World summit on sustainable development) goals (workshop held in January 2016).

1.4. Classification and Labelling (C&L) (Activity 4)

Classification and labelling of substances and mixtures enables the safe manufacture and use of chemicals. It is the obligation of manufacturers, importers and downstream users to classify and label substances and mixtures according to the legal requirements and notify the classification of hazardous substances.

ECHA maintains a database of all notifications of substances in the C&L Inventory. In certain cases, Member States or industry can propose harmonisation of the classification of a substance in the EU. Once the harmonised rule on classification and labelling of a substance is taken up in the CLP Regulation, all manufacturers, importers and downstream users are obliged to classify and label the substance accordingly. This is normally done for active substances in plant protection products (PPPs) and biocidal products (BPs). The classification of carcinogenic, mutagenic and reprotoxic (CMR) substances, as well as for respiratory sensitisers, is also normally harmonised. Other hazard classes may be harmonised if there is a need.

1. Main achievements in 2015

Handling proposals for harmonised classification and labelling (CLH)

The main task of ECHA regarding classification and labelling is to manage the proposals for harmonisation of classification. In 2015, Member State competent authorities submitted 51 CLH proposals and additionally 4 proposals from industry were received. For 40 substances, a public consultation was completed. The number of proposals in the process at the end of the year is 78.

To facilitate development of CLH proposals of high quality, ECHA generated, based on experience gained so far from the CLH process, a new annotated CLH template. Also a common template for CLH dossiers and dossiers for approval of active substances under PPP is under development, to further reduce the workload of the MSCAs while maintaining high quality of the dossiers.

Continuous attention to the quality of the proposals and increased support to dossier submitters, together with improvements of the process contributed to increased efficiency of RAC work. RAC opinions are based on the evaluation of often large and complex dossiers and numerous comments from third parties. In the context of the growing number of dossiers, and the increasing complexity of proposals incorporating new approaches into regulatory hazard assessment for CMR endpoints (e.g. mode of action studies, read-across as well as human relevance considerations), the ECHA secretariat support to the RAC rapporteurs has been important for the quality and consistency of opinions.

In total 38 opinions on CLH proposals were completed[18]. Among those were opinions on substances in consumer products (such as nicotine, linalool, silver zinc zeolites), in wide industrial uses (such as anthraquinone), and several plant protection and biocidal products (such as formaldehyde releasers). About 60% of all dossiers concerns active substances for plant protection products (PPPs) and biocidal products (BPs). As classification may have far-reaching consequences for the approval and renewal of active substances for plant protection products (PPPs) and biocidal products (BPs), ECHA used the flexibility in timelines in the CLH opinion development process to align as far as

[18] 14 opinions on REACH substance, 10 of which include classification for CMR hazard classes
12 opinions on pesticides, 3 of which include classification for CMR hazard classes
11 on biocides and 1 on both biocide and pesticide, 7 of which include classification for CMR hazard classes.

possible to the considerably shorter and less flexible approval processes under the PPP or BP Regulations.

Harmonised classification triggers and enables regulatory risk management actions under REACH and a wide range of other occupational, environmental and product legislation. For example the consumer uses of substances classified as CMRs (cat 1A/B) are normally banned. Classification also promotes substitution both via regulatory measures and via providing information which allows and encourages industry themselves to take action. In particular, the authorisation requirement can be applied for industrial substances with harmonised classification as CMRs and active substances in biocidal and plant protection products with CMR (cat 1A/B) classifications meet the criteria as candidates for substitution. Furthermore, in the absence of agreed criteria for endocrine disruption (ED), active substances classified as carcinogenic and toxic to reproduction category 2 are considered as EDs.

The quality of the CLH dossier has a large impact on the possibility to conform to the timelines for active substance approval. Therefore ECHA organised a workshop with competent authorities for biocides, pesticides and CLH, industry and the European Food Safety Authority (EFSA) to find ways to improve the efficiency and quality of the CLH dossier preparation.

Classification & Labelling Inventory (C&L Inventory)

ECHA is required to establish and manage a C&L inventory based on classification and labelling notifications from industry. The C&L Inventory also includes the list of harmonised classifications. The public inventory which was launched in February 2012 currently contains over 6.5 million notifications covering around 130 000 distinct substances, of which about 122 000 are included in the publicly disseminated notifications. This makes it the largest database of self-classified substances available globally. The inventory database is refreshed on a regular basis with new and updated notifications.

Different notifiers may indicate different classifications for the same substance, for instance where an impurity justifies a different classification. Over 25% of the substances have more than one classification. The 1 June 2015 deadline for classification of all mixtures according to CLP underlined the importance of more uniform self-classifications, explicitly agreed self-classification and clear reasons for any deviating classification.

Under CLP, notifiers are obliged to make every effort to come to an agreement on the classification and labelling of the substance. To facilitate this agreement-seeking, at the end of January 2013 ECHA launched a dedicated IT-platform, which allows discussions between notifiers on the classification for a particular substance without revealing their identity. The use of the Platform has however been disappointingly low. ECHA, in cooperation with the Commission and industry associations, carried out a pilot study with the aim to encourage notifiers and registrants to come to an agreement on the classification using the C&L Platform as a tool and to subsequently update their notifications. Around 100 priority substances covered by approximately 40 000 notifications were selected. Although the pilot managed to slightly reduce the number of notifications (by 2388, or 6 %) there was no noticeable difference in the number of different classifications per substance (slight increase in differences was observed). As the platform does not appear to be a tool that industry is willing or can use to come to the required agreement on the self-classification, ECHA together with the Commission and industry associations continues to look for other means to promote such agreement seeking.

Several improvements in the content of the C&L inventory have been made during 2015.

It is for instance now highlighted when a classification originates from a joint registration. The inventory has also been updated with information on SEVESO III substances. Information on substances for which there is harmonised classification and labelling has been complemented with the substance name translated in several languages.

The clarity and user-friendliness of the inventory has also been improved. The search function allows more complex searches in an easy to use format. The C&L inventory has also been integrated in the disseminated brief profiles which provide a better overview of the hazard classes with harmonised classification and of the different self-classifications.

Alternative chemical names

ECHA is in charge of handling requests for the use of alternative chemical names for substances in mixtures according to Article 24 of the CLP Regulation. Companies can make such requests for substances with certain hazardous properties in order to protect confidential business information. Before 1 June 2015 companies could submit such requests to either a Member State Competent Authorities or ECHA, but after this date ECHA is receiving all of these requests. However, this change has so far led only to a slight increase in the number of requests received.

In total, 38 new requests were accepted for processing and 29 decisions were completed leading to two requests being rejected and 27 accepted.

Classification of mixtures

As from June 2015 all substances and mixtures have to be classified according to CLP. This posed a large burden to industry, as millions of mixtures have to be reclassified and relabelled. Though the new system is similar to the old, there are differences and transposing classification to CLP is not always straightforward. To support Member State CAs, ECHA contributed to HelpNet and Forum activities regarding mixtures classification and developed information material intended for the general public. It is now up to enforcement authorities to examine the compliance of formulators with this obligation.

2. Objectives and indicators

Objectives

1. All dossiers related to harmonised C&L are handled in a transparent and predictable process with a high degree of scientific, technical and legal quality according to the standard approaches and procedures adopted by ECHA and within the legal deadlines or targets set.

2. Any request for the use of an alternative chemical name is concluded within the legal timeframe.

3. The Classification and Labelling Inventory and C&L communication platform are kept up-to-date and their functionalities and user-friendliness are further improved.

Performance indicators and targets

Indicator	Target in 2015	Result in 2015
Percentage of proposals for harmonised C&L and	100%	100%

requests for use of alternative chemical name processed within legal timeframe.		
Level of satisfaction of the Commission, MSCAs, RAC and industry with the quality of the scientific, technical and administrative support provided.	High	High

3. Main outputs

- Carried out 44 accordance checks of dossiers containing proposals for harmonised classification and published the new CLH template.
- Support provided to the RAC and its rapporteurs for their development of 38 opinions.
- Monitored the C&L Platform, carried out a pilot project to assess the possibilities and limitations of the platform and prepared action to stimulate industry to use the Platform and come to agreement on self-classifications.
- 29 decisions on the use of an alternative name issued.
- Developed a C&L dossier, for one out of 3 candidate substances within the joint OECD/UNSCEGHS pilot project on a global classification list.

1.5. Biocides (Activity 16)

The new Biocidal Products Regulation (BPR) entered into operation on 1 September 2013. This regulation extended ECHA's regulatory remit with regard to administrative, technical and scientific tasks related to the implementation of the BPR, in particular on the approval of active substances and the Union authorisation of biocidal products. The new regulation introduced many improvements and new elements in comparison to the previous Biocidal Products Directive. These include, for example, simplified and streamlined procedures for approval and authorisation processes, special attention to avoid the most hazardous active substances, provisions to reduce animal testing and for compulsory data sharing, and on articles treated with biocidal products.

1. Main achievements in 2015

ECHA continued working closely with the Member State competent authorities (MSCAs) to ensure an efficient and effective development of operations under the Biocidal Products Regulation. After the Management Board approved the budget increase and recruitment of more contract agents, and after further procurement of IT services, ECHA started to implement the first phase of this programme in December. This included continuous though slower development and deployment of the IT systems. Despite the significant financial and human resources constraints ECHA managed to release four new minor versions of the Registry for Biocidal Products (R4BP 3) which provided better support to applicants and MSCAs and enhanced the experience of the users in several areas. In parallel, ECHA carried out with the support of the MSCAs, a comprehensive program of correction of the product authorisations database to address inaccuracies mostly originating from the former R4BP2 tool.

In 2015, ECHA co-ordinated 4 109 submissions of which 3 631[19] were addressed to the Member State competent authorities. The rest of the submissions stipulated in the Annex 2 were handled by ECHA. To support the submissions by the applicants, the Biocides Submission Manuals and corresponding web pages have been updated to include the changes of the IT tools and revised based on feedback received to achieve more ready access to the relevant information. Additionally, throughout the year ECHA has offered direct support to individual applicants dealing with problematic submissions.

With regard to data sharing, ECHA received 152 inquiries and processed 172 inquiries. The number of new inquiries was much higher than the 50 estimated for 2015. In total, nine data-sharing disputes were received, mostly in August 2015, just before the Article 95 legal deadline, with only few in the beginning of the year and few after the deadline. ECHA issued seven final decisions (three favourable to the prospective applicants and four unfavourable).

In line with the agreement reached in 2014 with the MSCAs on the division of tasks concerning confidentiality requests, ECHA has continued to inform the MSCAs of the confidentiality requests made by the applicants at the time of processing the submissions.

For its second year as responsible for the support to the Review Programme of existing active substances, ECHA has, with the essential contribution of the MSCAs, further accelerated the assessments which resulted in the adoption of 46 opinions (on an annual total of 50) by the Biocidal Products Committee, which represents an increase of almost 50% compared to 2014. 20 meetings of the permanent working groups of the Biocidal

[19] Of these 3631 submissions, 591 were administrative changes of a national authorization and the rest were new applications.

Products Committee (BPC) were organised, as well as one ad-hoc working group meeting. The peer review process has continued to become significantly more efficient than in the past.

In March 2015, ECHA organised a workshop with the MSCAs to review the active substance approval process and explore possible ways of increasing further its effectiveness and efficiency. This resulted in proposals to modify the process and clarify certain elements such as the role of ECHA or the timelines for the applicability of new guidance. These proposals are discussed with the BPC and some have already been agreed in December.

Despite significant progress as compared to 2014 and due to delayed delivery of several MSCA's assessment reports, the number of finalised active substance assessments has remained lower than foreseen. Further discussions will be needed with the MSCA's to ensure timely delivery of the assessment reports in the future.

For the third year in a row since the entry into force of the BPR, the number of applications for new active substances (9) has exceeded the conservative forecast.

Forty-nine opinions were adopted by the BPC in 2015 following an application for the approval of an active substance for one or more product-types[20] (PT). Forty-two opinions contained a proposal to approve the active substance PT combination, while four contained a proposal to not approve: triflumuron in PT 18 (insecticide), triclosan in PT 1 (human hygiene disinfectant), cybutryne in PT 21 (antifouling products) and PHMB[21] in PT 1, 6 (preservative for products during storage) and 9 (preservation of fibrous or polymerised materials such as textiles).

In addition to the proposal for approval or non-approval of the active substance PT combination, the BPC opinion also indicates whether the active substance is considered as a potential candidate for substitution. Such active substances can be approved, but biocidal products containing them are subject to a comparative assessment[22] when companies apply for authorisation. In 2015, the BPC identified the following candidates for substitution: medetomidine, PHMB, cybutryne, triclosan and formaldehyde. The BPC opinions forms the basis for the decisions taken by the Commission after consultation of the Member States in the Standing Committee on biocidal products.

In relation to the legal deadline of 1 September 2015, a significant number (197) of applications for inclusion in the Article 95 list (list of active substances and suppliers) were made which resulted in an important assessment activity for ECHA with a notable peak in the third and fourth quarters. It should however be noted that for some biocidal products the applicable legal deadline will fall on 1 September 2016. The Article 95 list contained 546 suppliers out of which 77 resulted from a positive decision on an Article 95 application by 1 September 2015. As applications continued to arrive the list contained 588 suppliers (122 resulting from a positive decision on an Article 95 application) by the end of 2015.

[20] The BPR covers a very diverse group of products, including for example disinfectants, pest control products and preservatives. These products are categorised in 22 so-called product-types (PT). Active substances are approved per PT.

[21] Monohydro chloride of polymer of N,N'''-1,6-hexanediylbis[N'-cyanoguani¬ dine] (EINECS 240-032-4) and hexamethylenediamine (EINECS 204-679-6)/ Polyhexamethylene biguanide (monomer:1,5-bis(trimethylen)-guanylguanidinium monohydrochloride)

[22] If a biocidal product contains a candidate for substitution, the authorities have to perform a comparative assessment within the timeframe that is allowed for evaluating applications for product authorisation. The assessment has to decide whether there are any suitable alternatives to the product, either non-chemical alternatives or other authorised biocidal products. Based on this comparative assessment the authorities may decide to not grant the authorisation or grant it under certain conditions.

Also the number of Technical equivalence applications has increased and exceeded the forecast, with 26 applications received of which 21 for Tier I and five for Tier II assessments.

The first eleven applications for the Union Authorisation were received in the third and fourth quarter of 2015, in line with the original forecast of the Work Programme 2015 but significantly above the conservative estimates made by the Commission in the context of the budgetary discussions in 2014. In addition, two applications were received for same biocidal product authorisations referring to pending Union authorisation applications. The numbers of pre-submissions for the Union Authorisation rose significantly in 2015, as 23 pre-submissions were received.

Following the entry into force of the Review Programme Regulation in 2014, ECHA had to address previously unforeseen tasks (in particular notifications and declarations of interest to notify).

ECHA continued to strengthen its capacity to support the assessment of various types of applications in order to address their growing number and complexity. Specific preparations for the Union authorisation process were also initiated addressing in particular the MSCAs' verification of the Summary of Product Characteristics (SPC) translation. For this purpose, exchanges have taken place with the European Medicines Agency which has a similar task for the authorisation of veterinary medicines.

ECHA has provided a Secretariat for the Coordination Group (CG) and organised six meetings. The Secretariat also organised the meeting of a CG Working Party for the standardisation of SPCs of anticoagulant rodenticide biocidal products. The discussion of eight formal mutual recognition disputes has led to the settlement of six agreements during 2015. Two informal disagreements were also discussed, contributing to the early resolution of one of them. The other informal disagreement was not solved and was taken further as formal referral. The CG meetings have also addressed a number of issues related to product authorisations.

Overall, ECHA has carried out the biocides activities under significant human resources restrictions set by the European Commission because of the insufficient fee income in 2013 and 2014 and the uncertainty of the fee income for 2015. The high workload has been addressed with insufficient resources thanks to the high commitment and efforts of the staff. However, this situation is not sustainable and ECHA would need more flexibility regarding the recruitment of staff to support the biocides activities and its growing workload. This issue will be addressed with the European Commission in the context of the overall discussion on the structure of the ECHA biocides budget where the high volume of non-fee supported activities (like management of the Review Programme and horizontal activities like the development of IT tools like R4BP, helpdesk, guidance and communication) would justify a higher subsidy.

2. Objectives and indicators

Objectives

1. All dossiers and requests are processed according to the standard procedures adopted by ECHA and within the legal deadlines or targets set.

2. ECHA has good capacity to scientifically and technically support the evaluation work undertaken by the MSCAs.

Performance indicators and targets

Indicator	Target in 2015	Result in 2015
Percentage of dossiers processed within the legal timeframe.	100%	100%
Level of satisfaction with the quality of scientific, technical, and administrative support provided to the members of the BPC, Coordination Group, the Commission, MSCA's and industry.	High	High

3. Main outputs

- Scientific, technical, legal and administrative support to the evaluation of applications for active substance evaluation carried out by the MSCAs: 49 BPC opinions
- Assessment of applications for inclusion in the Article 95 list (active substances and suppliers): 159 decisions.
- Assessment of technical equivalence applications: 21 decisions.
- Handling of pre-submissions for Union Authorisation: 12 pre-submission consultations completed.
- Submissions: 4 109 processed of which 3 631 were addressed to the Member State competent authorities
- Assessment of Review Programme notifications: 8 decisions. Also 39 requests for change of elements in the Review Programme and nine requests for withdrawal were processed.
- IT tools: four new minor versions of the Registry for Biocidal Products (R4BP 3) have been released
- Workflows and processes for dealing with incoming dossiers tested for their usability and further developed where necessary.
- 172 inquiries (152 received in 2015 and 20 received in 2014) were processed.
- 7 decisions on data sharing disputes were issued.
- Participation and contribution to scientific events and workshops to further improve the understanding of the assessment of biocides (active substances and biocidal products).
- Cooperation and main working procedures reinforced with EFSA, EMA and relevant services of the Commission to ensure consistency of assessments for substances across different legislations.

1.6. PIC (Activity 17)

The Prior Informed Consent Regulation (PIC, Regulation (EU) 649/2012) administers the export and import of certain hazardous chemicals and places obligations on companies who wish 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. This regulation implements, within the European Union, the Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade.

ECHA is responsible for certain administrative and technical tasks. ECHA 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 European Commission.

1. Main achievements in 2015

In 2015 ECHA achieved the cruising speed in handling PIC notifications, an activity taken over from the European Commission in 2014. All notifications and related work, including the end-of-year peak, was carried out in a timely manner, although the number of notifications increased by 19% from 2014. 5460 export notifications were processed for the calendar year 2015; this number is significantly higher than the baseline figure due to the impact of new chemicals which have become subject to the PIC Regulation and presumably due to increased awareness in companies on their obligations related to PIC.

Of the 5460 export notifications , 1591 were for industrial chemicals, 3168 were for pesticides and 701 were for both use categories. Two Member States accounted for 60% of all notifications: 39 % of the notifications originated from Germany (2 120) and 21 % from France (1 160). Whereas Germany has always been the EU country with the largest number of PIC exports, the number of notifications from France has significantly increased due to one of the new chemicals added to the PIC Regulation in 2014. Last year, 11% of the export notifications from France were due to this chemical.

In 66 cases, the non-EU country informed us that they did not agree to the import of a given chemical. The exporting company was informed and the information was also made available by means of ePIC to EU Customs and, as of February 2016, to enforcement authorities too.

The legal timeframe for sending export notifications was met in almost all cases: 77 export notifications were received late from the responsible EU DNA and three notifications were processed late due to a technical problem in ePIC which was then promptly addressed.

For the first time ECHA co-ordinated the information gathering for the yearly report on realised imports and exports. The Agency developed the implementation of the reporting in ePIC and monitored and co-ordinated the DNA inputs. The report itself will be published in early 2016.[23]
The ECHA PIC team has maintained close and proactive links with the DNAs and has received very good feedback on its support to day-to day operations as well as the

[23] ECHA had committed to publishing by the end of 2015 the actual exports and imports of PIC chemicals which took place in 2014 (as per Article 10 of the PIC Regulation). However, the discussions with the European Commission on the format of the report were prolonged and the report will be published in 2016 instead.

ongoing refinements to ePIC. Additionally, ECHA attends the DNA meeting twice a year as well as other events and workshops organised by the Rotterdam Convention Secretariat or industry associations. ECHA remains on stand-by for any requests for scientific and technical support from the European Commission, but no such requests were made in 2015.

Text Box: The impact of the PIC Regulation (facts and figures)

- The European Union, by means of the PIC Regulation, makes a significant contribution to the environmentally sound use of hazardous chemicals in non-EU countries (third countries and economies in transition) by informing them on the potential import of hazardous chemicals into their countries and on the companies which are trading these chemicals. This gives them the opportunity to prevent the import of unwanted chemicals.
- In 2015:
  - Export notifications were sent to the authorities in 146 non-EU countries
  - The number of export notifications sent **within one year** was almost twice as large as the total number of import notifications (3129) received by the EU **from the rest of the world since 2003**
  - The import notifications received were mainly from two countries. 74% were from the United States and 24% from Switzerland

2. Objectives and indicators

Objectives

1. Ensure the successful implementation of PIC activities and effective management of the notifications.

Performance indicators and targets

Indicator	Target in 2015	Result in 2015
Percentage of PIC notifications processed within the legal timeframe.	100%	99%
Level of satisfaction with the quality of scientific, technical, and administrative support provided to the Commission, Member State DNA's and industry.	High	High

3. Main outputs

- In 2015 ECHA processed a total of 5 951 export notifications. Of these:
  - 2 555 were for exports which took place in 2015
  - 3 396 were for exports which will take place in 2016
- Significant email exchange (~1 500 emails) on cases where ECHA provided regulatory and/or technical advice and support to the Commission, EU- and non-EU DNAs.
- Delivery of three new versions of ePIC which included all the necessary functionality for submitting and aggregating the data for the reporting pursuant Article 10 (i.e. the data on the actual exports and imports of PIC chemicals that took place in the previous calendar year) as well as other improvements suggested by stakeholders.

- Collection of all the Article 10 data (from companies and DNAs) within the calendar year (for the first time) thanks to the ePIC functionality and the support provided by the PIC team.
- ECHA attended the 7th Conference of the Parties to the Rotterdam Convention and reached out to ~30 delegations from non-EU countries in order to clarify the provisions of the EU PIC Regulation and the differences to the Rotterdam Convention itself. Additionally, ECHA provided support to the Rotterdam Convention Secretariat by attending a Workshop to reinforce the cooperation on the implementation of the Rotterdam Convention between Designated National Authorities (DNAs) of the following countries: Burundi, Cameroon, Congo, Djibouti, Gabon and Rwanda.
- Assisting the Commission in preparing the template for the Article 22 report (i.e. the three-yearly report on the operation of the regulation) for DNAs as well as providing the draft ECHA reporting template

1.7. Advice and assistance through Guidance and Helpdesk (Activity 5)

The REACH, CLP, Biocides and PIC regulations all require ECHA to provide technical and scientific guidance and tools for industry, for the competent authorities and for other stakeholders.

Similarly, ECHA's establishing regulation stipulates that ECHA provides advice and assistance to manufacturers and importers as well as support to competent authorities and to the helpdesks established by Member States.

1. Main achievements in 2015

Guidance

The main guidance activities identified for finalisation in the 2015 Work Programme were completed. These included an update of Chapter R.12 on use description of the Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA) identified as a priority in 2014 under the CSA programme. Significant updates to the sections of Chapter R.7a on end-point specific guidance updated the terminology and methodology for skin/eye/respiratory irritation/corrosion/ and introduced the extended one generation reproductive toxicity study as an additional method which may lead to reduced numbers of animals being tested. Although an update of part of Volume I of the BPR guidance was de-prioritised a further three additional guidance documents and updates on Volumes II, III and IV were finalised as well as the foreseen new BPR guidance on Microorganisms.

June 2015 was a significant date for the end of transitions from the old Dangerous Preparations Directive (DPD) to full CLP implementation for mixtures. As a result of this (and to take into account adaptations to technical progress (ATPs) and other legal text changes) updates were published not only to the CLP guidance itself, but also to other guidance making reference to CLP (guidance on compilation of safety data sheets and guidance on the PIC regulation). An additional fast-track update to the guidance on requirements for substances in articles was made to take into account the judgement of the Court of Justice in case C-106/14.

During 2015 an exceptionally high number of consultations on further guidance updates were initiated to *inter alia* (i) bring the guidance in line with learnings and current best practice on occupational, consumer and environmental assessment, (ii) describe options for weight-of-evidence to predict acute oral toxicity from repeated dose toxicity and sources of information (potentially reducing animal testing) and (iii) to take account of scientific developments and activities at OECD level concerning sensitisation – all with a view to publish updated REACH guidance as far in advance as practicable before the 2018 deadline, ideally before June 2016.

To increase accessibility of documents direct links to relevant guidance and guidance in a nutshell documents (the latter provided in 23 official EU languages) have been incorporated into the REACH 2018 pages on the ECHA website.

During 2015, the procedures for new guidance and updates of guidance on the BPR have been incorporated into the "normal" ECHA procedures as defined in the updated guidance consultation procedure MB/63/2013 (final). This has extended the already implemented consultation of the Biocidal Products Committee whenever appropriate for REACH or CLP guidance and allowed for invitation to provide comments according to the procedure.

ECHA Helpdesk and BPR, CLP and REACH Helpdesk Network (HelpNet)

During 2015, the ECHA Helpdesk continued to provide advice and assistance to industry and support to Member States. The focus was on activities to make SMEs and "newcomer" duty holders aware of their regulatory obligations while ensuring support by the national helpdesks and ECHA in fulfilling these obligations and in understanding them. Particular emphasis was given to activities related to the REACH 2018 Roadmap.

Providing clear advice to companies was achieved by involving national BPR, CLP and REACH helpdesks in topical discussions, by revising previously published frequently asked questions (FAQs), and by revising the writing style of ECHA helpdesk replies. In order to provide FAQs in a more timely manner, HelpNet agreed to a revised FAQ procedure which allows updating FAQs on the BPR, CLP and REACH regulations on a quarterly basis.

Other SME oriented activities of the HelpNet included development of the guide "Chemical safety in your business - Introduction for SMEs" in collaboration between ECHA, national REACH helpdesks, and the Enterprise Europe Network. The guide provides an overview of BPR, CLP and REACH requirements and advertises the innovation-friendly mechanisms present in REACH. At its workshops, HelpNet discussed the SME benefits, SME verification under REACH, downstream user support and HelpNet collaboration in that area.

Joint communication activities on the REACH 2018 Roadmap were ensured by inviting HelpNet members to participate in the REACH 2018 Communicators' Network and by including related topics in the HelpNet REACH workshops. As substance identity is one of the core areas of the first phases of REACH registration, ensuring that national helpdesks are able to support companies with regard to substance identity was a priority for ECHA. Consequently, a workshop for national REACH helpdesks on substance identity was organised.

The CLP 2015 deadline for mixture classification also determined the work of the ECHA Helpdesk. The national CLP helpdesks participated in the Forum "Training for trainers 2015" event on mixture classification. In order to ensure a continuous flow of information on the most recent developments which could be useful for duty holders and national helpdesks, the HelpNet Secretariat began to publish a bi-monthly "HelpNet Update" newsletter. Additionally, the ECHA Helpdesk informed duty holders on top tips from ECHA's Newsletters.

ECHA's IT support comprises an extensive service to companies and national authorities in Member States in Europe, offering business and technical advice as well as hands-on help on the adequate use of the Agency's scientific IT tools e.g. IUCLID, REACH-IT, R4BP, SPC Editor, ePIC, Chesar, Portal Dashboard etc.

Building on support initiated in 2014, national authorities and their users have also benefitted from IT support with regard to their access to ECHA's IT systems and their use: the management and the administration of signed unified declarations of commitment with regard to standard security requirements, the handling of nominations for the foreseen security roles and issuing of ECHA's Executive Director Authorisation on unified access to ECHA's Information systems are prominent examples.

MSCA user administrators are kept duly updated about any development of ECHA's scientific IT tools by means of an information exchange platform. The planning, design and production of training materials including content management and collaboration platforms, the organisation of various workshops (e.g. webinars, webex sessions) and training activities round up the Agency's IT support portfolio.

Throughout 2015 the number of answers to questions received from stakeholders was significant with overall 4661 for REACH and CLP and 3109 for Biocides and PIC Regulations. The questions addressed regulatory aspects, legal interpretation, IT tools and submissions related questions.

Advice on PIC

ECHA also provided significant support to stakeholders on their obligations under the PIC Regulation. This area of activity created noticeable workload as ECHA addressed, approximately 3500 emails received from the Commission and EU-/non-EU DNAs on processing-related cases, i.e. those that trigger a task in ePIC (e.g. import notifications, acknowledgements of receipt, explicit consents, etc). In addition, companies approached ECHA via the ECHA Helpdesk, submitting 209 enquiries which ECHA replied to in 2015.

2. Objectives and indicators

Objectives

1. MSCA users of the ECHA IT systems, industry and national helpdesks receive timely and efficient support to fulfil their obligations under REACH, CLP, the BPR and PIC.

2. Industry receives support through high quality guidance documents to fulfil its obligations under REACH, CLP, the BPR and PIC.

Performance indicators and targets

Indicator	Target in 2015	Result in 2015
Percentage of ECHA Helpdesk questions answered within the established timeframe (15 working days).	90% (REACH/CLP) 75% (BPR) 75% (MSCA IT support)	94% (REACH/CLP) 92% (BPR) 94% (MSCA IT support)
Level of satisfaction of users with quality of ECHA Helpdesk services.	High	High
Level of satisfaction of MSCA user administrators with ECHA MSCA IT Support services	High	High
Level of satisfaction of HelpNet members with the HelpNet Secretariat	High	High
Level of satisfaction expressed in feedback from guidance users.	High	High

3. Main outputs

Guidance

- Guidance finalised with publication in 2015 (all updates, unless indicated as "new"):
    - Chapter R.12 (use description) of the Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA) identified as a priority in 2014 under the CSA programme;

- Guidance on IR&CSA, Chapter R.7.a; Sections R.7.6 – dealing with extended one generation reproductive toxicity studies (EOGRTS) and Section R.7.2 (Skin and eye);
- Guidance on the Biocidal Products Regulation (BPR): Guidance on Microorganisms (new);
- Guidance on BPR: Volume IV Environment Part B Risk Assessment (active substances) (new);
- Guidance on BPR: Volume III, Human Health Part B – Assessment (as well as corrigendum to previous version)
- Transitional guidance on Biocidal Products Directive (BPD) / BPR: : Efficacy Assessment for Product Type 8 Wood preservatives;
- Introductory Guidance on the CLP Regulation (plus corrigendum thereto);
- Guidance on the compilation of safety data sheets (update to take into account the end of transition periods and change in legal text of Annex II; plus corrigendum thereto);
- Guidance on requirements for substances in articles (fast-track update to take into account the judgment of the Court of Justice on substances in articles (case C-106/14)).

- Further corrigenda published to the following guidance documents in 2015:

  - Guidance on the PIC regulation (to take into account end of transition periods for the CLP Regulation);
  - Guidance on the Application of the CLP Criteria - Part 2 Physical Hazards and Part 3: Health Hazards (to take into account 4th Adaptation to Technical Progress (ATP));

- Guidance projects initiated and for which draft consultation documents were sent for consultation during 2015:

  - Guidance on IR&CSA – Part D (Framework for exposure assessment) and Chapter R.14 (Occupational exposure assessment);
  - Guidance on IR&CSA – Chapter R.15 (Consumer exposure assessment);
  - Guidance on IR&CSA – Chapter R.16 (Environmental exposure assessment);
  - Guidance on IR&CSA - Chapter R.7b (Sediment compartment);
  - Guidance on IR&CSA - Chapter R.7a, R.7.4 (Acute toxicity);
  - Guidance on IR&CSA - Chapter R.7.3 (Sensitisation);
  - Guidance on IR&CSA – Part E, Section E.2 Risk characterisation for physicochemical properties;
  - Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008;
  - Guidance on BPR: Volume II Efficacy Part B assessment, Disinfectants PTs 1-5;

ECHA Helpdesk

Support to companies

- 7 770 questions resolved by the ECHA Helpdesk.

- 59 one-to-one sessions provided at ECHA's 10th Stakeholders' Day, 23 one-to-one sessions provided at ECHA's 3rd Biocides Stakeholders' Day.

Support to MSCAs

- Support was provided for 80 cases of remote access establishment and deployment phases of ECHA's IT tools.
- Switzerland was granted access to ECHA's IT systems after the incorporation of BPR into the EEA agreement.
- 110 MSCA staff nomination procedures were handled.
- 4 Roll-out exercises for deployment of ECHA's IT tools were initiated.
- 1 178 questions from MSCA Users regarding access and use of scientific IT tools were replied to.
- 4 Trainings on R4BP 3.2, SPC Online Editor and IUCLID for Biocides were delivered; 1 user manual for MSCA Users, 1 Handbook for User Administrators, 2 quick guides and 12 monthly bulletins were produced.

Support to national helpdesks

- One HelpNet Steering Group meeting and six topical HelpNet workshops on BPR, CLP and REACH, respectively.
- Improvement of FAQ update procedure allowing the publication of FAQs four times per year per regulation: two new CLP FAQs, three new REACH FAQs, and one new BPR FAQ published on the ECHA website as agreed by HelpNet. Revision of content and simplification of style of REACH Roadmap Phase 1 and 2 related FAQs.
- Approximately 100 questions from national helpdesks addressed.
- Capacity-building, sharing of best practice and information exchange of national BPR, CLP and REACH helpdesks for customer support enabled through the HelpNet Steering Group meetings and HelpNet workshops, including e.g. a substance identity workshop, training on mixture classification, IT tools training on R4BP 3.2, and the SPC editor, and active engagement in REACH 2018 Roadmap communication activities.
- Bi-monthly HelpNet Update newsletter.
- Publication of the "Chemical safety in your business - Introduction for SMEs" contribution from national helpdesks and EEN on the ECHA website

1.8. Scientific IT tools (Activity 6)

The REACH, CLP and Biocidal Products regulations impact a significant number of companies and require submission, processing and the sharing of high amounts of data between industry and authorities. Therefore, ECHA has to be an IT-based agency and timely deliver fully functional IT systems for industry, Member States and the Agency's own use are the key to ECHA's success.

1. Main achievements in 2015

During 2015 ECHA continued to expand its IT support to the regulatory processes of the Agency.

A complete restructuring of the dissemination webpages on the ECHA website took place throughout 2015 to implement a new vision for the fulfilment of the dissemination tasks of ECHA. The new vision is much more focused on integration of related information on chemicals across processes and regulations and hinges on the concepts of InfoCards and Brief profiles. The new web pages enhance public access to the information on chemicals collected or created through all ECHA's processes (see Section 1.1).

The technical platform behind the dissemination webpages was rebuilt around a substance-centric view addressing the shortcomings, limitations and the constraints of the previous dissemination system. The new platform automates the data extraction and processing from several different ECHA systems. Development work for the first release was completed by the end of 2015; however the go-live and release to the public was scheduled to a more appropriate time in January 2016.

Release of the first version does not mean however, that the development of the Dissemination platform is over; further developement is foreseen during the next few years to fully complete the vision and respond to the new requests emerging from use.

Significant progress has been made with the development of tools supporting the registration deadline in 2018 - IUCLID, REACH-IT and Chesar - towards the launch of the new versions in 2016.

The technical upgrade of IUCLID was completed with the development of IUCLID 6. A beta version of the application was released on a revised IUCLID website in June 2015. This version is provided for users to allow familiarisation with the upcoming final IUCLID release scheduled for 2016. Internally in ECHA IUCLID 6 has been implemented for operational use since September 2015 to serve as the source of information for the new Dissemination platform and the new version of the Portal Dashboard.

Functional enhancements and other improvements for the final registration deadline has been reflected in the development of IUCLID 6 2016 -version that will be released in 2016 (see Section 1.1).

ECHA has also been exploring the interest of IUCLID users and financial and technical feasibility to provide IUCLID application as a service where ECHA would make the application available over the Internet and take care of operating, securing and upgrading the environment and data as needed. Further studies and analyses will be performed before conclusion or recommendations can be made to ECHA management board and the Commission.

REACH-IT has gone through a major technical upgrade, including adaptation to the new IUCLID 6 data structures and implementation of the architectural changes for a better future maintenance and interoperability. The release of the new REACH-IT will be soon

after the new IUCLID 6 2016 production release in 2016.

Chesar has been developed to support additional cases of safety assessment and to integrate with the new IUCLID version. Due to dependencies between these two systems, the new Chesar will be released simultaneously with the new IUCLID 6 in 2016.

The Portal Dashboard for MSCA was restructured, achieving substantial improvement of performance and user experience. At the same time, the work to consolidate the Portal dashboard and the REACH Information Portal for Enforcement (RIPE) functionalities into one Portal has been mostly completed. The consolidated version will be released early 2016.

The data integration platform, renamed as Business Intelligence and Data Integration (BIDI), has become an important hub for linking, transforming, validating and integrating data from different source systems and processes and providing this data for consumption in other applications. BIDI plays a pivotal role in integrating the information from several systems and providing it to the Dissemination platform as well as the Portal Dashboard for final processing and display.

The system for Prior Informed Consent regulation ePIC was released in September 2014 and it has served well the needs of the regulation. Some new functionality like support for annual reporting under Art 10 of PIC regulation and amending the list of chemicals were introduced during 2015 as part of the continuous maintenance of the application.

The development project for Biocidal Product Regulation system R4BP and SPC Editor was completed in 2014. For the most part of the 2015 these systems were in maintenance mode and only minor improvements were implemented. During the last few months of the year, a new major development initiative was started to cover changes needed due to recent legislative and policy changes (i.e. meta-SPC concept and changes to the Same Biocidal Product Regulation) and Review Programme Regulation and making progress with the still remaining functionality to complete the implementation of the biocides legislation (see Section 1.6).

The data generated during the previous Biocidal Products Directive was imported from the R4BP 2 system into the R4BP 3 however it proved to require considerable amount of cleansing and corrections in order to be fully usable and reliable in the new regulation. This work started in 2015 and will continue still in 2016 as a joint effort of ECHA, MSCAs, Commission and individual applicants.

The new Secure-CIRCA-BC, a dedicated collaboration solution hosted by the Commission and based on the well-known CIRCA-BC platform, was upgraded and security was hardened to permit exchange of confidential business information. ECHA facilitated the transition for its external users by managing the migration of the content and providing a support service.

In 2015, the “case management” IT systems were integrated with the new Dissemination Platform and the Enterprise Content Management (ECM) programme completed its roll-out to all REACH and CLP regulatory processes. The main business outcomes achieved since the beginning of this programme in 2011 have been the compliance with the legal and policy requirements of the Agency (e.g. audit trail, Conflict of Interest, legal deadlines), the simplification and standardisation of tasks, the achievement of synergies between regulatory processes, increased efficiency of the administrative support to the regulatory work.

The programme has also contributed to the improvement of document consistency, the management of ECHA’s records and has increased productivity.

2. Objectives and indicators

Objectives

1. ECHA provides specialised tools and related services, which efficiently support the MSCAs and industrial stakeholders in preparing and submitting dossiers to ECHA.

2. Well-functioning IT systems enable ECHA to receive and successfully process submissions, perform evaluations and risk assessment activities as well as to disseminate the public information, in the REACH, CLP, Biocides and PIC legislations.

Performance indicators and targets

Indicator	Target in 2015	Result in 2015
Level of satisfaction of external users with the IT tools (IUCLID, REACH-IT, R4BP 3, CHESAR, ePIC and Dissemination).	High	High

3. Main outputs

- New Dissemination Platform was developed and released to public in January2016
- IUCLID 6 technical foundations completed and a beta version containing the technical changes to the software was made available to the public in June and this version is in full use internally in ECHA since September
- REACH-IT technical foundation has been upgraded, changes for the 2018 registration deadline are underway
- S-CIRCA-BC platform secured and in use for all ECHA Interest Groups
- The use of the case management IT systems (e.g. ECM-DEP, Dynamic Case) covers all REACH and CLP processes
- Records are transferred from Dynamic Case to the records management system (RMS) according to a defined Retention schedule and in compliance with the minimum metadata described in the EUI draft guidelines
- RIPE functionalities have been consolidated into the Portal Dashboard application, final production release early 2016
- Identification and agreement together with DG SANTE and the user community of the next developments in the Biocides Regulation area to R4BP 3 and SPC Editor. Implementation started in 2015 and continues during the next years.

1.9. Scientific activities and technical advice to EU Institutions and Bodies (Activity 7)

ECHA is a regulatory organisation with a mission in a scientific and technical context. Therefore, ECHA needs to continually invest in developing its scientific and regulatory capacity further so that it can base its decisions, opinions and advice on up-to-date scientific or technical knowledge. This will also enable ECHA to give advice, on request, to EU Institutions and bodies on relevant issues, such as further development of the legislation.

1. Main achievements in 2015

ECHA continued implementing the Strategic Objective 3, supported by the Science Strategy established in 2014. The implementation of a systematic competence management continued with identification and design of the training programmes in three priority areas: human health exposure assessment and modelling, sensitive life stages and endocrine disruption, and impact assessment and socio-economic analysis.

ECHA contributed to the development of new or updated OECD Test Guidelines and Guidance Documents through several OECD Expert Groups, and by providing expert comments. Prioritised endpoint areas were: skin sensitisation, genotoxicity, endocrine disrupters and aquatic and terrestrial ecotoxicity.

Scientific input to ECHA Guidance update on reproductive toxicity was given to support the implementation of the extended one-generation reproduction toxicity study (EOGRTS) in line with the new REACH information requirements. ECHA internal guidance on evaluation of adaptation approaches for reproductive toxicity was drafted with the focus on weight of evidence adaptation. In addition, ECHA commissioned a study on global laboratory capacities to conduct the EOGRTS (published in January 2016).

ECHA contributed actively to the development and use of alternatives to animal testing, including via contributions to OECD. This included in particular participation in the drafting of an integrated approach for testing and assessment (IATA) on skin sensitisation, a Weight of Evidence approach to replace some acute oral toxicity studies for low-toxicity substances and contributions to the development of Adverse Outcome Pathways (AoPs) development at WHO and OECD level. In addition a project on examination of the usefulness of the Fish Embryo Toxicity (FET) test for REACH registration was conducted. Relevant guidance updates were initiated based on the above work with a view to the guidance moratorium, in preparation for the 2018 registration deadline. There was active engagement with the joint EU-industry funded research programme SEURAT-1, i.e. 'Safety Evaluation Ultimately Replacing Animal Testing'[24] to encourage the short-term regulatory application of new-approach methods to improve read-across justifications.

ECHA promoted dialogue between authorities and researchers on scientific issues by organising visits of leading researchers and participating in conferences and webinars, especially to promote alternatives to animal testing. This aspect is also embedded in the OECD QSAR Toolbox development by having management group meetings on a regular basis. A webinar on the use of the Toolbox for predicting aquatic toxicity and skin sensitisation was given to a mixed audience of more than 300 participants, thus promoting the use of the non-test methods in general, and the OECD QSAR Toolbox in particular.

[24] http://www.seurat-1.eu/

The Read-Across Framework (RAAF) for human health endpoints, to advise authorities and registrants on how to build and assess read-across justifications for toxicology studies was finalised and published. Progress was made to extend the RAAF to expand it to environmental studies.

The Topical Scientific Workshop on Soil Risk Assessment of over 200 experts, held jointly with EFSA, took place at ECHA on 7 - 8 October 2015. As lot of scientific developments on soil risk assessment have emerged since issuance of current ECHA guidance, areas for further collaboration and guidance updating were identified during the workshop.

Pending the on-going review of the Commission Recommendation on the definition of nanomaterial (696/2011) and the expected revision of REACH annexes to adapt them specifically to nanomaterials ECHA initiated the internal work on clarifying certain aspects of the existing guidance for REACH relating to nanomaterials. In particular, ECHA led a project where together with RIVM and JRC, a technical reference paper was developed describing how and when bridging data gaps between nanoforms of the same substance can be done. Through ECHA's coordination, the understanding in the field has been harmonised across ongoing research projects, Member States efforts as well as the methodology developed by the industry. This is a good example of ECHA acting as the scientific hub by providing the right tools to streamline resources and science at EU level to make progress on a specific topic.

In addition, this work will feed into the overall foreseen guidance update which also includes human health and environment as well as clarifying the term "nanoform" in line with the Commission Recommendation on the definition of nanomaterial (696/2011). ECHA continued chairing the OECD steering group for testing and assessment under the Working Party on Manufactured Nanomaterials.

ECHA's contribution to research projects over 2015 was focusing on the overarching FP7 project NanoREG[25]. Due to its scope of targeting regulatory science in the field of hazard assessment of nanomaterials, ECHA continued to monitor the project which also provides the organisation to stay at breast with the latest development in methodologies used in hazard assessment of nanomaterials.

Preparations for the second report by ECHA on operation of REACH and CLP ('Article 117.2 report') started with a view of its publication by 1st June 2016. Cooperation with the Joint Research Centre of the European Commission continued, and was strengthened by increased emphasis to the new developments in developing alternatives to animal testing. Also cooperation with other EU Agencies continued, via the EU Agencies network for scientific advice, where ECHA accepted to take on the chairmanship of the network in 2016.

Contrary to the Work Programme plans no request was received from the Commission to support the implementation of the future Fertiliser legislation.

2. Objectives and indicators

Objectives

1. ECHA delivers on request high quality scientific and technical advice on the safety of chemicals, including nanomaterials and endocrine disruptors, PBT-like substances, testing methods and the use of alternative methods.

2. ECHA is able to encompass scientific developments and emerging needs for

[25] http://cordis.europa.eu/project/rcn/107159_en.html

regulatory science.

Performance indicators and targets

Indicator	Target in 2015	Result in 2015
Level of satisfaction with the quality of the scientific, technical and administrative support provided to the Commission and MSCAs.	High	High

3. Main outputs

- Development of new or updated OECD Test Guidelines and guidance documents through several OECD Expert Groups, and by providing expert comments;
- Contributing to the release by OECD of 720 robust study summaries providing nano specific information for 11 commonly used nanomaterials.
- Common consensus at EU level (research community, MS, NGOs and Industry) on a scientific reference paper illustrating how bridging data gaps between nanoforms of the same substance, can be done.
- Internal agreement on updating existing guidance in the context of nanomaterials based on experience from operational work and advancement in science.
- Targeting expert contributions and completed update of the guidance on reproductive toxicity to implement the EOGRTS;
- Engagement in projects of regulatory science for the development of alternatives to animal testing;
- Publication of the revised Read-across Framework (RAAF) to advise authorities and registrants on how to build and assess read-across justifications;
- Co-operation with SEURAT-1 to adapt two of their read-across case studies for ECHA's 2016 Topical Scientific Workshop on New Approach Methodologies in Regulatory Science by means of applying the RAAF to examine the value of the new evidence to enhance read-across.
- International Topical Scientific Workshop promoting and targeting further developments in soil risk assessment, held jointly with EFSA;
- ECHA's cooperation with JRC reviewed and strengthened in relation to the application of new approach methods which are to decrease the need for animal testing;
- Driving guidance updates to reflect nanomaterials appropriately, in cooperation with the OECD Working Party on Manufactured Nanomaterials.

2. ECHA's Bodies and Cross-cutting Activities

2.1. Committees and Forum (Activity 8)

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 scientific and technical advice (i.e. agreements and opinions) as a basis 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.

1. Main achievements in 2015

Member State Committee (MSC)

The MSC unanimously agreed on 99% of the draft compliance check decisions on registration dossiers and draft testing proposal decisions (in total 75). In one compliance check draft decision the MSC did not reach unanimous agreement. In accordance with the legal requirement, the full documentation will be submitted to the Commission for their further decision-making.

In total, 33 substance evaluation draft decisions, as a result of evaluations addressing 32 substances carried out by Member States, were addressed by the MSC in its decision making during 2015; almost twice as much compared to 2014. For all, unanimous agreement on the draft decision was reached. In relation to the substance evaluation process, the Committee adopted its opinion on ECHA's draft CoRAP update for 2015-2017 in February 2015.

The MSC unanimously agreed on the identification of three substances as SVHCs that were subsequently included in the Candidate List. For one substance (i.e. HDDA), where it was the first time that a skin sensitizer was discussed at MSC, the Committee did not reach unanimous agreement. The MSC opinion and the minority view will be submitted to the Commission for decision-making.

The MSC adopted its opinion on ECHA's sixth draft recommendation for inclusion of priority substances in Annex XIV and published it on the ECHA website in June 2015. After MSC consultation ECHA included 12 substances in the public consultation for the draft seventh recommendation in November. The MSC rapporteur and a Working Group were established for drafting the MSC opinion on the draft seventh recommendation scheduled for adoption in 2016.

The MSC opinion on the persistency and bioaccumulation of the substances D4 and D5 (octamethylcyclotetrasiloxane and decamethylcyclopentasiloxane) was adopted as the first MSC opinion under Article 77(3)(c).

The regular stakeholder observers of the MSC and case owners (registrants) have been able to follow the MSC discussions on all five REACH processes since 2011. During 2015, the case-owners participated in the Committees' discussions in 70% of cases.

Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC)

RAC adopted a total of 38 opinions on harmonised classification and labelling in 2015. The ECHA Secretariat provided extensive support to the RAC rapporteurs in developing

opinions and scientific background documents and processed all CLH dossiers received from MSCAs and industry in 2015. The majority of the proposals for harmonised classification and labelling concerned biocidal and plant protection products. A high proportion of these dossiers contained CMR endpoints. Mechanistic studies, intended to explain 'mode of action' and thereby relevance of carcinogenic effects to humans, were more frequently presented for evaluation in 2015 and this trend seems set to continue. Particularly challenging dossiers in 2015 were three formaldehyde releasing biocides, three cadmium salts, nonadecafluorodecanoic acid and dibutyltin dilaurate, all of which required the addition of read-across to complete the evaluation as proposed by the respective dossier submitters.

The following opinions on proposals to restrict substances were adopted by the Committees::

- the use of **inorganic ammonium salts** in cellulose insulation materials;
- the placing on the market of **bisphenol A** used as a dye developer in thermal paper used, for example, in point-of-sale tickets and receipts;
- the use of **decaBDE** as a flame retardant in plastics and textiles;
- the manufacturing and use of **PFOA and its PFOA-related substances**, as well as of articles and mixtures containing these substances;
- the concentration of **methanol** in windscreen washing fluids and denaturated ethanol (RAC only)
- an amendment to the current derogation for diaphragms in electrolysis installations in an existing restriction on **chrysotile asbestos** (SEAC only);
- **cadmium and its compounds** in artist paints (SEAC only);

In 2015, RAC and SEAC agreed on 21 draft opinions on applications for authorisation and adopted 25 final opinions of which 7 were agreed already in 2014. The agreed and adopted final opinions concern uses of DEHP, HBCDD, lead chromate, trichloroethylene, sodium chromate, sodium dichromate and 1,2-dichloroethane (EDC).

RAC agreed on dose-response relationships for the carcinogenicity of MOCA, technical MDA and 1,2-dichloroethane (EDC) and on a DNEL for toxicity to reproduction of bis(2-methoxyethyl)ether (Diglyme). RAC and SEAC will use these non-legally binding 'reference' risk estimates to evaluate applications for authorisation in a predictable and transparent manner. To date, applicants have used such RAC reference values provided through the ECHA website.

The Secretariat supported RAC and SEAC in preparation for the peak in workload on authorisations commencing in November 2015 and expected to continue through 2016 well into 2017. In support of the authorisation process, suitable candidates for co-option as additional members were selected following an open call for expression of interests. Five co-opted members were subsequently appointed by RAC and four by SEAC. The total number of RAC members rose from 45 to 52, while SEAC rose from 37 to 43.
In 2015 RAC received one Article 95 request to resolve a conflicting opinion with another EU scientific body. The mandate is to develop a joint scientific opinion with the Scientific Committee on Occupational Exposure Limits (SCOEL), to resolve the differences between the occupational exposure limits (OEL) for 1-methyl-2-pyrrolidone (NMP) and the Derived No Effect Level (DNEL) developed by RAC in its restriction opinion on this substance.

A second Article 95 request received from the Commission concerns the creation of a Joint Task Force on the scientific aspects and methodologies related to the exposure of chemicals at the workplace. A critical assessment of RAC and SCOEL methodologies is requested in relation to a) the inhalation route, DNEL vs OEL methodology, b) non-threshold substances and c) the dermal route exposure, 'skin notation' and dermal DNEL. The mandate was issued by the Executive Director in December to RAC to work with SCOEL in setting up the task force.

Biocidal Products Committee (BPC)

The BPC adopted 49 opinions on applications for the approval of an active substance: 46 for existing active substances from the Review Programme and 3 for new active substances where the application was received under Biocidal Products Directive.

In addition the BPC identified, incorporating the results from the public consultation, the following candidates for substitution: **medetomidine**, **PHMB**, **cybutryne**, **triclosan** and **formaldehyde**. For formaldehyde the BPC concluded that this active substance also meets the exclusion criteria.

One opinion was adopted following an Article 75(1)(g) request from the Commission. This request related to **sulfuryl fluoride** which is an active substance used as a fumigant for wood preservation and insecticidal purposes. It was already approved under the Biocidal Products Directive. Sulfuryl fluoride contributes to global warming. Therefore monitoring data in remote areas were requested as a condition for approval. The Commission, having received the monitoring data over a 5 year period, asked the BPC to assess if the previous conclusions are still valid. The BPC concluded that the global warming potential is higher than originally estimated, but that the contribution to global warming compared to carbon dioxide is still relatively low. The BPC recommended to continue with the monitoring programme, and assess the aspect of global warming under the renewal process.

The Secretariat supported the BPC in preparation for two new processes. The first one is the renewal of active substance approval, where in 2016 opinions are expected to be adopted for 8 second generation anticoagulants used as rodenticides, while the second one is Union authorisation. In addition the Secretariat supported the BPC and the Working Groups in preparation for the peak workload in 2016 due to the first deadline of the Review Programme Regulation (EU) No 1062/2014 for product types 8, 14, 16, 18, 19 and 21.

Forum

In 2015, the Forum continued to focus on practical enforcement projects with three major projects (REACH-EN-FORCE projects abbreviated as REFs) and four smaller scale projects (pilot projects).

It completed and published the final report of the third coordinated enforcement project (REF-3) which focused on registrations and cooperation with customs authorities. The report indicates that there is room to improve compliance with the registration obligations. Further inspections along the multinational supply chains indicated that 32% of inspected Only Representatives (ORs) were in some way non-compliant, thus confirming the initial findings from the first phase of the project. In the course of 2015 the Forum also finalised the manual for its fourth coordinated enforcement project focusing on checking selected restrictions[26] (REF-4), allowing inspections to start in early 2016. Restriction entries were chosen so that they focus on the protection of consumers, but could also address protection of professional users and the environment. When checking compliance with restrictions inspectors will put emphasis on imported goods and to this end cooperate with customs authorities. In the middle of 2015 the Forum decided that the subject of its fifth major enforcement project (REF-5) will cover extended safety data sheets and exposure scenarios.

Good progress was also made on the Forum's pilot projects. The inspection phase of the first pilot project on authorisations was finished. Publication of its results is due in early 2016. The preparations (project manual finalised, translated and delivered to the

[26] http://echa.europa.eu/documents/10162/21774240/Annex_Forum_21.pdf

inspectors before the end of 2015) for the second project on authorisation were completed allowing to kick off the inspection phase in the beginning of 2016. The execution of these two pilot projects puts into practice one of the milestones of ECHA's MAWP 2014-2018.

The Forum has also embarked on two more pilot projects not explicitly covered by the Work Programme 2015. The first project focuses on CLP and its requirements for child resistant fastenings. During 2015 the project manual was prepared and the inspections were conducted, finishing the operational phase in December 2015. Comparable progress has been made on another pilot project focused on the use of harmonised classification for substances with CMR and skin sensitising properties. The project was to pilot the cooperation between ECHA and NEAs where the Agency is channelling information on potential non-compliance to the inspectors. The Forum also decided the subjects of two pilot projects for the coming years. In 2016 the Forum will pilot enforcement of internet sales of hazardous chemicals and in 2017 it will organise an enforcement pilot related to obligations for substances in articles.

The Forum has continuously assisted ECHA and the European Commission in on-going improvement and modernisation of the IT-tools available to inspectors, more particularly the new Portal Dashboard for National Enforcement Authorities (PD-NEA), which will replace RIPE[27] in early 2016 and the ICSMS[28] system which will be made compatible with the needs of REACH and CLP inspectors.
The Forum continued its work on specifying the interinstitutional interlinks and processes for enforcement of ECHA decisions and other cooperation between NEAs, MSCA, ECHA and the European Commission. The draft interlinks guide was prepared before the end of 2015, with the final version expected for adoption in mid-2016.

In order to build enforcement capacity at the national level, the Forum provided its "training for trainers" event, focusing on the classification and labelling of mixtures.

The Forum continued to advise RAC and SEAC on the enforceability of proposals for restrictions and substantially revised its advice forming process to make it more efficient. It also produced a compendium of analytical methods recommended for checking compliance with the restrictions as listed in Annex XVII of REACH. The compendium will be published in early 2016.

The Forum also finished discussion on improving its cooperation with the Accredited Stakeholder Organisations and communicated its results during the open session in November 2015.

2. Objectives and indicators

Objectives

1. The Secretariat will support and facilitate the work of the Committees efficiently and effectively so that the Committees will be able:
    - to respect the timelines given in the legislation, and
    - to deliver high quality scientific and technical advice, opinions and agreements that support the regulatory decision making in a transparent manner while ensuring the necessary confidentiality.

[27] RIPE: REACH Information Portal for Enforcement
[28] ICSMS: Internet-supported information and communication system for the pan-European market surveillance

2. The Secretariat will support and facilitate the work of the Forum efficiently and effectively and so that it will be able:
   - to further strengthen and harmonise the effective enforcement of the REACH and CLP regulations in the EU/EEA Member States, while ensuring the necessary confidentiality, and
   - to promote harmonised enforcement of REACH, CLP and the PIC regulations.

3. Conflicts of opinion with scientific committees of other EU bodies are prevented to a maximum degree and eventually solved through the sharing of information and the coordination of activities of mutual interest, and active cooperation between the respective Committees.

Performance indicators and targets

Indicator	Target in 2015	Results in 2015
Percentage of opinions/agreements delivered within the legal timeframe.	100%	99%
Percentage of unanimous MSC agreements.	80%	98%
Percentage of Committee opinions adopted by consensus.	80%	87%
Degree of Committee opinions taken on board in the final decision of the Commission.	High	High
Level of satisfaction of the members and other participants with the functioning of the Committees and the Forum.	High	High
Occurrence of conflicts of opinions with scientific committees of other EU bodies.	Only in well justified cases*	None

*Justified case.

3. Main outputs

Member State Committee:

- 75 unanimous MSC agreements on draft decisions on testing proposals and compliance checks.
- Preparation of 32 unanimous agreements on draft substance evaluation decisions (initially 33 draft decisions for 32 substances).
- Opinion on the third draft update of CoRAP.
- Opinion on PBT-properties of substances D4 and D5.
- Three unanimous MSC agreements on Annex XV proposals for identification of substances of very high concern (SVHC) prepared by MSCAs. One opinion on an SVHC proposal for a skin sensitizer.
- Opinion on ECHA's sixth draft recommendation for Annex XIV.

The above was achieved through six plenary meetings and additional preparatory working group meetings.

Committee for Risk Assessment

- 38 RAC opinions on CLH dossiers.
- 5 RAC opinions on restriction proposals.
- 25 RAC opinions on applications for authorisation.

The above was achieved through six RAC plenary meetings

Committee for Socio-Economic Analysis

- 6 SEAC opinions on restriction proposals.

25 SEAC opinions on applications for authorisation.

The above was achieved through four SEAC plenary meetings

Biocidal Products Committee

- 46 BPC opinions adopted on applications for the approval of an existing active substance for the Review Programme and 3 BPC opinions adopted for the approval of a new active substance where the application was submitted under the Biocidal Products Directive:
  - medetomidine, cybutryne, copper thiocyanate, coated copper flake, cuprous oxide in product type 21;
  - hydrogen peroxide in product types 1, 2, 3, 4, 5 and 6;
  - biphenyl-2-ol in product types 1, 2, 3, 4, 6 and 13;
  - C(M)IT/MIT in product types 2, 4, 6, 11, 12 and 13;
  - triflumuron and cyromazine in product type 18;
  - Bardap 26 and granulated copper in product type 8;
  - Ampholyt in product types 2, 3 and 4;
  - peracetic acid in product types 1, 2, 3, 4, 5 and 6;
  - PHMB in product types 1, 2, 3, 4, 6, 9 and 11;
  - triclosan and (L+) lactic acid in product type 1;
  - DBDCB in product type 6;
  - tolylfluanid in product type 7;
  - formaldehyde in product type 2 and 3;
  - *Bacillus amyloliquefaciens* in product type 3;
- 1 BPC opinion adopted following an Article 75(1)(g) request from the Commission.

The above was achieved through five BPC plenary meetings.

Forum

- Three Forum plenary meetings and 13 Working Group meetings;
- Final report of the third coordinated enforcement project (REF-3) on registration obligations and cooperation with the customs authorities;
- Manual of the fourth Forum coordinated REACH enforcement project (REF-4);
- Selected topic and scope of the fifth Forum coordinated REACH enforcement project (REF-5);
- Results and draft report of the Forum first pilot project on authorisation;
- Manual for the second pilot project on authorisation;

- Manual of the pilot project on child resistant fastenings and completion of the operational phase;
- Manual of the pilot project on CMRs and skin sensitises and completion of the operational phase;
- Updated “Manual of Conclusions”;
- Revised procedure for delivery of Forum advice on enforceability of restrictions;
- Forum Guide on Enforceability of Restriction proposals including the guide on advice drafting and a Forum guide for dossier submitters;
- Final draft of compendium of analytical methods for checking compliance with the restrictions as listed in Annex XVII of REACH;
- Four advices of enforceability on proposed restrictions;
- One open session with stakeholders;
- One training event on REACH and CLP for enforcement trainers on classification of mixtures;
- Draft interlinks guide;
- Decision on two new pilot projects for 2016 and 2017.

2.2. Board of Appeal (Activity 9)

The Board of Appeal (BoA) was established by the REACH Regulation. It decides on appeals brought against certain decisions adopted by the Agency under the REACH Regulation and the BPR.

1. Main achievements in 2015

26 appeals (three more than forecast) were brought in 2015. Of these, 13 were directed against compliance check decisions adopted following dossier evaluation, 7 against substance evaluation decisions, 4 regarded data sharing, 1 on the acceptance of a testing proposal and 1 challenged a registration decision. The BoA adopted 15 decisions in 2015, addressing a variety of important issues. 8 appeal cases were closed as the appellants withdrew their appeals after the Executive Director had rectified the contested decisions or the parties settled the appeal case, without there being a need for the BoA decision to go into the substance of the case. In two appeals, the cases were closed with the decisions of the Chairman of the BoA on manifest inadmissibility of the appeals. Each decision, a summary thereof and an announcement of each new appeal were published on the BoA section of the ECHA website. At the end of the year 29 appeals were pending.

Interpretation of REACH regulatory framework

In 2015 the BoA examined important elements of the REACH regulatory framework, including statements of non-compliance (A-019-2013), testing proposals (A-001-2014) and substance evaluation (A-004-2014, A-005-2014 and A-006-2014). Whilst BoA decisions are case-specific, the findings in those decisions may have broad implications for stakeholders and ECHA. In particular, the BoA's decisions have clarified the interpretation of a number of provisions of the REACH Regulation, and its implementation by the Agency.

In case A-005-2014, which concerned a substance evaluation decision, the BoA clarified certain aspects of the relationship between compliance checks as part of dossier evaluation and substance evaluation. The BoA decision found that a compliance check should normally be performed by the Agency before the substance evaluation process is initiated, so that data gaps relating to standard information requirements can be identified and filled through the most appropriate process. The BoA accepted however that, in certain circumstances and with adequate justification, the Agency can proceed directly to substance evaluation without a prior compliance check.

The BoA decisions in cases A-004-2014, A-005-2014 and A-006-2014 also clarified the requirements of the substance evaluation process, most importantly regarding the conditions which must be fulfilled by the Agency in order to demonstrate the necessity for any additional information requested. The BoA held that ECHA must be able to demonstrate that there is a potential risk, that this risk needs to be clarified, and that the requested information has a realistic possibility of leading to improved risk management measures.

With regard to testing proposals (A-001-2014), the BoA examined the Agency's role in ensuring that tests on vertebrate animals are performed only as a last resort. The BoA decision found that, amongst other things, the Agency cannot refuse to take into account substantial new information which comes to light after a certain point in the administrative procedure (the so-called 'cut-off point'), if doing so would risk the unnecessary performance of tests on vertebrate animals.

In case A-019-2013 the Appellant challenged a so-called statement of non-compliance (SONC), which is a letter issued by the Agency as the conclusion of a dossier compliance

check and addressed to the national authority competent for enforcement. The BoA considered that in that appeal case, pursuant to Article 135(1) of the REACH Regulation, a Member State Competent Authority's request for further information on the substance was equivalent to an Agency compliance check decision adopted in accordance with Article 51. The BoA found that after the compliance check decision the Appellant had provided substantial new information requiring a detailed assessment by the Agency, and that the REACH Regulation set up a specific procedure for the adoption of follow-up decisions to compliance check decisions. In this case the SONC *de facto* contained a substantive decision adopted without respecting the guarantees provided for by Article 51 of the REACH Regulation. It was therefore annulled.

Cases pending in 2015 regard important issues such as the definition of intermediates for the purposes of registration, joint submissions and the application of the principle of 'one substance, one registration', the scope of exposure assessment and the information requirements for nanomaterials.

It should also be highlighted that in 2015, for the first time, four appeals were brought under the BPR. Two of these, which were dismissed as inadmissible by the Chairman of the BoA, challenged the inclusion of two companies in the list provided for by Article 95 of the BPR. The other two appeals were directed against data-sharing decisions under the BPR.

Procedure and efficiency

In 2015 the BoA registered a 28% increase in its workload by number of procedural documents received and sent, compared to 2014. The legal and scientific complexity of the appeals before it also increased considerably. In order to handle these developments, the BoA and its Registry are continuously looking for ways to streamline the appeal proceedings, whilst having due regard of the parties' procedural rights.

One of the measures implemented towards this aim is the reduction of the number of procedural decisions to the ones that are strictly necessary for the further processing of an appeal, thus focussing the BoA's modest resources on the core issues at stake in the final decision. For example, the BoA follows the practice whereby its Chairman adopts a reasoned decision on the parties' request for confidential treatment of certain information in appeal proceedings, only when such a request relates to information that needs to be included in the announcement of appeal or when an intervener clearly objects to the confidentiality request.

It should also be noted that in 2015 the Chairman of the BoA used her powers under Article 93(2) of the REACH regulation for the first time, dismissing two manifestly inadmissible appeals within 30 days of their lodging. This allowed all parties concerned to save considerable resources. To the same end, the BoA has continued with its practice of allowing, under certain conditions, multiple appellants to bring joint appeals. Overall, 80 appellants brought 16 appeals in 2015. Where considered of benefit, similar or related cases were also considered in parallel.

In September 2015 a new full-time legally qualified member was appointed by the Management Board. Before this appointment, in order to process appeals at a satisfactory rate as foreseen by the REACH Regulation, four alternate legally qualified members participated in several cases.

2015 also saw the BoA hold five oral hearings, three more than in the previous year. These hearings have continued to prove extremely helpful in clarifying aspects of a case. Pursuing procedural efficiency, the preparation and conduct of hearings have been improved, with the result that hearings have become better targeted.

In addition, the BoA has further refined the requirements for allowing third parties who have an interest in the outcome of an appeal to participate in the proceedings as interveners. The BoA had previously examined the position of NGOs, industry associations and co-registrants in this regard. In 2015, it also clarified which conditions a Member State Competent Authority needs to fulfil in order to intervene in an appeal case. A consistent body of decisions on intervention is now available online. This raised awareness and provided clear guidance to potential interveners, in line with the Work Programme 2015. Interested parties thus could improve their applications for leave to intervene, allowing proceedings to run more smoothly and efficiently.

The practice of rectification of contested decisions by the Executive Director under Article 93(1) of the REACH Regulation has continued to develop satisfactorily. 50% of appeals brought in 2015 were withdrawn by the Appellant after rectification, or settled by the Agency.

Overall, the BoA continues to assert its independence and impartiality and to build on the trust of stakeholders. It has raised awareness of the appeals process through all available channels, including presentations at stakeholder events and conferences, in line with the Work Programme 2015. Its decisions also continue to assist the Agency to refine its operations and interpret the legislation as well as the roles and responsibilities of the various actors in the REACH regulatory framework. They have also assisted the EU institutions and stakeholders in their considerations regarding regulatory changes and developments. Finally, appeals have continued to function as a 'safety net', allowing the Agency to ensure that its decisions are of a consistently high quality.

2. Objectives and indicators

Objectives

1. High-quality decisions adopted by the BoA without undue delay.
2. Efficient management of the appeals process and related communications.

Performance indicators and targets

Indicator	Target in 2015	Result in 2015
Percentage of final decisions made within 90 working days of the closure of the written or oral procedure.	90%	93%

3. Main outputs

- 15 final decisions adopted and published online
- 20 procedural (intervention and confidentiality) decisions adopted
- Appeal announcements and summaries of final decisions are published online

2.3. Communications (Activity 10)

ECHA's communications activities are inherent in the work of an independent EU agency. They provide the vehicle for informing the Agency's audiences on the way in which ECHA fulfils its duties, for preserving the Agency's corporate identity and public reputation and for enabling its interaction with stakeholders. The ECHA website explains the Agency's regulatory processes, promulgates guidance and support to duty holders, provides the platform for disseminating information on chemical substances, and provides information on the aims of the legislation and the progress in its implementation to the general public. ECHA's internal communications inform and engage staff, thus contributing to the effectiveness of the Agency's work.

1. Main achievements in 2015

The Agency succeeded in reaching out to more organisations than ever before – raising the number of regular news readers from 17 000 to 19 000, regular website users from 1 500 000 to 1 900 000 and accredited stakeholders from 85 to 94. A particular feature of 2015 was the focus on smaller companies, and those new to the chemicals legislation. New products and online content were produced, in collaboration with accredited stakeholders, HelpNet correspondents and European Enterprise Network (EEN) advisors, which have been well received by companies, sectoral bodies and member state competent authorities.

A significant part of that outreach effort was also the reworking of online content and advice for companies preparing to register ahead of the REACH 2018 deadline. Material for the first two of the seven phases for a successful registration were launched in 2015, each accompanied by multi-layered online content, webinars and publicity. This work was done with the active support of a communicators' network comprising Member States and accredited stakeholders.

Similarly, awareness raising activities ahead of the 1 June CLP deadline for mixtures and the Biocides Article 95 deadline on 1 September helped to make sure that companies met their responsibilities. In this context ECHA organized specific webinars, web content, Newsletter articles, presentations, briefings for Accredited Stakeholders, press releases and news items

ECHA further developed its social media activities to reach out to individual citizens - increasing the number of followers during 2015 by 63% on Facebook, 55% on Twitter and 81% on LinkedIn. The two Stakeholders' Days were our most successful ever, with satisfaction rates of up to 94%, and 86% of participants saying that they will return next year.

ECHA's transparency policy was enacted, resulting in new web content and new features on the website – for example, the ability to see all rulings of the European Court of Justice where ECHA is a party

On internal communication, one important milestone was achieved: the relaunch of the Agency's intranet site, including a revamped knowledge base with case studies on the benefits of REACH and CLP.

2. Objectives and indicators

Objectives

1. ECHA's external audiences are communicated with effectively, in 23[29] official EU languages where necessary and particularly with a view to the needs of SMEs, and ECHA benefits from an accurate and proportionate media presence.

2. Accredited stakeholder organisations are involved in ECHA's work and are satisfied that their views are heard and taken into account.

3. ECHA's staff are well informed, have a sense of belonging and feel part of a common corporate endeavour.

Performance indicators and targets

Indicator	Target in 2015	Result in 2015
Level of reader satisfaction with ECHA's written output, including language availability (website, e-News, Newsletter, Press Releases, News Alerts). This to be measured in terms of timeliness, content and usability.	High	High
Level of accredited stakeholder satisfaction with the information they receive and their engagement with ECHA.	High	High
Level of staff satisfaction with internal communications.	High	High

3. Main outputs

- 43 new publications produced. These ranged from 11 guidance documents to 22 manuals and practical guides targeted at companies and 10 publications with a more general audience in mind – for example the factsheet "Information on chemicals - What you can find in ECHA's databases" .
- 1050 pages of text available in 23 official EU languages so that smaller companies and citizens can use ECHA's material more freely – documents, web pages, publications, guidance documents etc.
- Coordinated communication activities for:
    - SMEs – launch of the Getting started web pages and an introductory guide, both in 23 languages.
    - Companies planning to register – ECHA published its REACH 2018 Roadmap at the beginning of 2015 and has communicated according to the plan. In the course of 2015 ECHA launched two "phases" of the roadmap with web pages in 23 languages, webinars and publicity. ECHA is supported in this by a communicators' network consisting of the Member States and industry to help spread the word on the support available for registrants.
    - Companies interested in substituting dangerous chemicals with safer ones – a joint project with accredited stakeholders involving new web content in 23 languages and a webinar which has been viewed by almost 800 people. The second webinar in the series will come in early 2016.
    - Downstream users – ECHA produced and published two simple animations

[29] Irish Gaelic not included.

for downstream users; a series of presentations to be used by external speakers; updated webpages in 23 languages; and a number of publications. These provided a basis for building a downstream user communications strategy for the coming years – so as to coordinate the Agency's communications with those of partners to raise the awareness of downstream users' about their roles and obligations.

  - Consumers – social media content throughout the year (around 70 Facebook posts).
  - Workers – a joint leaflet on the 2018 deadline produced together with EU-OSHA and worker representatives.

- Two Stakeholders Days held, with a total of 1 150 participants (online and in person) and satisfaction rates of 92% and 94%.
- One annual strategic workshop with accredited stakeholders held, with 40 participants and 93% satisfaction rates, focusing on ECHA's efficiency, alternatives to animal testing and a general orientation on reaching the worldwide goals for safer chemicals.
- 91 press releases, news alerts and new items published. 52 weekly e-News bulletins and 5 issues of the ECHA newsletter produced and daily press reviews for internal use distributed. According to the news readership survey conducted in 2015, 96% of the readers of the e-News and 95.81% of the readers of the ECHA Newsletter are satisfied with the product. Both these figures are a slight increase on 2014.
- 5 webinars produced with 5 539 recording views and a satisfaction rate of 69%. The webinars covered the first two phases of the REACH 2018 Roadmap: "knowing your portfolio, finding your co-registrants and preparing to work together". Other topics included "an update for downstream users", "why opt for substitution" and an introduction to the OECD QSAR Toolbox.
- Videos produced
  - Awareness raising: 1 produced for the general public on the gradual substitution of hazardous chemicals, "Painting a Safer Europe", with 4 500 views
  - Training: 16 produced for companies to enable them to use updated IT tools, clarify the roles and responsibilities of downstream users and to help companies with the Biocidal Product Regulation (BPR) with a total of 9 087 views
  - News: 7 produced with a total of 1 463 views

- 1 700 updates to ECHA's website.
- A bimonthly Stakeholder Update published for accredited stakeholder organisations with a satisfaction rate of 90%.
- 8 general visits to ECHA with a satisfaction rate of 96%.
- Information provided daily for staff on the intranet and internal information screens, internal events organised on a monthly basis.

2.4. International Cooperation (Activity 11)

Acting upon the request of the European Commission, ECHA's efforts in international cooperation focus on harmonising chemical management tools and approaches. The chemicals trade is global by nature, so this exchange with international partners benefits not only ECHA but also the European industry.

One of the Agency's main platforms for international cooperation is the OECD. This allows ECHA to monitor the current state-of-play in regulatory science, anticipate the changes in the international chemicals management regimes and to see that the objectives of the REACH, CLP, Biocidal Products and PIC regulations are considered in a global context.

The international cooperation gives ECHA a recognised role in the field of chemical safety management at global level, and gives the Agency an opportunity to share its learning with partners in other regulatory areas as well as to learn from them in the fields in which they are more advanced. The Agency's focus is on the development of harmonised tools for hazard and exposure assessment. The development of formats for data reporting and exchange and making available information on properties of chemicals online is also a priority.

1. Main achievements in 2015

In 2015 ECHA continued its key contribution to the OECD work on Harmonised templates that has resulted in the update of all hazard templates, new use and exposure templates, and a new template on intermediate effects. This work was done in collaboration with the Joint Research Centre of the European Commission. Work with the IUCLID expert panel has focused on the definition and testing of the new IUCLID 6 in several meetings throughout the year. In addition, a number of contacts with different national authorities took place to promote the new IUCLID 6, namely Korea, Australia, US, New Zealand, Germany, Switzerland, Israel, Turkey and Canada.

As for the OECD QSAR Toolbox, the development of the new version 4 continued. It will have a completely new interface which foresees more intuitive command blocks, shorter paths to some actions and automation of workflows, where possible. More and improved profilers will support the application of read-across to substances with data gaps. The inclusion of adverse outcome pathways (AOP) knowledge base is still under discussion. Illustrative examples on how to use the Toolbox were published for several endpoints such as skin sensitisation, short-term toxicity to fish, etc. with the aim of better supporting non-experts to use it for the last registration deadline. The usage of the QSAR Toolbox has continued to progress with more than 8,000 users, making it the reference tool for data gap filling. The work on the development of the tool and the preparation of support material and examples support ECHA's contribution to the promotion of non animal methods.

Finally, ECHA continued its key contribution by being responsible for the project management and funding of the further development and hosting of the OECD Global Portal to Information on Chemical Substances (eChemPortal). The eChemPortal version incorporating the GHS search was released in mid-2015. The first searchable data on classification and labelling was provided by ECHA and the Japanese government. With the addition of this data the database has raised strong interest, especially in the USA and China, as the usage of the portal has increased by 77% since then. The further promotion to the public and finding new participants is ongoing in close collaboration with the OECD Secretariat and the OECD Steering group. The eChemPortal application needs to be compatible with new and modified OHTs (i.e. submit and search for data from the new and amended templates), while at the same time not losing compatibility with notifications arriving in an old format. The technical work to achieve this is

underway in 2016.

ECHA's third IPA[30] project started in September. It supports the EU candidate countries and potential candidates in the Western Balkans and Turkey by familiarising the beneficiary authorities with the work of the Agency and the role of the Member States under the EU *acquis* in order to enable them to build up capacity to manage their largely transposed domestic legislation and ultimately to allow them to be fully operational by the date of their accession.

The technical dialogue with the peer agencies in Australia, Canada, Japan and the USA continued actively via a number of video conferences as well as mutual visits of experts for topical meetings. An ECHA visit to Tokyo intensified the cooperation with Japan and initiated the review of the rolling work plan for 2015-18. Similarly, the NICNAS[31] reforms increased the sharing of information on ECHA's operational experiences and IT tools with Australia. The cooperation with the peers helps ECHA to stay abreast of regulatory science and risk management work in these four countries as well as to benefit from their technical input.

2015 was a busy year in sharing technical information and lessons learned with third countries. The Agency had close to thirty meetings with peer agencies most of which were virtual. In addition, ECHA was visited by authorities from seven countries and our speakers addressed industry and authorities in person or via a web link in over twenty events that took place in EU's key trading partners. This awareness building enables on one hand the overseas suppliers to become aware of the requirements for REACH, CLP and BPR compliance so that they can support their European customers' compliance work and on the other hand, the third country authorities to take benefit of lessons learned in implementing these pieces of EU legislation in their own work.

2. Objectives and indicators

Objectives

1. The Commission receives high-quality scientific and technical support for its international activities, especially in multilateral bodies, and in particular, ECHA contributes to OECD activities related to chemicals with a view to promoting the harmonisation of approaches, formats and IT tools in order to increase synergies and avoid duplication of work whenever possible.

2. ECHA builds up and maintains its bilateral relations for scientific and technical cooperation with key third country regulatory agencies that are useful for the implementation of the REACH, CLP, Biocides and PIC regulations and supports the EU enlargement and neighbourhood policy initiatives effectively and efficiently.

Performance indicators and targets

Indicator	Target in 2015	Result in 2015
Level of satisfaction of the interested parties (including the Commission) with the Agency's international cooperation activities (including scientific	High	High

[30] Instrument for Pre-accession Assistance (IPA)
[31] National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

and administrative support to the Commission).		

3. Main outputs

- ITEM – the IUCLID Template Manager
- GHS based search implemented in eChemPortal
- Scientific and technical support provided to the European Commission in preparation of and participation in the two annual UN GHS meetings.
- A joint EU side event “The 2020 Goal: the EU contribution to international chemicals management” with the European Commission and EFSA as well as an ECHA stand on enhanced dissemination of information on chemicals at the fourth session of the UN’s International Conference on Chemicals Management (ICCM4).
- ECHA’s third IPA-project started in September and delivered three first capacity building activities for the EU candidate countries and potential candidates.
- Technical support was provided to the European Commission in relation to the TTIP pilot projects with the USA on C&L and prioritisation of substances.
- Continued cooperation, including discussions on regulatory updates, IT tools and technical topics such as QSAR, read-across and specific substances, with the peer agencies in Australia, Canada, Japan and the USA with whom ECHA has cooperation agreements.
- Sixteen delegations from Asia (6 from Korea), Americas, Israel and New Zealand visited ECHA.
- ECHA delivered presentations on the EU chemicals legislation in 26 events for third country audiences

3. Management, Organisation and Resources

3.1. Management (Activity 12)

The Agency strives to ensure a modern corporate identity and management that complies with the highest EU standards, so that it can efficiently integrate new activities to its organisation. ECHA is governed by a 36-member Management Board, which is assisted by a Secretariat provided by the Executive Director. On a day-to-day basis, the Executive Director is supported in his internal governance function by the senior management (directors) and the Executive Office. ECHA uses an activity and project-based management and quality system to organise its operations in a hierarchical or matrix structure. The management of information is balanced between openness and security principles.

1. Main achievements in 2015

As before, the Management Board, ECHA's governing body, convened on a quarterly basis. During these meetings, the Board discharged all its statutory obligations as foreseen in the applicable rules and regulations, in particular by setting priorities through the (annual and multi-annual) work programmes in the new single programming format, adopting or amending the budget, and monitoring and reporting on the Agency's achievements and performance. In June, the Management Board organised a workshop to start the preparation of ECHA's strategic programming for the time after 2018.

In 2015, the Agency further developed its contacts with Member States through Executive Director visits and by organising a meeting with MSCA Directors to further review and improve the joint planning of BPR, REACH and risk management-related tasks. Furthermore, as a regular member of the Network of EU Agencies, ECHA continued to actively support this work, in particular through the implementation of the Common Approach on decentralised agencies. The Agency received several high-level visits over the course of the year, for example, by a delegation from the European Parliament Committee for Environment, Public Health and Food Safety (ENVI). The Executive Director regularly met with Members of the European Parliament, especially ECHA's liaison MEP, and European Commission representatives. As regards the Commission, particular attention was paid to establishing good working relations with the new Commission and DG SANTE as new policy DG responsible for ECHA's BPR tasks. In June, ECHA organised a seminar on chemicals regulation in the European Parliament. The annual exchange of views with the ECHA Executive Director was organised in the ENVI Committee in October.

The main focus in the work of ECHA's SME Ambassador was to establish and manage an 'SME visits programme', in cooperation with relevant industry associations, which took place in autumn 2015.

During the year, in line with strategic objective 4, further attention was paid to strengthening the effectiveness and efficiency of the Agency through different means. The certification of the Integrated Quality Management System (IQMS) according to the International Organisation for Standardisation was upgraded to the most recent standard ISO 9001:2015 and was further extended by including the Agency's activities in relation to the PIC Regulation. The Agency finalised a feasibility study on the integration of a relevant environmental management system in its IQMS and decided to develop a Green Action that should lead to the ISO 14001 certification. Furthermore, ECHA continued its corporate-wide efficiency development programme which consolidated its continuous strive for improvement opportunities. Six different pilot projects under this programme were initiated or continued (Dossier Evaluation, Substance Evaluation, Procurement and Finance, Application for Authorisation, Processing of External requests, Planning

Monitoring and Reporting). In addition, audits and consultancies were further performed for specific processes and activities, providing concrete recommendations for further improvements. A risk-based approach was further implemented to avoid unnecessary controls. During ECHA's annual reviewing and reporting cycle, stakeholder feedback was incorporated in these improvement initiatives. Planning of the Agency's activities and resources was considerably re-engineered in light of the new programming document. A dedicated tool (i.e. Matrix) was selected as proof of concept to further the planning and reporting cycle. During the year, record management was further strengthened and refined ensuring retention and access of important information throughout all processes.

The Agency further refined its senior and middle management view on the future staff reductions announced for EU agencies. The decision to implement staff reductions of two percent of statutory posts a year until 2018 was taken forward and caused a significant re-orientation in the organisation. This was most visible in the merger of certain units (helpdesk and guidance units; Classification and RMM identification units), as well as in decreased staffing of multiple horizontal support activities (e.g. communications and IT services). ECHA will grow further into a lean public organisation with effective regulatory output implemented in the future planning of activities. Focus on continuous improvement was further enhanced through formulation of explicit change objectives.

During the year, the Agency further ensured compliance with relevant regulations and internal policies, procedures and instructions by performing assurance audits, implementing its Anti-Fraud strategy, efficiently managing the declarations of interest of staff, Management Board and Committee members as well as protecting the security of confidential personal and industry information with a high standard security system. A comprehensive business continuity and crisis management system was maintained.

As in previous years, the high numbers of decisions taken by the Agency gave rise to an increased demand for internal legal support for decision making. There has been an increase in the number of actions, appeals and court cases lodged against ECHA and the complexity of the issues rose in these actions. Each year these actions cause more legal defense work.

In 2015, ECHA received 93 initial applications submitted on the basis of Regulation (EC) No 1049/2001 on public access to documents. The number of documents and pages remained high. Since the requests mainly concern industry-owned data of a complex scientific nature, it required a work-intensive consultation and negotiation procedure. In addition, ECHA fulfilled its obligations in the field of personal data protection, following the advice of the European Data Protection Supervisor (EDPS) and of its own Data Protection Officer (DPO).

According to ECHA's Financial Regulation, the Internal Auditor for ECHA is the Internal Audit Service of the European Commission (IAS). The IAS performed an audit on "Forecasting, Calculation and Collection of Fee Income and Charges under REACH, CLP and BPR" in 2015. Based on the results of the audit, the IAS raised two very important and one important recommendation.

In line with the Quality and Internal Control Standards and considering the Agency's risk profile, the local "Internal Audit Capability" (IAC), as a permanent resource, provided the Executive Director with additional assurance and consulting activities. In 2015, the IAC carried out assurance audits on "Performance Indicators in the General report", "ECHA Helpdesk" and "Contract management and payments". Adequate action plans have been developed in response to the IAS's and IAC's recommendations.

2. Objectives and indicators

Objectives

1. The Agency is governed through efficient and effective management, which ensures the proper planning of activities, allocation of resources, assessment and management of risks, safety of staff and security of assets and information, and provides an assurance of the conformity and quality of outputs.

Performance indicators and targets

Indicator	Target in 2015	Result in 2015
Percentage of very important audit recommendations implemented within the deadline (IAS).	100 %	NA[32]

3. Main outputs

- Four Management Board meetings and 15 working groups meetings, as well as two written procedures, organised to allow the Board to take all necessary decisions and perform its statutory obligations.
- One meeting for Member States/MSCA directors organised.
- ISO 9001:2015 certification further extended towards ECHA's activities related to the PIC Regulation
- Feasibility study on the integration of a relevant environmental management system in its IQMS and decision to apply for the ISO 14001 certification
- Legal support provided for the drafting of ECHA decisions and for their effective defence. The Agency provided around 200 procedural documents for defending its decisions in proceedings at the European General Court, the Court of Justice and the Board of Appeal
- Efficiency project under implementation on 6 processes.
- The Data Protection register contained 100% of the processing operations involving personal data identified by the Data Protection Officer and all sensitive processes requiring prior checking were submitted for review to the European Data Protection Supervisor.
- One meeting of the Security Officers' Network was organised with emphasis on monitoring the IT Security Audit planning for national authorities
- On 93 initial "access to documents" requests, ECHA issued 52 decisions on initial applications, which covered 184 documents (~3 400 pages). Two confirmatory applications and one access to own file request were handled in accordance with the applicable legislation. In many cases ECHA successfully negotiated the scope and/or the deadline of requests. In many instances ECHA was able to close the case without issuing decision by providing additional information or links to already disseminated data.
- 2 meetings of the Conflicts of Interest Advisory Committee (CoIAC) were organised.
- Regulatory multi-annual and annual plans and reports produced
- 41 ECHA staff members visited 39 SMEs in twelve Member States, providing them and the Agency with valuable insights into current SME challenges and concerns; they thereby had the opportunity to express themselves to ECHA staff in their own language.

[32] There were no very important audit recommendations due in 2015.

3.2. Finance, Procurement and Accounting (Activity 13)

This activity covers the general financial management of the Agency, financial programming and reporting. It also includes overseeing and ensuring the correctness of the budget implementation operations as well as accounting and treasury operations. Finance unit coordinates and provides advice on the planning, launching, reporting and publication of the Agency's procurement activities. In addition, the Finance unit performs SME company size verification to ensure that only genuine SMEs benefit from reduced fees and charges under REACH/CLP and BPR regulations.

1. Main achievements in 2015

The revenue from ECHA's REACH/CLP activities in 2015 amounted to € 24.8 million, stemming from fees and charges collected under the REACH regulation as well as interest income from the reserve. The accumulated fee income reserve of € 87 million at the start of the year, together with fresh fee income, allowed ECHA still to fund its REACH activities fully through own income in 2015. As the fee income during the year was higher than planned and the expenditure lower than planned, the Agency did not need the € 7.8 million subsidy approved by the Budgetary Authority for the financial year 2015 and even managed to end the year with a reserve of € 8.8 million.

The revenue under the Biocidal Products Regulation amounted to € 11.5 million. This revenue included an EU contribution of € 5.8 million, Biocidal Fee revenue of € 5.4 million and an EFTA contribution of € 0.3 million (including Switzerland). The much higher revenue than planned will result in reimbursement of more than € 3 million of the subsidy.

ECHA received an EU contribution for the PIC Regulation totalling € 1.2 million in 2015.

The overall budget implementation at the Agency level exceeded the annual targets for commitments and payments. The breakdown between the different regulations was as follows:

The budget execution for REACH/CLP exceeded the 2015 internal targets for both commitment and payment execution. For Biocides, the execution of commitment appropriations and payment appropriations was lower than the targets set, mainly due to uncertainty and timing of the fee income, which delayed the possibility to engage in certain expenditure operations. The amounts guaranteed by the EU subsidy were fully committed, however. Also the Biocides staff costs were lower than originally foreseen, mainly due to the uncertainty linked to the number of staff posts available for the coming years, forcing ECHA to leave some of the foreseen posts unfilled in 2015. For PIC, the execution of commitment appropriations fell slightly short of the target, whereas the execution of payment appropriations was above target.

The Agency continued its systematic verification of the status of companies that had registered as SMEs and had consequently benefitted from SME reductions. The verification was completed on a total of 423 companies who had registered under the REACH/CLP regulation. As a result of this work, a total of € 2.25 million of fees and charges were collected during 2015. In addition, the ex-ante verification of company size was also completed for 17 companies under the Biocidal Products Regulation, which is not subject to charges.

In 2015, the Agency also further developed its processes and streamlined its financial workflows for improved efficiency.

2. Objectives and indicators

Objectives

1. The Agency ensures correct, sound and efficient management of its financial resources in line with applicable financial rules and regulations.
2. The correctness of the SME fee reductions claimed by registrants is assured.
3. The Agency has effective financial systems in place to manage and report on several financially segregated legal bases.

Performance indicators and targets

Indicator	Target in 2015	Result in 2015
Number of reservations in the annual report on financial and accounting issues of the European Court of Auditors (ECA).	0	0
Commitment rate (of commitment appropriations at the end of the year).	97%	98%
Payment rate (of payment appropriations at the end of the year).	80%	88%
Compliance with MB guidance on cash reserves (MB/62/2010 final).	100%	100%
Number of SME status checks completed on REACH registrants.	400	423
Carryover rate (% of committed funds carried over into 2016).	<20%	11%
Cancelled carryover payment appropriations from 2014.	<5%	5%

3. Main outputs

- Rigorous budget and liquidity management.
- Close monitoring and management of Agency's cash reserves.
- Segregated financial reporting under different regulations.
- 423 verifications of registrants' SME status completed for REACH registrants and 17 verifications completed for registrants under Biocidal Products Regulation.
- Follow-up and execution of the budget to reach the targeted commitment and payment rates.
- 739 contracts signed, out of which 540 contracts under framework contracts and 199 contracts as a result of new tendering procedures.
- Annual accounts for 2014 timely prepared with due diligence.

3.3. Human Resources and Corporate Services (Activity 14)

Human Resources activity covers Agency's staff planning and reporting on an organisational basis, including implementation of ECHA's selection and recruitment plans. It also includes the development and implementation of Implementing Rules and policies, in line with the revised Staff Regulations and taking account of ECHA's specific circumstances. Other key activities include the management of personnel and payroll administration, in line with applicable rules and regulations; the management of staff welfare and wellbeing actions; the management of performance appraisal, reclassification and related HR exercises

Corporate Services cover the management of ECHA's building and related facilities, coordination of ECHA's security, business continuity and crisis management activities and involves providing events/meetings logistical and secretarial support, the management of ECHA's travel management services and the coordination of postal and courier services and the purchase and maintenance of office supplies.

1. Main achievements in 2015

Human Resources (HR)

In 2015, the recruitment target of the Agency was achieved, with 98% of posts filled at the end of the year for REACH/CLP and PIC, whereas the percentage of posts filled for biocides was slightly below the target, at 83%, due to the uncertainties over the number of authorised posts for 2016 (which impacted on 2105 recruitment planning). Average turnover of temporary agents throughout the year remained low at 3.6% and for contract agents at 7.6%. The resources planning exercise is increasingly demanding due to the annual post cuts that ECHA faces and the continuous uncertainties on the biocides area.

In the learning and development area a new learning and development framework was implemented, and the evaluation of training activities has been emphasised. An ECHA Corporate Day for 500 staff members on change management was successfully organised. In the career development area, a streamlined, project-based internal mobility process was developed and the competency mapping process continued through the development of a managerial competency framework. In 2015 a staff engagement survey was conducted, attaining a response rate of 87% and indicating a 9% overall increase in ECHA's staff survey index since the previous survey (and representing an overall 29% increase since the initial survey in 2011). In accordance with international benchmarking data provided by the service provider (TNS Gallup), the current overall staff engagement score categorises ECHA as an organisation of 'strength' in this important area.

In 2015, the first two modules of a new IT tool, the HR Portal, have been rolled out to staff in the areas of benefits and personal information and time and leave management. The aim of the tool is to empower staff to better manage and reviewown data and improve the efficiency of the underlying processes. The HR services can now also retrieve the necessary data for well-informed decision-making more easily and comprehensively.

Preparations have been made to take over from the European Commission the decision-making related to entitlements of staff upon recruitment and during their service at the Agency, which will generate a saving.

A special audit on management of conflicts of interest in selected Agencies, including ECHA, was closed with a positive result for the Agency.

Corporate Services

The execution of the Refurbishment Plan by the landlord continued in 2015. Major works included the installation of new device to improve the efficiency of the building's heating system, maintenance of window sealing, upgrade of the kitchen equipment and refurbishment of the main elevator doors.

In order to save rental expenditure and increase space efficiency ECHA agreed with the landlord to give up part of the rented space as from the beginning of 2016. The necessary works to facilitate that release were undertaken by both the landlord and ECHA before the year end.

As part of ECHA's continuing efforts to ensure security in the premises, access to the inner-yard has been reinforced through the use of access keys. An open procedure was also completed for security services (effective from 1 January 2016).

The operation of the Conference Centre was reviewed and a decision to move from analogue to digital system was made. An open procedure was launched and work was initiated in December 2015. The web conferencing tools were further developed and, in 2015, c. 6000 persons attended virtual meetings while ECHA hosted 9 560 external meeting participants in its premises (an increase of 3% from 2014). In total, ECHA received a total of 12,708 external visitors.
Further improvements were introduced in the areas of missions and meetings management through streamlining procedures and updating of internal Handbooks. In addition, ECHA signed a contract with a new provider for its canteen and cafeteria services, following an open procedure.

In view of the expiry of the current lease contract on ECHA's existing building on 31 December 2019, a Building 2020 Project Team within Corporate Services was established to manage the process leading to a decision, scheduled to be taken in 2017, on ECHA's future building requirement. In this respect, an analysis of ECHA's current way of working and investigating options to improve it was initiated. A technical support was procured to define the Agency's specific technical building specifications. An initial market survey of the Finnish real estate market was also conducted to determine interest levels in the local market.

2. Objectives and indicators

Objectives

1. The Agency has a sufficient number of skilled staff to ensure the implementation of the Work Plan and offers staff a well-functioning work environment.

2. The Agency has sufficient, secure and safe office premises that provide an efficient and safe working environment for the staff, and well-functioning meeting facilities for the Agency bodies and external visitors.

Performance indicators and targets

Indicator	Target in 2015	Result in 2015
Percentage of REACH and PIC establishment plan posts filled at the end of the year.	95%	98%
Percentage of Biocides establishment plan posts filled	88%	83%

at the end of the year.		
Turnover of Temporary Agents.	<5%	3.6%
Turnover of Contract Agents (excluding short-term CAs).	<12.5%	7.6%
Level of satisfaction of the Committee, Forum, and MB members with the functioning of the conference centre.	High	High
Level of satisfaction of staff with the corporate services.	High	High

3. Main outputs

Human resources

- Payroll for statutory staff and other payments to staff, SNEs and trainees (numbering c. 550 persons).
- 15 selection procedures (8 TA and 7 CA procedures) were launched and 11 completed.
- 42 recruitments were completed, out of which 13 were new contracts.
- Performance appraisal and reclassification exercise (c. 532 statutory staff).
- Advice and assistance delivered to staff and management on Human Resources (HR) matters, in particular on individual rights and wellbeing.
- Staff survey conducted and action plan being implemented
- Active management of the people and performance management processes and methods, including implementation of new general implementing rules
- Adoption of General Implementing Rules, giving further effect to the application of the EU Staff Regulations and Conditions of Employment for Other Servants in specific areas
- Implementation of a competence mapping process related to the strategic objective three
- Directorate, Unit and individual learning needs collected and implemented

Corporate services

- Timely purchase of equipment, materials and services through appropriate procurement procedures
- Efficient travel services for staff and external meeting participants
- Timely calculations and reimbursements of travel expenses for staff and external meeting participants
- Secure and safe office and building facilities
- Conducted fire safety and security trainings
- Timely implementation of action plans for the future ECHA building
- Execution of refurbishment and maintenance plan
- Efficient reception services

- Well-functioning conference and meeting facilities with high-level administrative and technical support
- Efficient mail/courier services
- Up-to-date and correct inventory of non-IT assets.
- Separation works done in Lönnrotinkatu side and modified rent agreement

3.4. Information and Communication Technology (Activity 15)

The ICT processes in the Agency cover a wide range of projects and services to maintain and run the ICT infrastructure of the Agency and to operate all the IT systems used internally and externally. It also provides the IT systems to support a wide range of needs for the administration of the Agency.

1. Main achievements in 2015

The outsourcing roadmap was fully achieved in 2015. At the end of the year the entire portfolio originally in scope for the outsourced hosting services contract awarded at the end of 2011 was transitioned to the Outsourcer's service delivery responsibility.

ECHA launched a major initiative to radically change the provisioning of ICT infrastructure to its needs based on a private cloud model, replacing the end-of-life current platform.
A first feasibility study had been performed in 2014 concluding that the transition plan proposed bore excessive cost and impact, albeit confirming the suitability for ECHA of a transformation from asset based infrastructure (capital expenditure) to a service based model (operational expenditure) in which ECHA would relinquish ownership of hardware, licences and maintenance contracts.

In the first part of the year ECHA performed a new study to leverage the capabilities of the current outsourced hosting services contractor to migrate towards a cloud model at optimised transition cost and more limited impact. On successful completion of this study, ECHA started the transition project in September aiming at completing the as-is transition of all its servers by the end of the year. The solution chosen is based on dedicated infrastructure owned by the outsourcer and used by ECHA as a service, so called "enterprise private cloud".

Later in November, ECHA was informed by the contractor of serious delays in the project, due to errors made during the study and underestimation of the complexity of ECHA's infrastructure. However, after careful assessment of the situation, ECHA deemed the solution still adequate and cooperated intensively with the contractor to redress the project according to an updated plan, hardened with additional risk mitigation measures. A compensation package was negotiated with the contractor to minimise the additional costs incurred by ECHA because of the delay as well as the operational impact caused by extending the lifetime of the old, capacity constrained, infrastructure.

Although the project has been delayed, nevertheless the ground work has been done to enable the new infrastructure to come on line during 2016, and secure ECHA's IT for the foreseeable future.

WiFi network coverage was extended to all meeting rooms during 2015, enabling more flexible working methods. In the first part of the year a secure solution for staff teleworking was launched after an extensive awareness raising programme on security aspects of working off-premise. These two innovations in the IT facilities for the workplace have significantly spurred flexible working practices and has been enthusiastically received by the staff.

Working with interested parties across the agency and beyond a policy has been established whereby under certain conditions remote access to production data from outside ECHA's premises is permitted for IT service providers, thereby providing a secure platform for the new infrastructure and other initiatives during the year.

The Identity and Access Management service has been extended to support the management of external and industry users. The new generation of ECHA applications

developed in 2015 (e.g. Dissemination, NEA Portal Dashboard, Dynamic Case) benefit from the streamlined and more secure management of access rights based on user roles, while the upcoming applications expected in 2015 (e.g. REACH-IT 3, IUCLID6) can rely on this new capability.

After the definition of the requirements and objectives for the planning and monitoring process improvement project, a technical solution was selected amongst the available options and a pilot project was initiated.

The internal information management platform upgrade was completed with all the legacy applications upgraded to the new MS SharePoint version, achieving the objectives in terms of savings, security and information management best practices.

The Human Resources Management System (HRMS) delivered new modules improving the management of performance and career management, learning and development. The project also achieved to integrate the different systems used for time management into one single solution. This initiative should be finally completed with the upcoming release of the external recruitment site.

2. Objectives and indicators

Objectives

1. Supporting ECHA administrative processes and management reporting with the assistance of well-functioning IT systems. ECHA makes effective use of its information; documents and records received, generated and used by its staff are properly controlled.
2. The technical ICT infrastructure of the Agency is operated at a high level of service and continuity, efficiency and security is maximised for all supported business operations.
3. The IT Business Continuity Plan adequately covers ECHA's mission-critical systems and is adapted to the evolution of the ICT infrastructure.

Performance indicators and targets

Indicator	Target in 2015	Result in 2015
Availability of mission-critical systems for external customers (i.e. uptime during service hours).	On average 98%	99.4%
Level of internal and Member States' user satisfaction with IT services, relative to staff/ support ratio.	High	High

3. Main outputs

- The full outsourcing roadmap was achieved. A plan for the revision of the ICT Infrastructure has been prepared taking Business continuity and disaster recovery into consideration.
- Wifi network coverage has been extended to all meeting rooms at ECHA's premises.

- Secure teleworking for staff was rolled out.
- A solution was identified for the planning and monitoring process improvement project and a pilot project based on the reuse of a solution developed in another EU Institution was initiated.
- The internal information management system is fully implemented and support ECHA's information management standards (e.g. filing plan, classification and handling of information, records management).
- The unified and centralised access management model supports internal and external users and streamlines the access to the new generation of IT systems that are being progressively released.
- The annual physical inventory exercise of IT assets was successfully concluded, with positive results, and a negligible number of un-locatable devices identified. No recycling took place during 2015.

4. Agency Risks

ECHA conducts an annual risk assessment exercise to identify, assess and manage the potential events that could put the achievement of the objectives defined in the annual Work Programme at risk. The exercise is an integral part of the Work Programme preparation. The senior management follows up the implementation and reviews the effectiveness of the risk mitigation measures on a quarterly basis.

Based on this assessment, ECHA's management identified seven main risks relating to the Work Programme 2015. The senior management had also agreed that all these risks should be reduced through specific actions that were described in the action plan relating to the Risk Register.

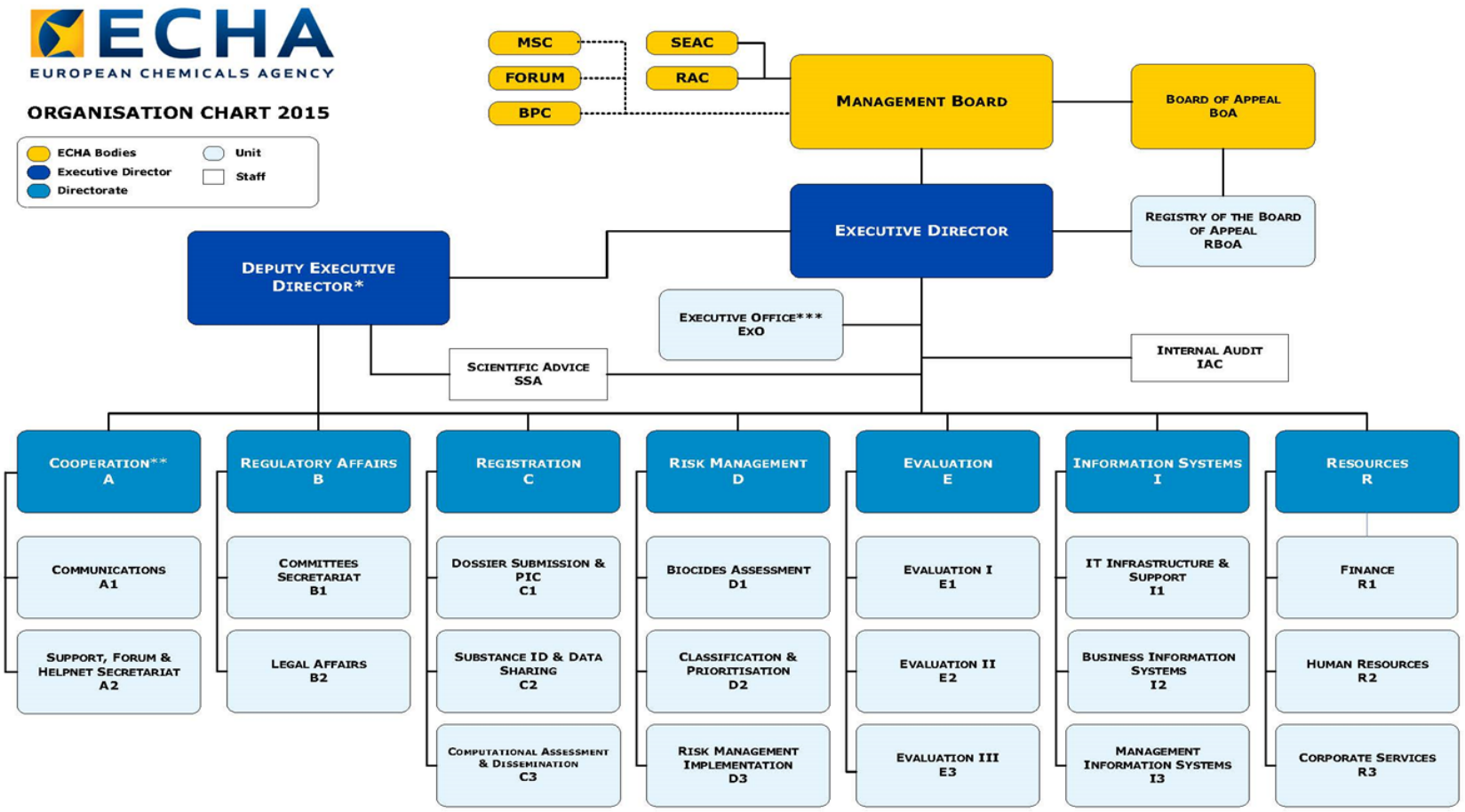
Regular follow-up of the actions was undertaken during the year. In the last follow-up done in the beginning of 2016, the Management concluded that the actions taken to mitigate the risks had been implemented according to the plan, had proved to be cost-effective and had not led to major secondary risks.

A number of risks that were identified for the year 2015 did not impact the Work Programme execution due to change in the external factors rendering the risk likelihood lower, however they continue to be relevant for Work programme 2016:

- Due to the higher income received than foreseen for 2015, ECHA was able to fully cover its expenditure and prepared to return part of the collected EU subsidy, thus the financial risk did not materialize in 2015.
- Due to delay on behalf of the Commission in processing the 216 dossier evaluation draft decisions on reproductive toxicity, expected to create additional workload for ECHA, no resubmitted testing proposals were received by ECHA in 2015. The risk is taken into account in the workload planning of Work programme 2016.
- The market risk for the authorisation applications related to a potential peak of applications didn't impact the output targets for 2015. Nevertheless, actions and fall-back plans such as building a contingency and increasing the process efficiency, have been taken to prevent the occurrence or mitigate the impact as the peak will now happen in 2016. These measures will continue to be further implemented in 2016.
- A number of Biocides -related risks were identified for Work programme 2015 that could have negatively impacted the Review programme targets and the ability of ECHA to process applications within legal deadlines. Among the most important actions completed in order to mitigate those risks are the exchange with MSCA on their resources needs, creating guiding templates, supporting the quality of the assessment reports and using scenario planning to be able to respond to different market situations. As a result of those, no legal deadlines were missed and the target of the Review programme was almost met (46 out of the foreseen 50 opinions were adopted in 2015). The risks with regard to balancing the uncertain Biocides income with the resources needs have been tackled through scenario planning and fall-back plans, however these risks will still remain high for the coming years.
- Clear scope and contract management has been effective in view of handling the risk related to ECHA's commitment to launch the new dissemination portal in 2015 and has helped to avoid causing delays in implementation. Some secondary risks related to the change of the contractor at a time when a new release is foreseen have emerged and will be handled in 2016.

- The risk with regard to the general maintenance problems further worsening the air quality of the building have been handled through careful implementation of the agreed refurbishment plan with the landlord, with a result that major projects have been completed in 2015 without any serious disruption of ECHA's normal work process or worsening of the air quality. The options with regard to the future of the building are being analysed as part of the Building 2020 project.
- The changes in the compliance check following the new strategy lead to the selection of more complex dossiers requiring more resources to conclude. This was originally not identified as a risk in the Corporate risk register. During the year it became apparent that the implementation of the new strategy had an impact on the constant delivery of compliance check outputs. Nevertheless, ECHA adapted to the situation and took relevant risk-mitigation measures, so that the newly set target of 100 concluded compliance checks for such substances was achieved by the end of the year. More details are available under Section 1.2 (Evaluation).

ANNEX 1: ECHA Organisation 2015



* 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

Ver 2.0/2015

Members of the Management Board on 31 December 2015

Chair: Nina Cromnier

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 DIPANE	Latvia
Marija TERIOSINA	Lithuania
Paul RASQUÉ	Luxembourg
Edward XUEREB	Malta
Hans MEIJER	Netherlands
Lidia WASOWICZ	Poland
Ana Lilia MARTINS	Portugal
Luminiţa 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
Anne LAPERROUZE

Representatives appointed by the European Commission	
Antti PELTOMÄKI	Directorate General for Enterprise and Industry
Kestutis SADAUSKAS	Directorate General for Environment

Michael FLÜH	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
Henrik ERIKSEN	Norway

Members of the MSC - Member State Committee on 31 December 2015

Chair: Watze DE WOLF

Member	Nominating state
Helmut STESSEL	Austria
Kelly VANDERSTEEN	Belgium
Tsvetanka DIMCHEVA	Bulgaria
Dubravka Marija KREKOVIĆ	Croatia
Maria PALEOMILITOU	Cyprus
Pavlina KULHANKOVA	Czech Republic
Henrik TYLE	Denmark
Enda VESKIMÄE	Estonia
Susan LONDESBOROUGH	Finland
Sylvie DRUGEON	France
Helene FINDENEGG	Germany
Aglaia KOUTSODIMOU	Greece
Szilvia DEIM	Hungary
Majella COSGRAVE	Ireland
Pietro PISTOLESE	Italy
Sergejs GAIDUKOVS	Latvia
Lina DUNAUSKINE	Lithuania
Alex WAGENER	Luxembourg
Ingrid BUSUTTIL	Malta
Jan WIJMENGA	Netherlands
Linda REIERSON	Norway
Michal ANDRIJEWSKI	Poland
Inês ALMEIDA	Portugal
Mariana MIHALCEA UDREA	Romania
Peter RUSNAK	Slovakia
Tatjana HUMAR-JURIČ	Slovenia
Esther MARTÍN	Spain
Ivar LUNDBERGH	Sweden
Amanda COCKSHOTT	United Kingdom

Members of RAC - Committee for Risk Assessment on 31 December 2015

Chair: Tim BOWMER

Member	Nominating state
Christine HÖLZL	Austria
Sonja KAPELARI	Austria
Stephka CHANKOVA-PETROVA	Bulgaria
Veda Marija VARNAI	Croatia
Marian RUCKI	Czech Republic
Kostas ANDREOU	Cyprus
Andreas KALOGIROU	Cyprus
Lea Stine TOBIASSEN	Denmark
Peter Hammer SØRENSEN	Denmark
Urs SCHLÜTER	Estonia
Riitta LEINONEN	Finland
Tiina SANTONEN	Finland
Stéphanie COPIN	France
Elodie PASQUIER	France
Norbert RUPPRICH	Germany
Ralf STAHLMANN	Germany
Nikolaos SPETSERIS	Greece
Christina TSITSIMPIKOU	Greece
Anna BIRO	Hungary
Katalin GRUIZ	Hungary
Stine HUSA	Iceland
Brendan MURRAY	Ireland
Yvonne MULLOOLY	Ireland
Paola DI PROSPERO FANGHELLA	Italy
Pietro PARIS	Italy
Normunds KADIKIS	Latvia
Jolanta STASKO	Latvia
Lina DUNAUSKIENE	Lithuania
Žilvinas UŽOMECKAS	Lithuania
Ruth MOELLER	Luxembourg
Michael NEUMANN	Luxembourg
Betty HAKKERT	Netherlands
Marja PRONK	Netherlands
Christine BJØRGE	Norway
Boguslaw BARANSKI	Poland

Sławomir CZERCZAK	Poland
João CARVALHO	Portugal
Radu BRANISTEANU	Romania
Mihaela ILIE	Romania
Anja MENARD SRPČIČ	Slovenia
Agnes SCHULTE	Slovenia
Miguel SOGORB	Spain
Ignacio de la FLOR TEJERO	Spain
Anne-Lee GUSTAFSON	Sweden
Bert-Ove LUND	Sweden
Stephen DUNGEY	United Kingdom
Andrew SMITH	United Kingdom
Elena-Ruxandra CHIURTU	*n/a (Co-opted)*
Elzbieta JANKOWSKA	*n/a (Co-opted)*
Christine NORTHAGE	*n/a (Co-opted)*
Rudolf van der HAAR	*n/a (Co-opted)*
Susana VIEGAS	*n/a (Co-opted)*

Members of SEAC - Committee for Socio-economic Analysis on 31 December 2015

Chair: Tomas ÖBERG

Member	Nominating State
Simone FANKHAUSER	Austria
Georg KNOFLACH	Austria
Simon COGEN	Belgium
Catheline DANTINNE	Belgium
Elina Velinova STOYANOVA-LAZAROVA	Bulgaria
Silva KAJIĆ	Croatia
Georgios BOUSTRAS	Cyprus
Leandros NICOLAIDES	Cyprus
Jiri BENDL	Czech Republic
Martina PÍŠKOVÁ	Czech Republic
Lars FOCK	Denmark
Andreas LÜDEKE	Estonia
Johanna KIISKI	Finland
Jean-Marc BRIGNON	France
Karine FIORE-TARDIEU	France
Karen THIELE	Germany
Ionna ALEXANDROPOULOU	Greece
Alexandra MEXA	Greece
Endre SCHUCHTÁR	Hungary
Stefano CASTELLI	Italy
Silvia GRANDI	Italy
Ivars BERGS	Latvia
Jãnis LOČS	Latvia
Ilona GOLOVACIOVA	Lithuania
Tomas SMILGIUS	Lithuania
Richard LUIT	Netherlands
Cees LUTTIKHUIZEN	Netherlands
Thea Marcelia SLETTEN	Norway
Izabela RYDLEWSKA-LISZKOWSKA	Poland
João ALEXANDRE	Portugal
Robert CSERGO	Romania
Maria OLTEANU	Romania
Janez FURLAN	Slovenia

Karmen KRAJNC	Slovenia
Adolfo NARROS	Spain
Maria NORING	Sweden
Åsa THORS	Sweden
Gary DOUGHERTY	United Kingdom
Stavros GEORGIOU	United Kingdom
Lars DRAKE	*n/a (Co-opted)*
Philipp HENNIG	*n/a (Co-opted)*
Derrick JONES	*n/a (Co-opted)*

Members of BPC – Biocidal Products Committee on 31 December 2015

Chair: Erik VAN DE PLASSCHE

Member	Nominating State
Nina SPATNY	Austria
Boris VAN BERLO	Belgium
Ivana Vrhovac FILIPOVIC	Croatia
Andreas HADJIGEORGIOU	Cyprus
Tomáš VACEK	Czech Republic
Jørgen LARSEN	Denmark
Anu MERISTE	Estonia
Tiina TUUSA	Finland
Aurélie CHEZEAU	France
Stefanie JÄGER	Germany
Athanassios ZOUNOS	Greece
Klára Mária CZAKÓ	Hungary
John HARRISON	Ireland
Maristella RUBBIANI	Italy
Julija BROVKINA	Latvia
Saulius MAJUS	Lithuania
Jeff ZIGRAND	Luxembourg
Wayne GIORDMAINA	Malta
Corine KOMEN	Netherlands
Christian DONS	Norway
Barbara JAWORSKA-LUCZAK	Poland
Teresa BORGES	Portugal
Mihaela-Simona DRAGOIU	Romania
Denisa MIKOLASKOVA	Slovak Republic
Petra ČEBAŠEK	Slovenia
María Luisa GONZÁLEZ MÁRRQUEZ	Spain
Edda HAHLBECK	Sweden
Manuel RUSCONI	Switzerland
Michael COSTIGAN	United Kingdom

Members of the Forum for Exchange of Information on Enforcement on 31 December 2015

Chair: Szilvia DEIM

Member	
Eugen ANWANDER	Austria
Paul CUYPERS	Belgium
Elena ZIDAROVA	Bulgaria
Dubravka Marija KREKOVIC	Croatia
Tasoula KYPRIANIDOU-LEONTIDOU	Cyprus
Oldřich JAROLÍM	Czech Republic
Birte Nielsen BØRGLUM	Denmark
Aljona HONGA	Estonia
Marilla LAHTINEN	Finland
Anne-Catherine ALFANO	France
Katja VOM HOFE	Germany
Eleni FOUFA	Greece
Szilvia DEIM	Hungary
Appointment pending	Iceland
Sinead MCMICKAN	Ireland
Mariano ALESSI	Italy
Appointment pending	Latvia
Manfred FRICK	Liechtenstein
Otilija GRINCEVIČIŪTĖ	Lithuania
Kim ENGELS	Luxembourg
Dawn GRECH	Malta
Jos VAN DEN BERG	Netherlands
Gro HAGEN	Norway
Katarzyna KITAJEWSKA	Poland
Graca BRAVO	Portugal
Mihaela ALBULESCU	Romania
Dušan KOLESAR	Slovakia
Vesna NOVAK	Slovenia
Pablo SÁNCHEZ-PEÑA	Spain
Mats FORKMAN	Sweden
Mike POTTS	United Kingdom

ANNEX 2: Baseline numbers

Main drivers of ECHA activities	Estimate for 2015	Total in 2015	Actual %
Dossiers arriving			
Registration dossiers (including updates)	5 700	8243	145%
Confidentiality requests (new claims received)	240	173	72%
PPORD notifications (including requests for extension)	400	247	62%
Inquiries	1 400	1368	98%
Data sharing disputes	7	5	71%
Substances on the CoRAP to be evaluated in 2015 by Member States	55	48	87%
Testing proposals	60	24	40%
Restriction proposals (Annex XV)[33]	9	4	44%
Out of which restriction proposals developed by ECHA	3	0	0%
Proposals for identification as SVHC (Annex XV)	50	9	18%
Out of which developed by ECHA	5	1	20%
Authorisation applications	70	7	10%
Alternative name requests	150	38	25%
Proposals for harmonised classification and labelling (Annex VI of CLP Regulation)	60	55	92%
Access to data older than 12 years	350	394	113%
ECHA decisions			
Decisions on data sharing	7	4	57%
Decisions on completeness check (negative, i.e. rejections)	60	41	68%
Decisions on confidentiality requests (negative)	30	28	93%
Decisions on PPORD	50	40	80%
Revocations of registrations numbers	20	23	115%
Final decisions on dossier and substance evaluation			
testing proposals	180	194	108%
compliance checks	120	144	120%
substance evaluations	40	29	73%
Decisions on access to documents request	120	55	46%
Decisions on SME status (negative)	200	150	75%

[33] The actual number of SVHC dossiers arriving will depend on the number of RMO analyses concluded. ECHA will contribute, upon request by the Commission, to the preparation of up to five RMOs. Depending on the conclusions drawn this may as well lead to the development of up to five proposals for identification as SVHCs.

Main drivers of ECHA activities	Estimate for 2015	Total in 2015	Actual %
Others			
Appeals submitted	20	22	110%
Appeal decisions	15	15	100%
Draft CoRAP for substances subject to evaluation	1	1	100%
Dossier evaluation follow-up examinations	400	268	67%
Recommendations to the Commission for the Authorisation List	1	1	100%
Questions to be answered (REACH and CLP, as well as respective IT tools)	4 800	4 661	97%
MSC meetings	6	6	100%
RAC meetings	6	6	100%
SEAC meetings	5	4	80%
Forum meetings	3	3	100%
General enquiries by [phone or] email	600	607	101%
Press enquiries	500	385	77%
Press releases and News alerts	60	91	152%
Management Board meetings	4	4	100%
SME status checks	400	423	106%
Recruitment due to turnover	25	14	56%
Main drivers of Biocide & PIC activities			
Number of active substances to be assessed under the Review Programme	50	49	98%
Biocides inquiries	50	152	304%
Biocides Data sharing disputes	5	9	180%
Applications for new active substance approval	2	9	450%
Applications for renewal or review of active substances	3	7	233%
Applications for Union authorisation for biocidal products	12	11	92%
Applications for active substance suppliers (Article 95)	150	197	131%
Applications for technical equivalence	20	26	130%
Applications for chemical similarity	10	1	10%
Submissions to Member States	3 000	3631	121%
SME status checks	30	17	57%
Appeals	3	4	133%
BPC meetings	5	5	100%
BPC WG meetings	20	22	110%
PIC notifications	4 300	5460	127%

Main drivers of ECHA activities	Estimate for 2015	Total in 2015	Actual %
Questions to be answered (BPR, PIC Regulation, respective IT tools)	1 200	3109	259%
Recruitment due to turnover for Biocides and PIC	3	0	0%

ANNEX 3: Resources 2015

The numbering below refers to the WP 2015, not to the numbering in the budget	REACH						BIOCIDES					
	Staff Resources 2015				Budget 2015		Staff Resources 2015				Budget 2015[34]	
	AD	AST	CA	Total	Final available commitment appropriations	Committed	AD	AST	CA	Total	Final available commitment appropriations	Committed
Implementation of the Regulatory Processes (Operational activities)												
Activity 1: Registration, Data-sharing and Dissemination	40	8	11	59	10 002 094	9 914 274	1	1	2	4	578 064	535 542
Activity 2: Evaluation	71	10	2	83	14 937 112	14 809 868				0	0	0
Activity 3: Risk Management	39	5	4	48	8 216 830	8 144 024				0	0	0
Activity 4: Classification and Labelling	10	2	2	14	2 239 513	2 218 949				0	0	0
Activity 5: Advice and Assistance through Guidance and Helpdesk	14	4	2	20	3 360 604	3 324 893	4		1	5	765 080	696 485
Activity 6: IT Support to Operations	29	9	8	46	21 166 399	20 995 361	3	2	2	7	2 482 800	2 407 931
Activity 7: Scientific Activities and Technical Advice to EU Institutions and Bodies	7	2		9	1 631 687	1 615 156				0	0	0
ECHA's Bodies and Supporting Activities												
Activity 8: Committees and Forum	19	6	5	30	6 219 992	6 163 940	3	2		5	1 042 300	962 589
Activity 9: Board of Appeal	3	3	3	9	1 538 187	1 485 261			1	1	164 516	137 544
Activity 10: Communications	7	8	8	23	6 544 416	6 498 321			1	1	309 516	296 477
Activity 11: International Cooperation	4			4	794 761	788 886				0	0	0
Management, Organisation and Resources												
Activity 12: Management	26	16	6	48	8 835 830	8 640 300	1			1	335 866	260 368
Activities 13-15: Organisation and Resources	33	44	39	116	18 555 964	18 385 580	2	2	1	5	722 580	669 427
Activity 16: Biocides					0	0	16	2	1	19	2 745 805	2 543 824
Activity 17: PIC					0	0				0	0	0
Total	**302**	**117**	**90**	**509**	**104 043 390**	**102 984 814**	**30**	**9**	**9**	**48**	**9 146 527**	**8 510 186**
In establishment plan:	[430	98					48	10]				

[34] The reported amounts correspond to the current year appropriations for 2015 (Fund source C1)

	PIC						ECHA (Total)					
	Staff Resources 2015				Budget 2015		Staff Resources 2015				Budget 2015[35]	
The numbering below refers to the WP 2015, not to the numbering in the budget	AD	AST	CA	Total	Final available commitment appropriations	Committed	AD	AST	CA	Total	Final available commitment appropriations	Committed
Implementation of the Regulatory Processes (Operational activities)												
Activity 1: Registration, Data-sharing and Dissemination		2		2	112 456	106 417	41	11	13	65	10 692 615	10 556 233
Activity 2: Evaluation				0	0	0	71	10	2	83	14 937 112	14 809 868
Activity 3: Risk Management				0	0	0	39	5	4	48	8 216 830	8 144 024
Activity 4: Classification and Labelling				0	0	0	10	2	2	14	2 239 513	2 218 949
Activity 5: Advice and Assistance through Guidance and Helpdesk				0	0	0	18	4	3	25	4 125 684	4 021 378
Activity 6: IT Support to Operations		1		1	451 143	438 687	32	12	10	54	24 100 342	23 841 980
Activity 7: Scientific Activities and Technical Advice to EU Institutions and Bodies				0	0	0	7	2	0	9	1 631 687	1 615 156
ECHA's Bodies and Supporting Activities												
Activity 8: Committees and Forum				0	0	0	22	8	5	35	7 262 293	7 126 529
Activity 9: Board of Appeal				0	0	0	3	3	4	10	1 702 703	1 622 804
Activity 10: Communications				0	209 500	208 689	7	8	9	24	7 063 432	7 003 487
Activity 11: International Cooperation				0	0	0	4	0	0	4	794 761	788 886
Management, Organisation and Resources												
Activity 12: Management				0	0	0	27	16	6	49	9 171 696	8 900 668
Activities 13-15: Organisation and Resources		1		1	224 913	212 834	35	47	40	122	19 503 457	19 267 842
Activity 16: Biocides				0	0	0	16	2	1	19	2 745 805	2 543 824
Activity 17: PIC	1	1	1	3	224 913	212 834	1	1	1	3	224 913	212 834
Total	**1**	**5**	**1**	**7**	**1 222 924**	**1 179 461**	**333**	**131**	**100**	**564**	**114 412 841**	**112 674 462**
In establishment plan:	[6		1				484		109	593]		

[35] The reported amounts correspond to the current year appropriations for 2015 (Fund source C1)

ANNEX 4: Candidate List of substances of very high concern (SVHCs)

Substances added to the Candidate List in 2015

Substance name	EC number	CAS number	Date of inclusion on Candidate List	Reason for inclusion	Candidate List Decision	Submitted by
Nitrobenzene	202-716-0	98-95-3	17/12/2015	Toxic for reproduction (Article 57c)	ED/79/2015	Austria
1,3-propanesultone	214-317-9	1120-71-4	17/12/2015	Carcinogenic (Article 57a)	ED/79/2015	ECHA
2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	223-383-8	3864-99-1	17/12/2015	vPvB (Article 57 e)	ED/79/2015	Germany
2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	253-037-1	36437-37-3	17/12/2015	vPvB (Article 57 e)	ED/79/2015	Germany
Perfluorononan-1-oic-acid and its sodium and ammonium salts	-	-	17/12/2015	Toxic for reproduction (Article 57c); PBT (Article 57 d)	ED/79/2015	Sweden
1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters or mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)	-	-	15/06/2015	Toxic for reproduction (Article 57c)	ED/39/2015	Sweden
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] covering any of the individual stereoisomers of [1] and [2] or any combination thereof	-	-	15/06/2015	vPvB (Article 57 e)	ED/39/2015	Netherlands

ANNEX 5: Management Board Assessment of the Consolidated Annual Activity Report for 2015

MB/03/2016 FINAL
18/03/2016

ASSESSMENT OF THE CONSOLIDATED ANNUAL ACTIVITY REPORT OF THE AUTHORISING OFFICER FOR THE YEAR 2015

THE MANAGEMENT BOARD,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),

Having regard to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP),

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR),

Having regard to Regulation (EU) 649/2012 of the European Parliament and of the Council of 04 July 2012 concerning the Prior Information Consent on the export and import of hazardous chemicals (PIC),

Having regard to the Financial Regulation of the European Chemicals Agency (MB/WP/03/2014), and in particular Article 47 thereof (ECHA FR),

Having regard to the Work Programme of the European Chemicals Agency for the year 2015 adopted by the Management Board at its meeting of September 2014,

Having regard to the Consolidated Annual Activity Report of the Authorising Officer of the European Chemicals Agency for the year 2015 as submitted to the Board on 7 March 2016,

Having regard to the Commission Staff Working Document concerning the guidelines on key performance indicators (KPIs) for directors of EU decentralised agencies,

WHEREAS,

The Authorising Officer shall report to the Management Board on the performance of his duties in the form of a consolidated annual activity report, containing information on the implementation of the Agency's annual work programme in line with the Multi-Annual Work Programme, budget and staff resources, management and internal control systems, audits and the actions taken on those, budgetary and financial management, confirming that the information contained in the report presents a true and fair view except as otherwise specified in any reservations related to defined area of revenue and expenditure,

By no later than 1 July each year, the Management Board shall send to the Commission, Parliament, Council and the Court of Auditors an assessment of the consolidated annual activity report on the previous financial year. This assessment shall be included in the annual report of the Agency, in accordance with the provisions of REACH.

HAS ADOPTED THE FOLLOWING ASSESSMENT:

1. Welcomes the results presented in the Consolidated Annual Activity Report of the Authorising Officer as well as the high performance level achieved with regard to discharging the tasks under REACH and CLP. This is reflected in the fact that 40 performance targets were achieved, 14 exceeded and only 3 missed by a small margin, out of the total 58 performance targets[36] set in the Work Programme 2015. Satisfaction was high in all of the 21 areas measured which shows improvement compared to 2014, when there were 2 areas with medium satisfaction.
2. Appreciates ECHA's strategic and operational work performed in 2015 and, in particular, the achievements in:
    a. Starting the implementation of its strategic approach focussed on delivering operational and impactful regulatory work as a lean public organisation in line with its founding legislations, and demonstrating its added value to the European citizens.
    b. Managing external constraints, staff reductions and risks in an effective and efficient manner, thus producing higher regulatory output in terms of decisions and opinions compared to 2014.
    c. Refining the models and measuring ECHA's four strategic objectives; and demonstrating progress towards their achievement.
    d. Realising measurable savings in the first two projects under the Efficiency programme and starting the implementation of another four projects and a number of horizontal initiatives to be able to cope with staff reductions while facing increased workload.
    e. Starting the implementation of the first two phases of ECHA's 2018 REACH Roadmap by developing multi-lingual support material and submission tools accessible via dedicated webpages and webinars, focussing on the small and medium sized enterprise (SME) perspective.
    f. Creating a user-friendly dissemination portal 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 user-friendly manner.
    g. Implementing and meeting the target of the new compliance check strategy by delivering 107 new compliance checks on the high priority cases while introducing the new approach in selecting and prioritising dossiers, although the overall number of compliance checks concluded fell short by 17.
    h. Exceeding the annual targets for final decisions on dossier evaluations by concluding the examination of 194 testing proposals (target 180) and 144 compliance checks (target 120).
    i. Updating for the fourth time the Community rolling action plan for substance evaluation for the years 2015-2017, containing now 138 substances.
    j. Supporting an increasing number of Member States submitting proposals for regulatory risk management measures under the REACH or CLP as well as the percentage of these conclusions which received further follow-up through the various regulatory risk management processes.
    k. Successfully processing the applications for authorisations received in 2015 and engaging future applicants in 29 pre-submission information sessions.

[36] One not assessed

l. Finalising the sixth Annex XIV recommendation to the European Commission for inclusion of a further 15 priority substances in the Authorisation List and preparing the seventh recommendation.

m. Adding 7 Substances of Very High Concern (SVHCs) to the Candidate List bringing the total number of substances on the Candidate List to 168 by the end of the year.

n. Continuing the implementation of the SVHC 2020 Roadmap Implementation Plan and issuing the first annual report on the progress made so far.

o. Maintaining an up-to-date Classification & Labelling inventory with information on 130 000 distinct substances, of which 122 000 included in the publicly disseminated notifications.

p. Providing direct support to duty holders via the ECHA Helpdesk and in producing updated and new guidance documents for industry and engaging national helpdesks via the HelpNet in this effort.

q. Increasing significantly the number of opinions adopted by the Committees: 38 Risk Assessment Committee (RAC) opinions on harmonised classification and labelling dossiers[37], 5 RAC and 6 Socio-Economic Analysis Committee (SEAC) opinions on restriction proposals, 25 RAC and SEAC opinions on applications for authorisation and 49 Biocidal Products Committee (BPC) opinions on approval of new or existing active substances.

r. Further supporting SMEs by direct interactions of 41 staff members visiting 39 SMEs in 12 Member States, promoting the multilingual communication and improving understanding to meet the current SME challenges. In addition, including actions targeting SMEs under the Chemical Safety Assessment (CSA) programme, helping them to evaluate the impact of REACH on their business and comply with their regulatory obligations.

s. Handling a higher number of applications made under the Biocides Regulation than originally estimated: in particular issuing 159 decisions on applications for inclusion in the active substance and suppliers list (Art 95), 21 decisions on technical equivalence, and handling 11 applications and 23 pre-submissions for the Union Authorisation.

t. Providing support to industry and Member State Competent Authorities on the biocides processes, including further development of guidance and dedicated IT tools.

u. Achieving cruising speed in the PIC activity taken over from the European Commission in 2014, by handling 5383 export notifications[38] in a timely manner.

v. Complying with the new ISO 9001:2015 Quality Management Standard and including also the PIC processes.

w. Achieving a high rate of budget execution of commitment appropriations - 98% for all Regulations, and filling 98% of the establishment plan posts for temporary agents for REACH, CLP and PIC Regulations.

3. Congratulates the Agency on reducing its carry-over rate to 11% on the average for all Regulations and encourages the Agency to continue its efforts to reduce the carry-over where possible. Notes the relatively high rate (5%) of cancelled payment appropriations carried over from 2014.

4. Welcomes the Agency's integrated regulatory strategy, and the further strengthening of its processes aiming to increase the effectiveness and coherence of all operations of

[37] Covering 14 industrial substances, 11 biocides, 12 pesticides and 1both biocide and pesticide

[38] All received notifications (5460) covered 1591 industrial substances, 3168 pesticides and 701 substances with dual use as industrial chemicals and pesticides

ECHA and its partners and thus to ensure improved dossier compliance and safe use of substances.

5. Welcomes the new internal decision on risk management, the effectiveness of the corporate risk mitigation measures, as well as the progress in implementing the cost-risk-benefit concept at process level in view of eliminating multiple controls and ensuring both effectiveness and efficiency of the internal control systems in line with Article 30 of ECHA FR.
6. Welcomes the ex-ante and ex-post evaluation framework and approach as adopted by the Management Board in December 2015, in compliance to ECHA Financial Regulation and Commission's Better Regulation Guidelines.
7. Welcomes the Agency's continuing work to support the access of Member State authorities to ECHA's systems, as well as the secure use of the information in these systems.
8. Welcomes the work of the Secretariat in ensuring and improving the functioning of ECHA Committees, and especially in supporting RAC and SEAC in preparation for the peak in workload on authorisations commencing in November 2015 and expected to continue through 2016 well into 2017.
9. Welcomes the work of the Member States Committee (MSC) in reaching 99% of unanimous agreement of the draft compliance checks and testing proposals decisions, as well as the work of Forum on the enforcement of the provisions of REACH, CLP and PIC Regulations with three major projects (REACH-EN-FORCE projects in planning, execution or reporting) and four smaller scale pilot projects.
10. Welcomes that the appeal system, with 15 final decisions adopted and published in 2015, provides effective and efficient legal redress to companies under REACH and BPR.
11. Welcomes that during 2015, a staff survey was conducted with a 9% increase in staff satisfaction reported, bringing the level to a strong organisation, and a corporate action plan was developed.
12. Welcomes that ECHA has taken action on the recommendations of the Management Board in last year's assessment of the annual report:
    a. All 'very important' audit recommendations were followed up as high priority by ECHA's Management.
    b. Diverse actions have been implemented in 2015 to promote the multi-lingual communication and support towards SMEs.
    c. The Agency has been promoting competitiveness and innovation in 2015 by using the tools it has within its remit in the areas of PPORD inquiry, authorisation, substitution and guidance.
    d. In 2015, ECHA, through the ENES network, provided industry with high quality scientific and technical support under the CSA programme.
    e. In 2015, ECHA continued measuring the four indicators towards the progress of dossier quality (Strategic Objective number 1). The indicators show improvement in the quality of data compared to 2014.
    f. In preparation for the Workshop on REACH 2020 goals which took place in January 2016, ECHA took a number of actions in the area of dissemination, risk management, evaluation and international cooperation in order to contribute to achieving the 'WSSD 2020 goals'.
    g. In 2015, ECHA has continued to provide support to its Committees and to the Member State Competent Authorities in the implementation of their tasks in multiple areas such as authorisation, restrictions and Biocides.

h. The implementation of the efficiency programme has been a priority for the Management for the year 2015. Measurable improvements have been realised in important cross-organisational projects.

13. Notes the continued high quality of the scientific advice provided by the Agency, as acknowledged by high appreciation from stakeholders, in particular in relation to alternatives to animal testing (e.g. skin sensitisation, read across framework), chemical safety assessment, nanomaterials, Persistent, Bioaccumulative and Toxic substances, endocrine disruptors and aquatic and terrestrial ecotoxicity.
14. Notes the effectiveness and efficiency of ECHA's internal control systems, as well as the continuous efforts of the Agency to further increase the compliance with the requirements of ECHA's Integrated Management Standards.
15. Notes that the revenue from fees and charges under REACH, CLP and Biocides activities in 2015 amounted to 29 million euro thus significantly exceeding the forecasts. Notes with concern the difficulties of the Agency, in the absence of a financial reserve, to obtain additional subsidy in those years where the financial revenue will be lower than estimated.
16. Notes that the number of establishment plan posts for REACH and CLP reduced from 441 posts in 2014 to 430 posts in 2015.
17. Notes the concerns expressed by the European Parliament in its resolution of 25th November 2015 related to the opinions delivered in the context of an application for authorisation on DEHP.
18. Recommends that ECHA in 2016:
    a. Starts implementing its new integrated regulatory strategy in order to strengthen REACH and CLP in achieving the "WSSD 2020 goals" and reflects on the activities beyond 2020.
    b. Engages with its stakeholders to find the most optimal way to implement the recommendations that emerge from the Art. 117(2) report and cooperates with the European Commission in the upcoming review of the REACH regulation.
    c. Continues to provide dedicated SME services for substance suppliers and downstream users, based on relevant tools, guidance and multilingual communication.
    d. Draws lessons from concerns expressed by the European Parliament on some of the first opinions on Authorisation Applications and pro-actively reviews the opinion making process on Authorisations and Restrictions.
    e. Further improves the budget execution to achieve the target of cancelled carry-over payment appropriations from 2015 (maximum 5%) and implementation of commitment appropriations (at least 95%).
    f. Supports Member States and encourages them to take up their roles under the legislations and provide adequate resources and expertise.
    g. Proposes actions to industry, Member States and the Commission to arrive at more agreements on the self-classifications by industry of their hazardous substances.
    h. Takes firm actions to deal with the existing backlog of the SME verifications.
    i. Continues implementation of the efficiency programme.

For the Management Board

The Chair

Nina CROMNIER

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ECHA-16-A-02-EN - ED-AG-16-001-EN-N – ISBN: 978-92-9247-836-0 - ISSN: 1831-712X- doi: 10.2823/030467

Publications Office