ECHA
EUROPEAN CHEMICALS AGENCY

General Report 2014

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General Report 2014

Helsinki, March 2015
Doc: MB/04/2015 final adopted on 20.03.2015

Reference:
ISBN:
ISSN:
Publ. date:
Language: EN

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Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovakian, Slovenian, Spanish and Swedish

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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
DU	Downstream user
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	REACH and CLP Helpdesk Network
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
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 Building for the future"

Welcome to this report from ECHA on our activities in 2014 - the year of building for the future. I'm pleased to report that a great deal of very productive ground work has been done and I hope that you enjoy reading about it here. In this brief foreword, I want to highlight four tangible products which.

First of all, the work to prepare for the 2018 registration deadline. Although we don't yet have a clear picture of the numbers of companies, substances and dossiers involved in that last deadline, we do know that the numbers of all three will be much bigger than before. With that in mind, we have taken a radical look at all our registration processes, tools and support material and have embarked on thorough effort to simplify and clarify wherever we can. Now we have a clear plan to help inexperienced companies, called 'REACH 2018 Roadmap'. We're determined to make sure with the help of the national helpdesks that any company with the will to comply should be able to do so, no matter how small they may be.

Secondly, our approach to checking the compliance of registration dossiers has been reviewed based on the first years' experience. The 'new compliance check strategy' will make sure that we are targeting substances that matter most for human health and the environment.

Thirdly, we are continuing to lead the way towards the EU policy target of having all relevant substances of very high concern on the Candidate List for Authorisation by 2020. Together with the member state authorities, we are progressing through the substances of concern and gradually reaching a common view on the extent to which further risk management is needed. You can also now see on our website the substances being looked at or already under EU risk management.

Fourthly, we have produced our 'regulatory science strategy', which sets out our direction of travel in terms of promoting research and developing understanding in scientific areas that are of regulatory interest – like nanotechnology and endocrine disruption.

At the same time as building for the future, ECHA is also facing resource cuts, and so we are trying to progress in the most efficient and cost effective way that we can also on the two regulations which we have recently taken over. We have in particular started to work on agency-wide efficiency projects that build on the concept of lean management.

Finally, I would like to mention a significant development for us. Like many of your organisations, we have tried to build quality management into how we work. This effort culminated in receiving the ISO certification for our REACH and CLP processes.

I am convinced that we are now well equipped to face the challenges of our first strategic plan: we have prepared the way well; we are highly motivated to succeed; we have strong relations with our stakeholders, very supportive relationships with the member states and a productive co-operation with the European Commission and Parliament.

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 "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><td>Vision</td></tr>
<tr><td>ECHA aspires to become the world's leading regulatory authority on the safety of chemicals.</td></tr>
</table>

Highlights - Summary

ECHA initiated the pursuit of the four strategic objectives, as planned, by focusing on the re-assessment of the foundations of its operations and resources in dialogue with its stakeholders and its Management Board and agreeing on new strategies, roadmaps and efficiency improvements. Although the focus was less on output numbers in this starting year of the five-year strategic plan, based on the results from the measurements used for monitoring the progress, the year has seen progress in the achievement of each of the four strategic objectives (see results in the next chapter).

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

As far as the registration activity is concerned, 2014 was a regular year of REACH implementation, the number of updates having been, however, far more than expected. On dossier quality, ECHA's registration efforts, concentrated on improving the substance identification in the dossiers through a letter campaign, resulted in a large number of updates. Moreover, the substance identification checks were included in the Validation Assistant tool, which enables companies to check their dossier in one go both for completeness and for potential other commonly observed anomalies before sending their dossier to ECHA.

Based on extensive stakeholder consultation, ECHA created a roadmap for the last registration deadline in 2018 with plans to further enhance the IT tools, processes and company support, bearing the challenges of SMEs in mind especially.

The new REACH 2018 Registration web pages launched in autumn 2014 provide an example of this approach by presenting information according to seven steps to be taken by potential registrants as well as by providing it in three levels of complexity.

ECHA met its targets in dossier evaluation. More resources were devoted to the final decision-making on draft decisions issued in previous years as well as on the follow-up of evaluation decisions taken in past years to ensure compliance also with the help of national enforcement authorities. In parallel, ECHA developed and got endorsement on a new strategy for compliance check focused on the selection of substances of potential concern and on a more complete hazard, use and exposure assessment, and on its implementation for the period of 2015-2018.

The development of the revamped dissemination website, which is planned to be published in 2015, continued. The key aspects of the forthcoming website, such as the substance information cards and brief profiles were widely consulted and agreed with ECHA's stakeholders.

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

The implementation plan for 'The EU Roadmap for SVHC identification and implementation of REACH risk management measures to 2020' provided the basis for ECHA's work in the area of identifying candidate substances for further regulatory action. The work carried out in 2014 has laid a foundation for efficient and effective screening of the registration information allowing for the identification of candidate substances for further manual screening and potential regulatory intervention. The Risk Management Option Analysis (RMOA) has become a standard approach to enhance common understanding between authorities on the need for and type of further regulatory action. The interim target set out by the Commission to have 80 substances subject to an RMOA by the end of 2014 was met.

In total, 10 substances of very high concern were added to the Candidate List. ECHA provided the fifth recommendation for inclusion of priority substances in the Authorisation List to the Commission and developed its sixth recommendation using the agreed new prioritisation approach, which is based on the use of registration and other REACH/CLP data. ECHA started publishing substance-specific information on RMOAs on its website, including conclusions of the finalised analyses, which allow industry and other interested parties to monitor the roadmap implementation more closely.

ECHA published the second update to the Community rolling action plan covering 2014–2016 which contains 120 substances. The criteria set in 2011 for prioritising substances were considered still valid and aligned to the SVHC 2020 Roadmap. Alignment and harmonisation of the approaches used by the different evaluating Member States was achieved through ECHA advice and a workshop for all evaluating MSCAs and accredited stakeholders. The number of substance evaluation decisions has also increased which has also led to appeals.

In 2014, the application for authorisation process really took off. ECHA received 19 applications for authorisation covering 33 different uses for five different SVHCs included in the Authorisation List. RAC and SEAC adopted 21 joint opinions, which on average have taken seven months for the committees to agree on the draft opinions – substantially less than the 10 months stipulated in the REACH Regulation. Overall, given the novelty of the process and recognising that all parties are learning, the application for authorisation process worked well both in terms of quality and efficiency and delivers on the objectives set out by REACH.

ECHA worked on the preparation of two new restriction proposals, amongst others on the flame retardant Decabromodiphenylether, and delivered two review reports. RAC adopted five restriction opinions and SEAC four. ECHA, the Commission and Member States worked together in the Restriction Efficiency Task Force (RETF) and produced 57 recommendations to further improve the efficiency of the restriction process.

RAC adopted a total of 51 opinions on harmonised classification and labelling which is a sharp increase in comparison with previous years. The C&L Inventory database is refreshed on a regular basis with new and updated notifications. The database now contains over 6.1 million notifications covering about 125 000 distinct substances.

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

ECHA's Regulatory Science Strategy was finalised, and will be published in early 2015. It steers ECHA's regulatory science activities, for example, by setting priorities, by relying strongly on a demand driven approach serving operational needs, and by clarifying ECHA's role in interacting with research and development projects (such as under Horizon 2020). ECHA introduced the foundation for proactive scientific capacity building for its own staff by establishing an approach for systematic competence management.

ECHA's scientific work was pursued through contributions to OECD work (test guidelines, alternatives to animal testing), developing a Read-across Framework (RAAF) and nanomaterials.

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

ECHA took over support to the Review Programme of existing active substances from the Commission's Joint Research Centre and achieved a substantial speeding up of the assessments which materialised in the adoption of 34 opinions by the Biocidal Products Committee. ECHA also issued its first decisions on different types of applications, assisted duty holders in responding to a fast growing number of enquiries, improved the R4BP IT tool and issued further pieces of guidance. Overall, it should be noted that ECHA has carried out the biocides activities under severe budgetary and human resource restrictions. The much lower number of applications compared to what was originally anticipated has resulted in significantly lower than foreseen fee income which has put heavy financial constraints on the Agency.

The PIC operations were successfully handed over to ECHA in March 2014, allowing undisturbed processing of more than 5 000 PIC notifications. The new ePIC IT system was launched in September and the new guidance was published in December.

In order to increase efficiency of the Committees work, RAC and SEAC agreed on a streamlined working procedure for developing and agreeing authorisation and restriction opinions.

ECHA received an ISO 9001 certification for managing and performing the technical, scientific and administrative aspects of the implementation of the REACH and CLP regulations and developing supporting IT applications.

ECHA achieved its targets with regard to financial and human resources and explored how it can accommodate the 10% staff cut over 2014-2018 without seeing too negative effects on its strategic planning. The administrative IT systems were improved through the delivery of the Human Resources management system.

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 first results are presented below:

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

The action area – improving the quality of information in dossiers – is measured by four indicators covering four different parts of the dossier and diverse aspects of quality of information. The indicators should not be taken as absolute values for quality nor are they a direct measure for compliance with information requirements; they are rather measurements of certain anomalies or inconsistencies. However, the trend over time allows progress towards the achievement of Strategic Objective 1 to be monitored as well as indicating on which part of the dossiers specific actions should be taken.

Overall, the dossier quality has increased since 2010, i.e. new registrations or updates submitted in 2014 are of better quality than previous ones. The main improvements are observed in those areas impacted by ECHA's actions and are explained below:

- Substance identification: Compared to the 2013 baseline, the number of dossiers received in 2014 which did not present shortcomings has increased (from 71% to 78%), illustrating the impact of compliance check decisions, ECHA's 2014 letter campaign on this topic and other support actions running since 2010.
- Uses for substances registered as intermediate: The analysis of historical results clearly shows how the letter campaign targeting information on intermediate uses that took place in 2012 led to a major improvement not only on the dossiers targeted by the campaign but also on those submitted for the 2013 registration deadline or in 2014 which proved to be of sufficient quality (96% without inconsistencies).
- Hazard: This indicator shows the number of dossiers for which no deficiencies were identified in the IT-screening of the information submitted on physico-chemical, environmental and human health hazards. Although there is a steady improvement in this indicator, especially in the areas of concern targeted by the compliance check activity, it remains at a relatively low level (39% in 2014). This will be the focus for the near future in line with the ECHA strategy on compliance checks[1] and other actions discussed in the related workshop in 2014[2].

The fourth indicator, Classification, which shows the number of dossiers for which the registrants have adequately applied the harmonised classification for their substances, taking into account their detailed composition, has had a high steady value since 2010 (96% in 2014). It seems unnecessary to put resources in improving this indicator other than on specific concerns, such as dossiers for substances with potential carcinogenic, mutagenic or toxic to reproduction (CMR) properties[3].

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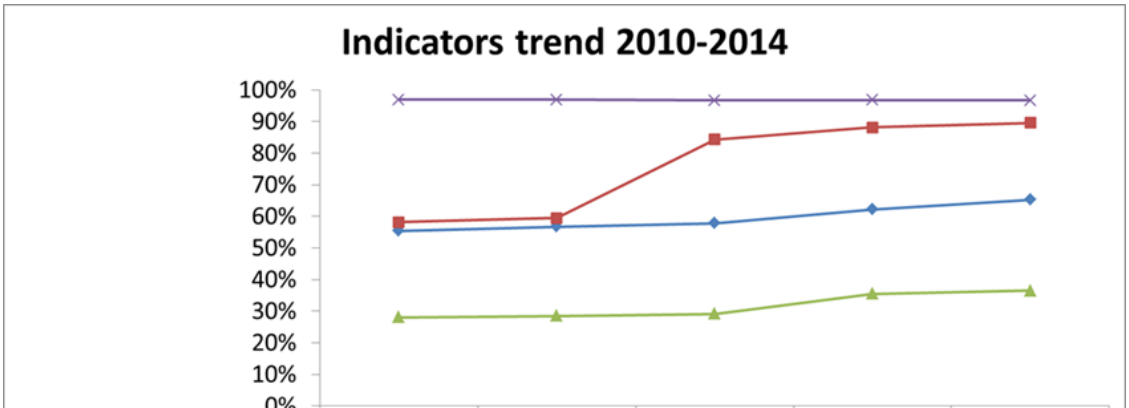
[1] http://echa.europa.eu/documents/10162/13608/echa_cch_strategy_en.pdf

[2] Proceedings of the CCH strategy workshop 31 March-1 April 2014: http://echa.europa.eu/documents/10162/13628/cch_workshop_en.pdf

[3] *Reference to the published CMR study*

Table 1 - Cumulative results for 2010-2014



	2010	2011	2012	2013	2014
Substance identification (~ 40 000 dossiers)	55%	57%	58%	62%	65%
Classification (~ 40 000 dossiers)	97%	97%	97%	97%	97%
Uses (~ 9 000 dossiers)	58%	60%	84%	88%	90%
Hazard (~ 4 500 dossiers)	28%	29%	29%	36%	37%

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

A set of indicators to measure the progress in the implementation of strategic objective 2 ("Mobilise authorities to use data intelligently to identify and address chemicals of concern") has been developed in close coordination with the progress monitoring indicators that will be used in the annual report on the substances of very high concern (SVHC) Roadmap. The indicators focus on three areas (1) substance screening; (2) substance evaluation; and (3) regulatory risk management.

With regard to screening, over 80% of substances that were picked up by the IT based mass-screening were found to require further follow-up actions. The intelligent use of the data stored by ECHA through an IT-based screening therefore appears to be a very viable way of identifying (potential) substances of concern and will be continued and where needed further optimised in the coming years. In total, 17 Member States and EEA countries participated in the manual screening in 2014.

It is too early to draw any conclusions on trends, effectiveness and efficiency regarding substance evaluation as there is only experience from two years and, for most of the substances, the process has not been completed. Data from 2012 and 2013 indicate a high percentage of substances for which further information is requested. Only in a small number of cases (four) no regulatory action was considered necessary. Nearly three quarters of the Member States are active on substance evaluation but last year's reduction in participation was a set-back.

Around one-third of Member States submitted proposals for regulatory risk management measures under the REACH or CLP which is still limited. The extent to which risk management options analysis (RMOA) conclusions receive follow-up is also low (17%) but this relates to the fact that for most substances these conclusions were drawn quite recently and therefore there has not been sufficient time to initiate the follow-up actions.

3. Address the scientific challenges by serving as a hub for scientific and

regulatory capacity building of the Member States, European institutions and other actors

The aim of strategic objective 3 is to 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 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 area – the milestones – are mentioned in the MAWP Annex. Their completion is key for the specified priority area as well as for ECHA's success in meeting the goals under this objective. Therefore, ECHA's corporate performance in relation to these milestones is measured. The overall implementation rate for the milestones in 2014 was high.

The Regulatory Science Strategy has successfully been developed and communicated inside and outside ECHA. The strategy identifies priority areas of practical relevance to the work of ECHA. The priority areas will be taken as a basis for the efforts on ECHA's internal capacity building and to steer R&D at a high level in the research community and in cooperation with DG Research of the Commission.

The development of a knowledge management framework followed by the start of competence mapping in ECHA have been successfully implemented in 2014. This will allow ECHA to start a systematic and regular assessment of identified competence gaps and identify, at ECHA-level, the necessary capacity-building actions and projects.

In order to be 'working as a hub' ECHA undertook the following actions: the topical scientific workshop on nanomaterials, the creation of a network on socio-economic analysis, the follow-up of the second report on alternatives for testing, the development of a read-across assessment framework and the review of bilateral international agreements. The purpose of these actions was either to take a particular topic in regulatory science further, to communicate about key (interim) results to relevant stakeholders or to establish the mode of cooperation and appropriate working methods for future exchange as such. External partners, who participated in these, expressed satisfaction with ECHA's initiatives and contributions.

In addition, questions related to ECHA's capacity to act as a hub of excellence in regulatory science were responded to by stakeholders in the 2014 stakeholder survey, with medium level satisfaction as the result. The responses showed that ECHA is assessed to be able to perform excellently, but needs to be more actively driving, quicker and visible: while stakeholders appreciate ECHA's efforts to arrange and contribute to relevant discussions of regulatory science, ECHA is proposed to assume a more driving role.

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

ECHA developed a composite score "Decisions and opinions equivalent" to measure the fourth strategic objective. It represents 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), as a proportion to the maximum annual staff capacity (including both operational and supporting personnel as well as consultants and operational interim personnel present over the whole year). The correlation between the 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 measurement with the data of 2011-2014 shows that the “Decisions and opinions equivalent” follows an increasing trend during the years thus showing a positive trend in efficiency (see the table below).

Table 2. Efficiency score

INDEX TREND	2011	2012	2013	2014
TOTAL WEIGHTED DECISIONS	15 852	18 738	24 323	25 873
TOTAL STAFF	541	558	592	621
Decisions equivalent (No. of weighted decisions/opinions divided by the maximum annual staff capacity)	39.1	44.8	54.8	55.6

% change	2012/2011	2013/2012	2014/2013
TOTAL WEIGHTED DECISIONS	18%	30%	6%
TOTAL STAFF	3%	6%	5%
Decisions equivalent (No. of weighted decisions/opinions divided by the maximum annual staff capacity)	14.6%	22.4%	1.4%

Operational output grows faster than the number of personnel employed by ECHA. It is normal that the improvement in 2014 is smaller than the one achieved in 2013, as 2013 was the time of the registration peak where the focus has been on producing outputs.

In 2014, in line with ECHA’s strategy to build solid foundations for each of the four strategic objectives, focus has been given on learning and development rather than on producing more outputs than in 2013. Still, the positive trend observed in previous years continues in 2014. The efficiency measures put in place through the efficiency development programme and the annual review cycle of all of the certified REACH/CLP processes will permit a stronger growth in 2015.

1. Implementation of the Regulatory Processes

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

Registration is one of the cornerstones of REACH, as it enables companies to demonstrate that they comply with the regulation and that the chemicals are safely manufactured and used. 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 on ECHA's website.

Due to the registration process, ECHA holds a unique database on chemicals, which can be efficiently utilised 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.

In 2014, these extended safety data sheets started to appear in the supply chain for substances registered by the second registration deadline of 2013. The practical experience steadily becoming available e.g. through the ECHA-Stakeholder Exchange Network on Exposure Scenarios (ENES), will enhance these new extended safety data sheets as well as those for substances registered in 2010. It is, therefore, crucial that the registration information at the top of this chain of communication is of adequate quality to ensure that the key objectives of REACH are achieved. In practice, this means that the information is compliant with the regulations, fit for purpose and easily accessible to all parties. For example, the authorities and downstream users, who receive the exposure scenarios as part of the chemical safety report or the safety data sheet respectively, are able to understand the uses that are covered and the conditions of safe use.

1. Main achievements in 2014

Registration and dossier submissions

Registration

In 2014, there was no registration deadline for phase-in substances, and it can thus be considered a regular year of REACH implementation as far as the registration activity is concerned. However, the number of updates was far more than expected, mostly due to ECHA's proactivity in enhancing the quality of the registration dossiers, especially in the substance identification area (see below).

ECHA received many more dossiers than expected, 30% of which were new registrations. In terms of substances, 391 substances were registered for the first time under REACH, of which 240 were non-phase-in substances. When scrutinising the registration activity of companies of different size, both for initial registrations and updates, the ratio of large, small and medium-sized (SME) companies stayed the same – 80/20 – as in 2013. Hence, there seems to be no increased SME activity yet for substances to be registered by the 2018 registration deadline.

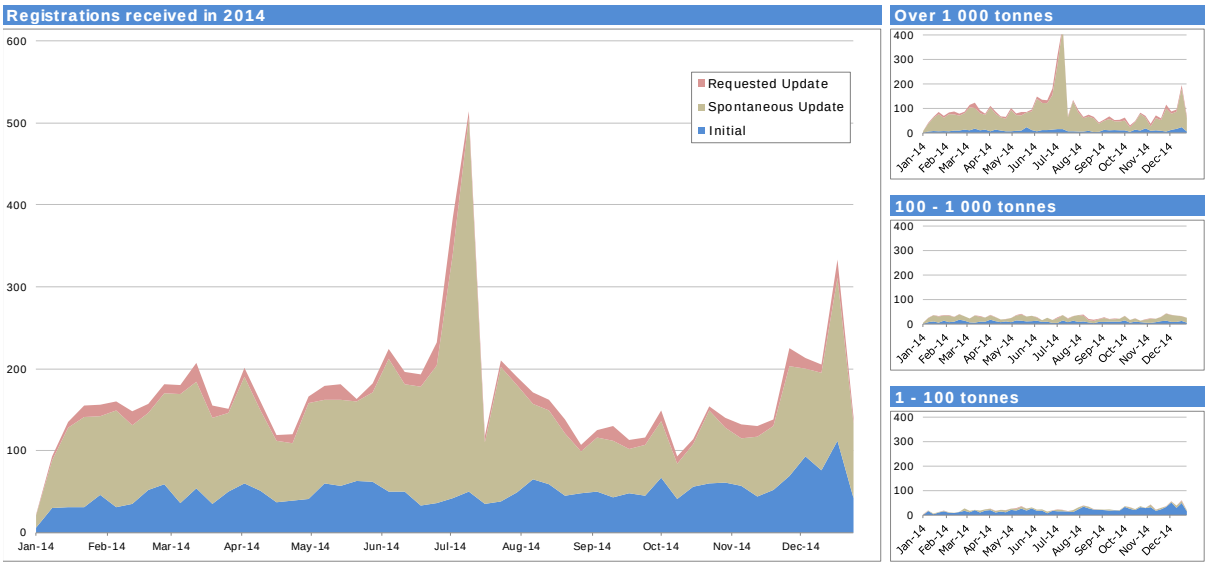


Figure 1. Registrations received in 2014.

The majority of the registrations received in 2014 were updates and mostly concerned phase-in substances. Of these updates, 91% were done spontaneously by the registrant, typically as a response to ECHA's letter campaign on substance identification (see Table 6 below). Nine percent of the updates were a response to a regulatory decision sent by ECHA, such as a dossier evaluation decision or a decision on a confidentiality request. The two main reasons for spontaneous updates as reported by the registrants themselves were i) updates further to ECHA letter campaign (35%) and ii) new or updated chemical safety reports (CSRs) and subsequent guidance on safe use (20%).

Croatian companies had a transitional registration deadline on 1 July 2014. ECHA supported them by means of dedicated workshops, specific web pages and translated material, as well as direct company support. By the deadline, 60 substances were registered by 10 Croatian companies.

ECHA's efforts to enhance the registration process focused on two main areas in 2014: on activities that increase dossier quality and on setting the basis for preparing for the 2018 registration deadline.

On dossier quality, ECHA's efforts concentrated on improving the substance identification in the dossiers. To achieve this, ECHA conducted a campaign where 1 350 letters were sent to registrants with observations on potential substance identification anomalies in their registration dossiers. As a result, substance identification in the targeted dossiers improved markedly as over 75% of the dossiers were updated by the end of the year.

As a matter of fact, the effects of the campaign reached much further than to the registrants who received the letter, as 800 additional dossiers not targeted by the campaign, were also updated when companies learnt about ECHA's activities through the other registrants or their associations. This translates into an improved efficiency in subsequent regulatory processes, as unambiguous substance identification is a pre-requisite for them. Certain dossiers, where substance identification anomalies were deemed to have a significant effect on safe use, were targeted for compliance check.

As further evidence on the impact of the letter campaigns, the first screening campaign of the registration dossiers for intermediates conducted in 2012 seems to have had a clear impact on the quality of those dossiers submitted for the 2013 deadline. The number of use description anomalies in registration dossiers for intermediates found in 2014 was so low that there was no need to redo the exercise.

Work done in screening and evaluation activities gives ECHA valuable information on how to better support companies so that they can themselves improve the quality of their dossiers. Similar to the intermediate uses check, the substance identification checks were included into the Validation Assistant which combines the former technical completeness check tool and the dossier quality assistant. The updated version of the tool was released in spring 2014. The advantage of this all-encompassing tool is that companies can check their dossier in one go both for completeness and for potential other commonly observed anomalies before sending their dossier to ECHA, thus gaining efficiency for both authorities and themselves.

Finally, ECHA's project plan on the revised technical completeness check rules was endorsed by the Member State competent authorities, and the technical implementation for inclusion in the International Uniform Chemical Information Database (IUCLID) 6 will take place in 2015. The feasibility of also conducting manual checks during the completeness check process, especially on the substance identification part, was analysed as planned, with a view to concluding the discussion in March 2015.

To pave the way for successful registration of substances manufactured or imported between 1-100 tonnes per year by the last registration deadline in May 2018, ECHA created a roadmap for its planned actions. ECHA plans to enhance the IT tools, processes and company support for the 2018 registrants in various ways in 2015-2018, bearing the challenges of SMEs especially in mind. The roadmap document went through extensive stakeholder consultation in order to make sure that the issues and solutions were correctly identified. As a first concrete outcome, ECHA published REACH 2018 web pages in October 2014, outlining the seven steps to successful REACH registration.

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 can assess them and impose conditions and, when a prolongation is requested, grant an extension to the exemption, in consultation with Member State competent authorities. In 2014, an efficient process for assessing the PPORD notifications was established and agreed with the Member State competent authorities by setting criteria and listing the relevant information required for both extensions and for imposing conditions.

In 2014, ECHA received close to 250 PPORD notifications. Almost 70% of them were for substances that have not yet been registered by any other company. Fine chemicals represented almost half of the notifications with substances that are used to manufacture pharmaceuticals and biopharmaceuticals (30%), and products for plant protection or other special agrochemicals (10%). Speciality chemicals represented about 40% of the notifications. The remaining notifications covered petrochemicals, oleochemicals and other energy sectors. By the end of 2014, ECHA had received registrations for almost 20% of substances which were notified as PPORD in the previous years. Finally, ECHA has noticed that the PPORD exemption is used by a relatively small number of companies in Europe (~350) which are typically large. Therefore, in 2014 ECHA invested in communicating on the PPORD exemption and in developing more SME-oriented support material (see Activity 5).

Biocide dossiers submission was markedly enhanced in 2014, both from an industry and an ECHA perspective, as new versions of the Register for Biocidal Products (R4BP) tool were published (see Activity 6). For submissions related to the PIC Regulation, a major milestone was reached on 2 September when the new submission tool ePIC was released, replacing the old European Database of Export and Import of Dangerous

Chemicals (EDEXIM) system. This enabled ECHA to successfully manage the end-of-year peak in notifications (see Activity 17).

Chemical Safety Assessment (CSA) Development Programme

The Exchange Network on Exposure Scenarios (ENES) continued as a well-established platform for developing and sharing ideas on best practice on exposure scenarios and their communication in the supply chain. The network is central in the implementation of the cross-stakeholder Chemical safety report/Exposure scenario (CSR/ES) Roadmap which sets the priorities agreed by ECHA and its stakeholders to improve the safe use of chemicals. The work progressed on several fronts in 2014.

In terms of supply chain communication, the publication of examples and templates by ECHA in 2014 was a major step towards improving the consistency of both the format and the structure of the exposure scenarios that are communicated to downstream users. ECHA also contributed strongly to the industry-led ESCom project which, by developing a catalogue of standard phrases for risk management, and an electronic format, will allow industry to communicate these phrases in their exposure scenarios in an automated and consistent manner. In addition, the e-Guide on receiving safety data sheets published by ECHA was a novel means to explain to downstream users, in an easily accessible format, the essentials of safety data sheets and exposure scenarios. The templates, harmonised phrases and the instructions on how to read exposure scenarios will greatly help end-users to understand the risk management information communicated by their suppliers and to ultimately put better risk management measures in place.

In addition, the methodology development for converting substance-related REACH information into advice on the safe use of mixtures continued throughout the year. Activities in the area of supply chain communication sought to integrate REACH downstream user activities and obligations with other legal requirements on occupational safety, health and the environment, as this approach is likely to be effective with users of chemicals.

In agreement with the CSR/ES Roadmap Coordination Group, ECHA also began work on improved use maps. With them, it is foreseen that downstream user sectors can provide clearer and more accurate input to the registrants' chemical safety assessments, which in turn will result in clearer and more practically useful advice on conditions of safe use provided by registrants. To further enhance the information submitted by the registrants to ECHA, in 2014 a major effort was put into developing an internationally agreed structure for reporting use and exposure information by having a new harmonised template endorsed at the Organisation for Economic Cooperation and Development (OECD). These structured fields will be implemented in IUCLID 6. Work was also initiated to enhance the transparency of the assessment information for complex cases in IUCLID.

To better support registrants to improve their chemical safety assessments, ECHA developed a plan to update the ECHA chemical safety assessment-related Guidance in 2014. The aim is to streamline the available support material and give more emphasis to risk management. The plan also includes generating more examples and templates to illustrate the different concepts.

Data sharing and substance identification

Ahead of registration, companies need to submit either an inquiry or a late pre-registration in order to get into contact with other potential and existing registrants so that they can share the data needed for registration. In 2014, inquiries came in as a

steady flow. Of them, 61% were initial inquiries and 39% were resubmissions as ECHA could not immediately identify which substance the inquiry was about due to missing or inconsistent data. However, the proportion of inquiries accepted on the first submission has continued to increase as companies are better at identifying their substances unambiguously. As a novelty, in addition to the normal process of providing industry with the data submitted more than 12 years before for inquiries for free, ECHA started to also do this for companies who asked the information for read-across purposes.

In total, the inquiries were submitted for 575 individual substances in 2014, mainly by large companies (80%) and in more than 50% of the cases for substances imported into the EU (30% of companies were importers and 23% only representatives). Over half of the inquiries submitted in 2014 were for non-phase-in substances, a portion that seems to be fluctuating around 50% over the years. When observing the trend over the years, it seems that two thirds of the inquiries lead to the registration of the substance in the end. The delay may be quite long, as for inquiries submitted in 2014 only around 50% were registered in the same year.

Data-sharing disputes arrived in small numbers as expected for a year with no registration deadline. Over the year, the data-sharing resources were targeted for developing support material for the 2018 deadline with the aim of clarifying the steps for successful data-sharing negotiations between the companies as much as possible. Specifically, ECHA published all data-sharing dispute decisions issued so far on its website to allow transparent scrutiny of them.

A significant amount of substance identification resources were channelled into the letter campaign targeting the substance identification information in registration dossiers and supporting evaluation and risk management processes (see Activities 2-4). However, efforts in the area of substance identification were also put into clarifying the substance sameness approach, where progress was made: ECHA's proposal was discussed in a workshop and it is currently being tested by various industry sectors in practice. In addition, ECHA contributed to the European Commission study on identification of UVCB substances, a project which is expected to be finalised in 2015 and give useful insight also into the substance sameness conclusions.

Dissemination – electronic public access to information

Dissemination of information from the registration dossiers has been a stable activity for quite some time. However, the median time from registration to dissemination has constantly improved and in 2014 it took on average only 26 days to publish information from a registration dossier. Improvement of the dissemination infrastructure has also enabled highly efficient publication of data for biocides. In 2014, typically within two days of an active substance product-type combination being tagged in the database as approved, or within two days of a product authorisation being indicated as granted in the database, the relevant information was published on the ECHA website. Publication of information from the ECHA dissemination website was linked to the OECD Global Portal to Information on Chemical Substances (eChemPortal).

2014 was also the year of development for the revamped dissemination website which is planned to be published in 2015. Several aspects of the forthcoming website, such as the substance information cards and brief profiles were widely consulted with ECHA's stakeholders. Specifically, ECHA held a workshop for Member State competent authorities, industry and NGO stakeholders on how to design useful and user-friendly access to substance information for the use of EU citizens. Based on the findings and recommendations from the workshop, ECHA is currently proceeding with the development of the brief profiles structure to be incorporated into the new dissemination website in 2015.

In parallel with the dissemination of a dossier, the confidentiality requests made by the registrants in their dossier must be assessed. The level of this activity was low for the 2013 deadline dossiers, so all requests introduced in 2013 (476 requests) were assessed. They concerned mostly the company name (26%), the company's tonnage band for the substance (25%) and the IUPAC name of the substance (21%). In 80% of cases, the request was accepted while further information was requested in 20% of cases leading to a final decision in 2015. Altogether, ECHA assessed 636 confidentiality requests, including 160 cases where further information supporting the requests had been requested from the registrant in 2013. Of those where further information was demanded, 41% of the requests were accepted based on the additional information, 43% were rejected (mostly confidentiality claims on the IUPAC name), and 16% were withdrawn by the registrant.

ECHA also verified all public names provided by companies when they claim the full name of a hazardous substance as confidential, ensuring that it still allows the hazardous properties of the substance to be deduced although the full chemical identity is masked.

2. Objectives and indicators

Objectives

1. All REACH, 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 & Labelling (C&L) notifications, as well as from biocides dossiers within a reasonable time after the registration/submission of notifications.

Performance indicators and targets

Indicator	Target in 2014	Result in 2014
Percentage of registrations, PPORD notifications, biocide applications and PIC notifications processed within the legal timeframe.	100%	100%
Percentage of inquiries concluded within the internal timeframe (20 working days).	80%	85%
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.	98%	100%
Level of satisfaction of interested parties with dossier submission and dissemination activities of ECHA, as	High	High

well as with ECHA's activities on improving the quality of CSRs and exposure scenarios for communication.		

3. Main outputs

Registration and dossiers submissions (see the tables below also)

- 48 decisions on PPORDs were taken.
- 2 094 biocides applications (applications for new active substances, renewals or review, Union authorisations of products) were processed and transmitted to the Member States.
- 4 678 PIC notifications were processed.
- The Roadmap for the 2018 registration deadline was endorsed by stakeholders.

Dossier quality

- The plan for upgrading the completeness check was drafted and presented to CARACAL and the ECHA Management Board.
- The upgrade of the Dossier Quality Assistant, and its integration into the Validation Assistant was published.
- The dossiers for substances registered as intermediates in 2013 were verified but the level of identified shortcomings was low and did not require action.
- The substance identification was checked in all registrations submitted since 2008 and a range of dossiers was prioritised for a letter campaign.
- A series of actions for addressing the quality of substance identification was planned as part of the review of the completeness check process and of the 2018 Roadmap.
- The framework of screening/prioritisation tools was put in place.

CSA programme

- Second CSR/ES Roadmap implementation plan published.
- Exposure scenario for communication: Illustrated examples and annotated templates published. Guidance on the development of structured short titles for Exposure Scenarios published.
- e-Guide on safety data sheets and exposure scenarios published.
- A proposal for structured CSR data was made as an OECD harmonised template, completed by certain items specific to REACH that will be implemented in IUCLID.
- Examples to illustrate how scaling can be implemented in CSR were developed and consulted with industry.
- A survey of downstream users (DUs) was undertaken regarding their experience with preparing DU chemical safety reports and this input informed the development of a Practical Guide on the DU CSR.

- A systematic approach for the compliance check of the chemical safety report submitted with the registration dossier was devised.

Substance identification and data sharing

- Approximately 1 500 new inquiries were processed within the target timeframe and, when accepted, given an inquiry number (see text).
- Five REACH data-sharing disputes were resolved.

Dissemination

- 456 confidentiality requests from 2013 underwent initial assessment.
- Information from the registration, the C&L Inventory and biocides dossiers was published on the ECHA website. Information from registration dossiers was linked to the OECD eChemPortal.

TABLE 3: NUMBER OF DOSSIERS (INCLUDING UPDATES) SUBMITTED (INPUT) IN 2014 AS COMPARED TO THE WORKLOAD ESTIMATES IN THE WORK PROGRAMME 2014

Dossier type	Actual	WP 2014 estimates
Registrations	9 001	5800
Full registrations	7 615	-
Transported Isolated Intermediates	990	-
Onsite Isolated Intermediates	396	-
Other types of dossiers		
PPORD notifications	234	300
Inquiries (including updates)	1 488	-

TABLE 4: DOSSIER TYPES OF NEW REGISTRATIONS IN 2014

	Total	Non-phase-in	Phase-in
Registrations	2 088	387	1 701
Transported Isolated Intermediates	515	163	352
Onsite Isolated Intermediates	135	63	72
Total	2 738	613	2 125

TABLE 5: COMPANY SIZES OF THE REGISTRANTS SUBMITTING NEW REGISTRATIONS IN 2014

Total	Large	Medium	Small	Micro
2 738	80.6%	10.3%	5.7%	3.4%

TABLE 6: DOSSIER TYPES OF REGISTRATION UPDATES IN 2014

	Total	Non-phase-in	Phase-in	NONS
Full registrations	5 657	262	5 099	296
Transported Isolated Intermediates	484	48	414	22
Onsite Isolated Intermediates	256	6	250	0
Total	6 397	316	5 763	318

TABLE 7: TYPES OF UPDATE OF REGISTRATION DOSSIERS UPDATED IN 2014

	Total	REACH	NONS
Updates following regulatory communication	510	474	36
Spontaneous updates	5 887	5 605	282
Total	6 397	6 079	318

TABLE 8: MAIN REASONS IDENTIFIED FOR SPONTANEOUS UPDATES IN 2014

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

1.2. Evaluation (Activity 2)

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

Substance evaluation aims to gather information in order to clarify whether a substance constitutes a concern for human health or the environment. Substance evaluations are performed by the Member State competent authorities (MSCAs) and involve an assessment of all available information and 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. Substance evaluation effectively bridges ECHA's strategic objective to improve the quality of the registration dossiers with another strategic objective, ensuring intelligent use of data for effective regulatory chemicals management.

1. Main achievements in 2014

Dossier evaluation

In 2014, the focus of dossier evaluation shifted from compliance check to testing proposal examination to ensure meeting the legal timeline (1 June 2016) for concluding on testing proposals from the 2013 registration deadline. ECHA concluded 228 examinations and exceeded its target regarding 2013 testing proposals.

Under compliance check, ECHA continued the enhanced computer-assisted selection of registration dossiers for targeted compliance checks on priority endpoints to address severe non-compliances in over 1 000 tonne per year and 100-1 000 tonne per year dossiers. ECHA also continued to examine the compliance of entire dossiers – based either on a random selection or using concern-based criteria. In selected cases, and when triggered by evidence of non-compliance, the check also included the chemical safety report (CSR). All in all, ECHA gained more experience on the compliance check of the CSR, and could get feedback from Member States in the decision making of related decisions. On this basis, a systematic approach for the compliance check of the chemical safety reports submitted with the registration dossier was developed based on the experience collected during the evaluation and decision-making phases, improving the effectiveness, efficiency and consistency of the evaluation of the CSR's.

ECHA had to devote important resources to the final decision-making on draft decisions issued in previous years. 70% of compliance check decisions were taken without proposals for amendments from the MSCA's. For the testing proposals, 53% were taken without referral to the Member State Committee (MSC) because the MSCAs did not propose amendments.

ECHA also conducted follow-up evaluations, examining whether the registrants had provided the information requested in ECHA's decisions. A slight increase in compliance compared to the previous year was observed.

In 2014, ECHA used its extensive experience of compliance checks to refine the overall approach, priorities and objectives for dossier evaluation. Based on an internal review and consultation of Member States' authorities, the Commission and stakeholders in a dedicated workshop and competent authorities meeting, ECHA developed an overall

strategy for compliance for the period 2015-2018. ECHA's revised approach to compliance check[4] was endorsed by ECHA's Management Board in September 2014 and will be implemented from 2015 onwards. According to the new approach ECHA will maximise the impact of compliance check on the safe use of chemicals, by improving the selection of substances of concern and by better coordinating different REACH and CLP measures to address these concerns effectively.

Despite the progress made in the planned amendment of the legal requirements on reproductive toxicity testing, Member State competent authorities and the Member State Committee continued to disagree on the appropriate test method. As a result, since 2011 up to 2014, altogether 33 draft decisions on compliance checks and 183 draft decisions on testing proposals have been referred to the Commission for decision making.

ECHA made progress in such scientifically complex topics as nanomaterials, integration of relevant new test methods in REACH information requirements and read-across assessment.

Substance evaluation

Community rolling action plan

ECHA published the second update to the Community rolling action plan covering 2014–2016 in March 2014. The CoRAP (2014-2016) contains 120 substances distributed among 20 Member States: 52 substances already included in the previous update and 68 newly allocated substances.

The preparation of the next CoRAP update (2015-2017) has been based for the first time on a common screening of registered substances serving and ensuring coordination among different REACH and CLP processes: substance evaluation, harmonised classification and labelling, authorisation and restriction. It also allowed the identification of candidate dossiers for compliance check. The common screening has been developed and implemented in collaboration with Member States and is further described under Activity 3. Besides the common screening, Member States could notify other substances of interest. The proposal for the CoRAP 2015–2017 update covers 143 substances. It was submitted to the Member States and the ECHA Member State Committee and published in October 2014 with a view to having the update of the CoRAP adopted in March 2015.

The criteria set in 2011 for prioritising substances were still considered valid and aligned to the SVHC 2020 Roadmap. The IT screening algorithms and scenarios were further refined in the common screening approach and in collaboration with Member States. The focus remained on potential persistent, bioaccumulative and toxic (PBT) properties, endocrine disruption, carcinogenicity, mutagenicity and reproductive toxicity, in combination with wide dispersive use, consumer exposure and high aggregated tonnage. The selection and allocation of CoRAP substances also took into consideration structural similarities in order to identify common concerns and ensure coordination among Member States in the evaluation of grouping approaches.

[4] http://echa.europa.eu/documents/10162/13608/echa_cch_strategy_en.pdf.

Substance evaluation process

In 2014, ECHA has managed the processing of evaluations started in 2012, 2013 and 2014, for a total of 134 substances.

Since the publication of the CoRAP update 2014-2016 in March, evaluating Member States started the evaluation of 51 new substances. For those substances, ECHA provided aggregated datasets on the dossiers to be evaluated, templates of outcome documents and revised instructions on performing substance evaluation.

In parallel, ECHA has managed the processing of evaluations started in 2012 and 2013. The decision making on most of the 2012 evaluations was completed. For the first time, one case could not find unanimous agreement in the Member State Committee and was referred to the Commission. Of the 47 substances evaluated during 2013, the evaluating Member States concluded that 38 of these required further information in order to clarify the suspected concern(s). As with previous years, ECHA offered to screen the Member States' draft decisions for consistency before they are officially submitted to the Agency, and almost all Member States used this possibility. As a measure to ensure consistent approaches in requesting further information, ECHA submitted proposals for amendments on the draft decisions prepared by evaluating Member States in 86% of the cases.

By the end of the year, final decisions were taken on 26 substances (24 finalised in 2014), out which six were appealed. For three substances, the requested information has been received and is now under evaluation. Conclusions of the evaluations were published for 13 substances (nine in 2014).

Alignment and harmonisation of the approaches used by the different evaluating Member States were achieved through ECHA advice and a workshop for all evaluating MSCAs and accredited stakeholders. Recommendations on the interaction between the evaluating Member States and registrants, as agreed in 2013, were published on ECHA's website. The workshop held in 2014 focused on the substance evaluation outcome documents and the interaction with the regulatory risk management process. Two working groups were formed to revise the templates and set best practice for the substance evaluation report and for the draft decisions. As a result, a new proposal for the substance evaluation report and conclusion document was submitted to Member States for commenting; it aims to reduce the workload for Member States while keeping transparency on the process outcomes and ensuring alignment with the risk management option analysis (RMOA) process.

Reporting

ECHA's Evaluation Report[5] was published by the end of February with recommendations to potential registrants in order to improve the quality of future registrations.

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 multi-annual planning steered by ECHA's strategic approach.

[5] REACH Art. 54.

2. All substance evaluations are planned in the CoRAP, 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.

3. The compliance with dossier and substance 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.

Performance indicators and targets

Indicator	Target in 2014	Result in 2014
Percentage of dossier and substance 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.	33%	45%
Percentage of compliance checks concluded to reach the 5% target for the dossiers submitted by 2013.	20%	20%
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%	82%
Level of satisfaction of MSCAs with ECHA's support for substance evaluation.	High	High

3. Main outputs

- 129 decisions on testing proposals and 273 decisions on compliance check processed in decision making and adopted.
- 283 new compliance checks concluded, leading to 172 new draft decisions.
- 228 testing proposal examinations concluded, of which 204 with a draft decision.
- 282 dossier evaluation follow-up evaluations.
- Annual evaluation report (Article 54) and related communications.
- Scientific, administrative and legal support to Member State competent authorities for their tasks on evaluation.
- Workshop on review of the compliance check strategy. The review of the strategy completed, new strategy endorsed.
- The second update of the CoRAP adopted on 26 March 2014. The third draft update, which includes 75 newly selected substances, submitted to Member State Committee in October.
- Final decisions on 24 substances requesting further information and nine conclusions under substance evaluation published.
- Consistency screening performed on 38 substance evaluation draft decisions.

- One workshop and two working groups organised in support of substance evaluation.

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 the authorisation applications. Substances of concern 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 the 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, together with Member States, implements common screening approaches for all REACH and CLP processes to identify the substances and uses which may require further information generation and/or regulatory risk management measures, and facilitates the risk management option analysis approach to choose the most appropriate combination of regulatory instruments. To increase predictability and transparency towards stakeholders, ECHA publishes generic and substance-specific information on the activities which precede actual regulatory risk management actions on its website.

1. Main achievements in 2014

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 November 2013, provides the basis for ECHA's work in identifying candidate substances for further regulatory action. The progress made so far will be published in the first annual report foreseen for March 2015.

In collaboration with Member States, ECHA further developed the common approach for screening to identify substances with certain hazards (human health, environment), exposure and ultimately risk profiles and process them using the most appropriate REACH or CLP processes: substance evaluation, harmonised classification and labelling, authorisation and restriction (see Figure below). This common screening approach is intended to ensure the swift progress of the screening activities, avoid duplication of work by different authorities and to minimise the risk of having the same substance being identified as a suitable candidate for different processes (unless there are valid reasons for that) and that parallel processing is done in a coordinated manner.

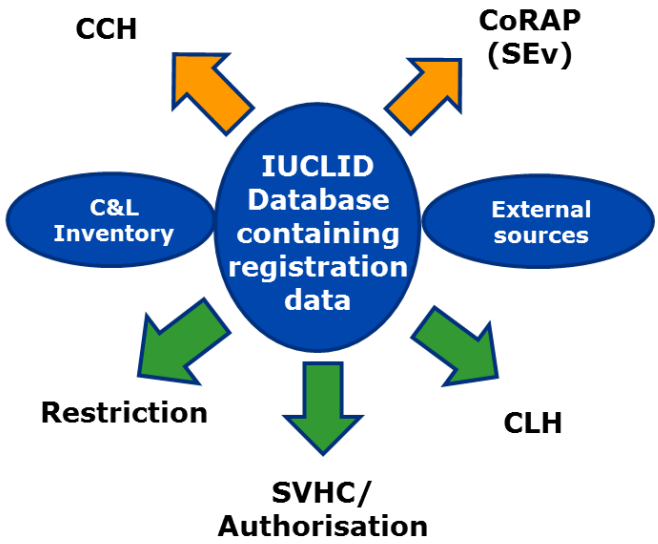


Figure 2. Common screening approach

To enhance a common view between authorities on which substances matter most and therefore need to be further addressed ECHA has set up coordination and expert groups to gather Member States' input to the screening. These groups also aim to make sure that the identified substances are duly processed further. To further support the integration of the different REACH and CLP processes, cooperation between authorities and to increase efficiency, ECHA has developed workflows, instructions and common templates as well as tools to share and record the screening and follow-up work.

Over the course of 2014, substantial effort has been spent by ECHA and the coordination and expert groups to define and further develop so-called mass screening scenarios that serve all REACH and CLP processes. Particular efforts were made to implement screening algorithms for finding substances that are structurally similar to known SVHCs (one of the supplementary activities of the SVHC Roadmap to 2020). ECHA's IT mass screening work provided authorities with substances identified as potential good candidates for the CoRAP and SVHC identification which were followed up by manual screening. In line with the new compliance check strategy, these methods were also used for the first time to identify dossiers requiring compliance checks under dossier evaluation.

ECHA continued to facilitate the coordination and cooperation between Member States in regulatory risk management activities. This includes support to the development, sharing and discussion on risk management option analyses (RMOAs) for identified substances. This coordination and cooperation work aims to enhance the common understanding and information exchange across the regulatory risk management activities and to increase efficiency and effectiveness of the practical work. To this end, ECHA organised three risk management expert meetings in cooperation with volunteering Member States.

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 currently supports ongoing assessments for around 100 substances, half of which are substance evaluation cases and the other half preliminary assessments which may lead to initiating evaluation and cases which do not require further information generation to conclude their PBT status. Furthermore, the group has concluded on 24 substances. The ED group started in 2014 and has commenced work on 14 substances, most of which (11) are substance evaluation cases.

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 substances that are positively identified which

increases the efficiency of the subsequent formal decision making.

With a view to widen the group of Member States actively participating in the SVHC Roadmap implementation, ECHA organised a workshop in January and supported a practical session for those Member States who wish to initiate their own RMOAs.

To increase the transparency on the roadmap implementation, ECHA started publishing substance-specific information on RMOAs on its website, including conclusions of the finalised analyses. At the end of 2014, the so-called public activities coordination tool (PACT) included RMOA information on 98 (groups of) substances. For 24, an RMOA conclusion is available and for the remaining 74 the RMOA work is ongoing. By this, the interim target set out by the Commission to have 80 substances subject to a RMOA by the end of 2014 has been met. PACT will be further complemented with substance specific information on PBT and ED assessments. Furthermore, further information on screening will be added to the roadmap web page.

Authorisation

Identification of SVHCs and Annex XIV recommendations

Based on proposals submitted by the Member States, 10 substances of very high concern were added to the Candidate List in June and December 2014. Three substances were identified because there is scientific evidence of probable serious effects on multiple organs after repeated exposure and two are PBT and vPvB (very persistent and very bioaccumulative) substances. Furthermore, one substance, DEHP, which was previously included in the Candidate List due to its toxicity to reproduction, was identified as also having endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment. By the end of 2014, the total number of SVHC substances included in the Candidate List was 161.

ECHA provided the fifth recommendation for inclusion of priority substances in the Authorisation List to the Commission in January. Inclusion of five substances from the Candidate List was recommended and suggestions for the application and sunset dates were made. To increase transparency and predictability a list containing the priority assessment for all substances in the Candidate List, i.e. also for those substances which are currently not recommended, is made available on the website. However, substances newly included in the Candidate List are not assessed for their priority to allow industry sufficient time to ensure that their registration information, in particular on uses and tonnages, is up to date.

ECHA developed its sixth recommendation using the agreed new prioritisation approach which is based on the use of registration and other REACH/CLP data. To address the concerns and wishes of industry stakeholders, ECHA decided to delay the start of the public consultation on the sixth recommendation, which now took place from September to November. As a consequence, the MSC opinion forming and finalisation of the sixth recommendation will take place in spring–summer 2015. This year, ECHA also facilitated the Commission's call for information on the possible socio-economic consequences of the inclusion of substances in Annex XIV. This call for information took place parallel to the public consultation on the draft recommendation. The information received was transferred to the Commission in early December.

Authorisation applications

In 2014, the authorisation application process picked up with an increasing workload. Overall, given that the process is new and all parties are learning, it worked well both in terms of quality and efficiency. 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, 14 PSISs were held in 2014. ECHA has continued to receive very positive feedback on the usefulness of these sessions.

In 2014, ECHA received 19 applications for authorisation covering five different substances[6]) and 33 different uses. ECHA successfully launched four public consultations to collect information on alternative substances or technologies.

In 2014, RAC and SEAC adopted final opinions for 30 uses in eleven applications. 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.

TABLE 9: Key data on applications for authorisation for 2012-2014

	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
Total	**186**	**24**	**27 (43)**	**55**	**31**	**35**	**2**

[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 April 2014. ECHA also participated in numerous conferences, workshops and webinars organised by industry, Member States or NGOs to clarify different aspects of the authorisation process. In addition, cooperation continued with the European Aviation Safety Agency and the European Space Agency to increase the mutual understanding of how authorisation might affect these sectors.

To clarify open issues, ECHA prepared and published 27 new questions and answers and one frequently asked question on its website. Up to now, ECHA has published 82 questions and answers and eight frequently asked questions in total. ECHA updated the application formats making the documentation of the Socio-economic Analysis more transparent to the public. It is now also possible to document the Analysis of Alternatives and Socio-economic Analysis jointly. These two improvements should increase the transparency and the efficiency of the application and opinion-making processes.

To improve the efficiency of RAC's work and to provide guidance for applicants in a transparent manner, RAC has derived dose-response relationships for the arsenic substances included in the Authorisation List. All this information is available on the dedicated support section on ECHA's website. Capacity building of ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC), which started in 2012 was continued in 2014. The first recommendations of the working group on how SEAC

[6] Lead sulfochromate yellow (C.I. Pigment Yellow 34), Lead chromate molybdate sulphate red (C.I. Pigment Red 104), Diarsenic trioxide, Hexabromocyclododecane (HBCDD) and Trichloroethylene.

could better analyse the costs and risk reduction relating to non-threshold substances, such as PBTs and vPvBs, were agreed in SEAC.

In 2014, ECHA actively contributed to the work of the Task Force on simplified approach for special cases by developing simplified formats for the chemical safety report, analysis of alternatives and socio-economic analysis. ECHA delivered the drafts of simplified "fit-for-purpose" application formats, which will be made public when the Commission consults on its policy for "low tonnage" special cases in early 2015.

Restrictions

Following several requests by the Commission, ECHA worked on the preparation of two new restriction proposals and delivered two review reports. Work was undertaken to prepare a proposal to extend the entry on cadmium in plastics, but this proposal was withdrawn (January 2014) due to the absence of sufficient information to demonstrate a risk that would justify an extension. The Annex XV restriction report on this analysis will be published on ECHA's website in 2015.

ECHA submitted its restriction dossier on chrysotile in January 2014, following restriction preparation work in 2013, and proposed several changes to the existing derogation of diaphragms (entry 6 of Annex XVII). In August 2014, ECHA completed the Annex XV restriction on the flame retardant, Decabromodiphenylether (DecaBDE) and submitted a proposal to restrict the substance, on its own, in mixtures and in articles. ECHA also submitted in December 2014 an updated report to the Commission in advance of a possible request to prepare a restriction on various uses of five cobalt salts. The Commission also requested ECHA 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). This work commenced with ECHA consulting suppliers of the relevant substances to gather relevant information and will continue in 2015.

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 developed its strategy for implementing this requirement and presented this to CARACAL in November 2014. Work has started on six substances: Musk xylene, MDA and four phthalates (DEHP, BBP, DBP, and DIBP). Regarding the phthalates, ECHA also received a request from the Commission to assess recent biomonitoring data (from the so-called DEMOCOPHES project) to assess if this information indicated if there was a risk that needed to be addressed. This work will continue in 2015.

During 2014, the ECHA Secretariat gave administrative, technical and scientific support to process nine restrictions proposed by Member States and two restrictions proposed by ECHA. In the following table the work on restriction proposals is summarised. The Committees and Forum section gives the details of these.

TABLE 12: Key data on restrictions for 2012-2014

	Received intentions	Restriction dossiers submitted by Member States	Restrictions prepared by ECHA	RAC-SEAC opinions*	Commission decisions
2009	4				
2010	1	3	1		
2011	3	1		4	
2012	2	2	1	1	4

2013	7	3	1	2	
2014	3	4	2	5	3
Total	**20**	**15**	**5**	**11**	**7**

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

In 2013, together with the Forum for Exchange of Information on Enforcement (Forum) and Helpdesk, ECHA identified some further needs to clarify the restriction entries. As a follow-up, ECHA, in close cooperation with the Commission, developed several Questions and Answers on restriction entries and published them on its website in 2014. In addition the definition for 'prolonged contact with skin' in relation to nickel entry was developed and finally agreed at CARACAL in 2014.

In October 2014, the Commission requested ECHA to develop guidelines on three restriction entries (nickel, polycyclic organic hydrocarbons and lead) with the aim to clarify which articles and subtypes of articles fall under the scope of these entries. This work will continue in 2015.

To improve the efficiency of the restriction process, ECHA, the Commission and Member States worked together in the Restriction Efficiency Task Force (RETF) during 2014. The RETF produced 57 recommendations (many that were addressing more than one actor) related to the following topics:

- Opinion making procedures in Committees;
- Extent of analysis required (dossiers and opinions);
- Main challenges in preparing proposals;
- Scope and targeting;
- Proportionality;
- Technicalities (Annex XV format, guidance).

The key priority now will be to implement these recommendations during 2015.

Other activities related to risk management

ECHA continued to increase the evidence base and professional capacity to support the practical application of socio-economic analysis. The project to estimate economic values for preventing a range of human health outcomes was finalised. Dissemination of the results will take place in 2015. ECHA launched a study of how to use quality and disability adjusted life years in chemicals regulation and continued to survey the efforts of preparing applications. ECHA hosted the third meeting of the Network of REACH SEA and Analysis of Alternatives Practitioners (NeRSAP), an informal network for those involved in undertaking practical SEA work exchange experiences of methodological and practical issues and problems.

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 legal 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, including further development of the use of exposure scenarios.

Performance indicators and targets

Indicator	Target in 2014	Result in 2014
Percentage of registered substances preliminarily screened for further regulatory risk management.	25%	>25%
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

- The first common screening round implemented, including screening of the 2013 registration dossiers.
- Three RMOAs and one preliminary assessment of equivalent level of concern were submitted to the Commission.
- A section for substance-specific RMOA information was published on the website.
- Two updates of the Candidate List.
- Agreed revised prioritisation approach and priority assessment of substances on the Candidate List published on the website.
- ECHA's fifth Annex XIV recommendation submitted to the Commission.
- Scientific, administrative and legal support to both submitters of proposals for restrictions and to the RAC and SEAC, and its rapporteurs for their development of opinions on restrictions and applications for authorisation.
- Two Annex XV restriction dossiers and two review reports prepared.
- Plan developed on how to prepare restriction proposals of Annex XIV substances in articles after the sunset dates.
- Initial plan developed on the registry of downstream users to notify ECHA the use of authorised substances.
- Formats for applications for authorisation revised to further increase transparency and efficiency of public consultations on broad information on use.
- The approach on how socio-economic analysis is carried out for PBTs was agreed, with the help of the working group, in SEAC.
- New questions and answers (27) and one frequently asked question on authorisations developed and web pages improved to enhance support to applicants.
- At the request of the Commission published several guidelines on restrictions as Q&As.
- Prepared and published the definition of prolonged contact with skin.

- Report of the Restriction Efficiency Task Force to recommend how the restriction process can be improved in Member States, ECHA and the Commission.
- One seminar organised on applications for authorisation, including socio-economic analysis (SEA), with industry and other interested parties.
- Two SEA-related workshops through the NeRSAP.
- Report on the willingness-to-pay for human health endpoints.

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 these notifications in the C&L Inventory. In certain cases, Member States or industry can propose harmonisation of the classification of a substance in the EU, thus obliging all manufacturers and importers or downstream users to classify that substance in accordance with the harmonised classification. ECHA supports the Member States and RAC rapporteurs during the preparation of proposals for this harmonisation and the development of opinions by RAC. This is normally done for carcinogenic, mutagenic and reprotoxic (CMR) substances, as well as for respiratory sensitisers, but other hazard classes may be harmonised if there is a need. As the harmonised classification has direct implications for the approval of active substances for plant protection products and biocidal products, ECHA actively aligns its opinion development on C&L with the respective approval processes.

1. Main achievements in 2014

Handling proposals for harmonised classification and labelling (CLH)

The main task regarding classification and labelling is to manage the proposals for harmonisation of classification. In 2014, Member State competent authorities submitted 41 proposals and three proposals from industry were received. For 46 substances, a public consultation was completed. The number of proposals in the process however is considerably larger (about 100). Continual attention to the quality of the proposals and increased support to dossier submitters enabled RAC to increase its efficiency. ECHA also provided extensive support to the RAC rapporteurs in developing opinions and scientific background documents. In total, 51 opinions on CLH proposals and one opinion following Article 77(3)(c) were completed. Among those were opinions on complex and important substances such as Bisphenol-A, anti-coagulant rodenticides, borates and the environmental classification of copper compounds. In comparison with previous years, there is a sharp increase in the number of proposals received and the number of opinions agreed by the RAC.

In the context of this growing number of dossiers, and the increasingly complex hazard assessment for carcinogenicity, mutagenicity, reproductive toxicity, the support of the scientific dossier managers (SDMs) has shown to be important for the quality and consistency of opinions. Conclusions are generally based on the evaluation of sizeable and complex dossiers and numerous comments from third parties.

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 the CLH opinion development process to align as far as possible to the considerably shorter and stricter regulated approval processes. This concerns about 70% of all dossiers. The quality of the CLH dossiers has a large impact on the possibility to conform to the timelines for active substance approval. Therefore, ECHA organised workshops 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.

Additionally, ECHA hosted a workshop focusing on scientific issues regarding the use of studies on the mode of action for classification. A systematic way of these studies appeared of particular relevance for the classification of new active substances.

Classification & Labelling Inventory (C&L Inventory)

ECHA is required to establish and manage a C&L Inventory based on C&L notifications from industry, which also includes the list of harmonised classifications. The public inventory was successfully launched in February 2012 and has been updated several times with improvements made to user friendliness (see Activity 6).

The database now contains 6.4 million notifications covering over 133 000 distinct substances, of which over 118 000 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, also in cases where, for instance, an impurity might justify a different classification. Over 25% of the substances have diverging notifications. The 1 June 2015 deadline for classification of all mixtures according to CLP underlines the importance of more uniform self-classifications, explicitly agreed self-classification and clear reasons for any deviating classification. Notifiers are obliged to make every effort to come to an agreement on the C&L 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 is disappointingly low however. ECHA, in cooperation with the Commission and industry associations prepared 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.

ECHA conducted an analysis on the extent to which notifiers adhere to the harmonised classification and labelling for CMRs and identified CMR substances that have a stricter self-classification than the harmonised classification (if any). The study, published in January 2015, concluded that the harmonised classifications for CMR properties are very well followed. In addition, over a thousand substances were identified for which notifiers suggest a classification or stricter classification for CMR properties.

Alternative chemical names

ECHA is also in charge of handling requests for the use of alternative 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 to Member State competent authorities and ECHA. From 1 June 2015, companies can only make requests to ECHA and preparations are completed to receive a larger number of requests.

The number of requests accepted for processing (28) was much lower than expected.

Mixture classification and support to industry for the 2015 CLP deadline

From June 2015, all substances and mixtures have to be classified according to CLP. This poses a significant workload 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. In order to raise awareness with industry, mostly SMEs, and to inform about mixture classification under CLP, ECHA participated in a number of national workshops, offered support to industry associations and conducted two well attended webinars.

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 2014	Result in 2014
Percentage of proposals for harmonised C&L and requests for use of alternative chemical name processed within legal timeframe.	100%	100% (harmonised C&L) 97% (alternative chemical name)
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 37 accordance checks of dossiers containing proposals for harmonised classification and labelling and offered support advice to dossier submitters at their request.
- Provided timely support, of a high scientific quality, to RAC and its rapporteurs for their development of 51 opinions and additionally one opinion on Article 77(3)(c) requests, and of scientific background documents for such opinions.
- Included all notifications and updates in the classification and labelling database, with the public C&L Inventory updated accordingly.
- Completed the study on classification of CMR substances, identified substances to be prioritised for risk management.
- Monitored the C&L Platform and prepared action to stimulate industry to use the platform and come to agreement on self-classifications.
- Concluded 31 dossiers with requests for an alternative name.
- Two successful workshops on improving the CLH proposals for biocides and pesticides and on the use of mode of action studies for classification.
- Provided scientific and technical advice to the Commission on further development of Global Harmonised System of classification and labelling of chemicals (GHS) criteria and for implementing the fifth GHS revision into the CLP Regulation.

1.5. Biocides (Activity 16)

The Biocidal Products Regulation (BPR) entered into operation on 1 September 2013. This regulation extends 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 regulation introduces 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 2014

ECHA has continued liaising closely with the Member State competent authorities (MSCAs) in order to ensure an efficient and effective development of operations under the Biocidal Products Regulation. This includes the continued development and deployment of the IT systems in particular. ECHA managed to release two new major versions of the Registry for Biocidal Products (R4BP 3) which have brought better support to applicants and MSCAs and enhanced the experience of the users in several areas. In addition, ECHA made available a new practical tool: the SPC editor which has been accompanied by a major restructuring of the R4BP 3 data model. In parallel, ECHA has updated the MSCA's R4BP 3 user manual. ECHA has also finalised the migration of the information related to biocidal products from the former tool of the Commission, R4BP2, to R4BP 3.

In 2014, ECHA has processed 2 094 submissions for biocidal products and biocidal active substances, the large majority of which were addressed to the Member State competent authorities. 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 have also been revised based on feedback received to achieve more ready access to the relevant information. In addition to this general activity, ECHA has throughout the year offered direct support to individual applicants when there have been of problematic submissions.

With regard to data sharing, ECHA received 90 inquiries, with 60 arriving in a peak further to a presentation of the procedure at the Stakeholders' Day in September 2014. The first data-sharing disputes were received in mid-2014 in the context of placing a substance on the Article 95 list by the deadline of September 2015. ECHA could not decide in favour of the prospective applicant in any of these cases and requested the parties to continue their negotiations. In three cases, the disputes have been withdrawn due to parties having reached an agreement before ECHA issued a decision. ECHA also contributed to the drafting of the Commission User Guides on Data sharing, Letters of Access, Consortia, and SME-specific considerations in preparation of the Article 95 deadline.

Agreement was reached with the MSCAs at the competent authority meeting on the division of tasks concerning confidentiality requests, and ECHA has started to set up the process. ECHA has informed the MSCAs of the confidentiality requests made by the applicants at the time of processing the submissions.

In January 2014, ECHA has taken over support to the Review Programme of existing active substances from the Commission's Joint Research Centre and has achieved a substantial speeding up of the assessments which materialised in the adoption of 34 opinions by the Biocidal Products Committee. 17 meetings of the permanent working groups of the Biocidal Products Committee (BPC) were organised, as well as one ad-hoc

working group meeting. The peer review process has, as foreseen, become significantly more efficient than in the past (3.5 times more), amongst others due to the efficient management of the process and meetings and the scientific support provided by ECHA.

The number of assessments finalised has been lower than foreseen and further discussions will be needed with the Member State competent authorities to ensure timely delivery of good quality evaluation reports in the future. In the context of the peer review of one of the active substances, ECHA liaised with the European Food Safety Authority in order to ensure consistency and coordination with the assessment of the same substance under the Plant Protection Products Regulation.

Significant progress has also been made on the finalisation of the preparations for the new tasks and challenges under the BPR that could not be finalised in 2013. However, new or amended tasks have arisen from new regulations and also from interpretations of the existing legal texts. ECHA has had to adapt its processes and guidance and communication on Article 95 due to the changed legal provisions following the amendment of the BPR (Regulation (EU) No 334/2014 of the European Parliament and the Council of 11 March 2014) which entered into force in April. The new Review Programme Regulation (Commission delegated Regulation (EU) No 1062/2014 of 6 August 2014) which entered into force in October has also defined new tasks for the Agency and in November the Member State competent authorities agreed on a way forward for the *in situ* generated active substances, which is expected to lead to the addition of 50 to 150 new active substance/product-type combinations in the Review Programme.

ECHA has also built up its capacity to support the assessment of various types of applications and more specifically those related to technical equivalence and inclusion in the Article 95 list (list of active substances and suppliers). The assessment of the first applications has been a useful learning process that helped to clarify the data requirements and practical guidance to the applicants.

ECHA has provided the Secretariat for the Coordination Group (CG) and organised six meetings. The discussion of four formal mutual recognition disputes has led to the settlement of two agreements. Two informal disagreements were also discussed, contributing to their early resolution. The CG meetings have also addressed a number of issues related to product authorisations.

Overall, it should be noted that ECHA has carried out the biocides activities under severe budgetary and human resources restrictions. The much lower number of applications compared to what was originally anticipated has resulted in significantly lower than foreseen fee income which has put heavy financial constraints on the Agency. If this situation continues and is not compensated by a higher subsidy, it will be extremely difficult for ECHA to continue to deliver on all its non-fee related obligations.

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 2014	Result in 2014
Percentage of dossiers handled according to standard procedures and legal deadlines.	100%	89%
Level of satisfaction with the quality of scientific, technical, and administrative support provided to the members of the BPC, CG, 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.
- Assessment of suppliers' applications of active substances and maintenance of the list of approved suppliers: one decision.
- Assessment of technical equivalence applications: seven decisions.
- Assessment of chemical similarity of active substances: one case.
- Workflows and processes for dealing with incoming dossiers tested for their usability and further developed where necessary.
- 69 (out of 90 received) inquiries were processed.
- Four 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 established 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 import and export 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.

The regulation has transferred the responsibility for administrative and technical tasks from the Commission's Joint Research Centre (JRC) to ECHA. ECHA also provides assistance as well as technical and scientific guidance to industry, the designated national authorities (DNAs) both from the EU and from third countries and the European Commission.

1. Main achievements in 2014

The PIC operations were successfully handed over from JRC to ECHA in March 2014, allowing the processing of PIC notifications to be undisturbed. In September, ECHA switched to the new submission system, ePIC, which brought more efficiency in the processing of notifications (see Activities 1 and 6), for example, by allowing all actors to monitor their deadlines closely, or by increasing the traceability of submissions, making available the full history for submissions and related messages. As a result, most communication needs for both authority and industry users can now be handled within the system.

At the same time, staff was trained to handle the expected end-of-year peak in notifications which could be managed successfully. Overall, about 5 300 notifications were processed in 2014, 15% by the JRC before the handover in March and the remaining 85% by ECHA. Of those, 4 500 referred to the export year 2014, while the remaining ones were processed in the last quarter of 2014 but referred to the export year 2015. This corresponds to an increase of 32% over the year 2013. Three Member States covered 65% of all notifications: 35% of the notifications originated from Germany, 20% from France and 10% from Belgium.

Throughout the year, ECHA maintained close and proactive links with the DNAs and received very good feedback on its support to day-to-day operations as well as the ongoing refinements of the ePIC system. Specifically, ECHA organised two workshops welcoming feedback from the DNAs and industry on the development of the application and for training purposes. ECHA also provided live WebEx sessions for the discussion of specifications, enabled external testing of the application by stakeholders and provided webinars as part of the training programme.

With regard to scientific and technical advice to the European Commission, ECHA was in continuous dialogue with them, and initial preparations for exchange of information were made. The work will continue into 2015.

2. Objectives and indicators

Objectives

1. Ensure the successful kick-off for the PIC activities in March 2014 and effective management of the first notification peak at the end of 2014.

Performance indicators and targets

Indicator	Target in 2014	Result in 2014
Percentage of PIC notifications processed within the legal timeframe.	100%	100%*
Level of satisfaction with the quality of scientific, technical, and administrative support provided to the Commission, Member State DNA's and industry.	High	High

* Figure rounded up.

3. Main outputs

- Procedures and workflows were ready for submission and handling of notifications.
- Campaign for raising awareness for entry into force of the recast was carried out.
- A total of 5 289 notifications were processed, of which 4 500 referred to the export year 2014.

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

The ECHA Helpdesk gives advice to companies which is helpful in preparing high quality dossiers, notifications and reports; it clarifies obligations under the regulations and provides support to users of the ECHA scientific IT tools (such as IUCLID, Chesar, REACH-IT, ePIC and the Register for Biocidal Products (R4BP 3)), including assistance with the submission of data. The services of the ECHA Helpdesk also encompass question and answer sessions during webinars, one-to-one sessions at workshops and at ECHA's annual Stakeholders' Day, as well as training on scientific IT tools.

The network of national BPR, CLP and REACH helpdesks (HelpNet) aims to foster a common understanding of the REACH and CLP (and BPR) obligations among national helpdesks and thereby harmonise their responses to questions from industry. Through the HelpNet, national helpdesks will further develop their knowledge which is required to act as the first point of contact for companies. ECHA manages the HelpNet, chairs its Steering Group, provides national helpdesks with the Helpdesk Exchange Platform (HelpEx) and facilitates agreement on REACH, CLP and BPR frequently asked questions (FAQs) to be published on the ECHA website.

The REACH, CLP, Biocides and PIC regulations all require that ECHA provides technical and scientific guidance and tools for industry, for the MSCAs and for the benefit of other interested parties.

1. Main achievements in 2014

ECHA Helpdesk and HelpNet

The workload of providing advice and assistance to companies by replying to industry questions further increased in 2014, also due to the fact that the entry into force of the Biocidal Products Regulation resulted in about 17% of resolved questions pertaining to duties under this piece of legislation. Overall, 69% of the resolved questions related to ECHA's scientific IT tools (from industry and MSCAs) and 25% to regulatory topics. Apart from an increase in numbers, questions from industry also tended to be more sophisticated than in the past. BPR-related questions also challenged the ECHA Helpdesk to develop related sets of topical replies.

Subsequent to the extension of the HelpNet to also include correspondents from the national BPR helpdesks, the HelpNet Secretariat applied the format of organising specific HelpNet workshops with CLP correspondents back-to-back with a CLP Seminar hosted by the European Commission in Brussels in September and with BPR correspondents back-to-back with ECHA's second Biocides Stakeholder Day as well as with REACH correspondents back-to-back with the HelpNet Steering Group meeting.

This format allowed the correspondents of national helpdesks to focus on their specific topical areas and to attend the above-mentioned topic meetings and draw conclusions for providing advice and assistance to duty-holders in light of the outcome of these key conferences. The HelpNet Steering Group meeting also included the BPR correspondents, somewhat reorienting itself towards items of common value to all three types of national helpdesks.

A main achievement lay in the Agency's decision to set up a specific MSCA IT Support service. The roles of MSCAs in ECHA's regulatory processes make it necessary for their staff to master the various IT tools that are essential in the interaction between ECHA and MSCAs as provided by the legislation. A dedicated MSCA IT support team provided customer-oriented support during the roll-out of new and updated scientific IT tools,

brought together and consolidated a network of users and user administrators, organised training events, established and issued user manuals and revamped the MSCA IT support contact form to allow for a single point of contact.

Supporting industry and MSCAs in the context of the release of new IT tools needed particular effort. A series of webinars and WebEx sessions which were organised for MSCAs, along with manuals, video-tutorials, the revamp of our contact forms and FAQs that were also created for industry, particularly in view of the roll out of ePIC 1.0, R4BP 3.2 and an ECHA accounts system resulted in a very intensive second half of the year.

Guidance

As the 2018 REACH registration deadline concerns substances at a tonnage range up to 100 tonnes, registrants for 2018 will most likely include a higher proportion of less experienced as well as smaller companies than ever before. In this light, ECHA published an additional simplified guidance in a nutshell document on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD) to support innovation. ECHA continued to support SMEs by providing translations of appropriate documents from English into a further 22 official EU languages.

ECHA continued to expand the guidance available on the Biocidal Products Regulation and published a series of transitional guidance documents to facilitate the transition from the previous biocides legislation.

As the PIC Regulation (Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals) entered into operation on 1 March 2014, ECHA published its first guidance on PIC.

In addition, ECHA continued to improve the accessibility of guidance for all interested parties by producing and maintaining supportive documentation and web pages (question and answer pairs, “Guidance in a nutshell” documents, web pages for specific REACH and CLP processes and the REACH terminology database (ECHA-term) in 23 EU languages.

Overall, the output on Guidance was considerable, reflecting the need to keep duty holders updated, the routine that ECHA has developed in producing such documents as well as the Agency’s aim of presenting them in user-friendly formats.

2. Objectives and indicators

Objectives

1. Industry (duty holders) receives timely and efficient support from the ECHA Helpdesk, and through high quality guidance documents, to fulfil its obligations under REACH, CLP, BPR and PIC.

Performance indicators and targets

Indicator	Target in 2014	Result in 2014
Percentage of ECHA Helpdesk questions answered within the established timeframe (15 working days).	90% (REACH/CLP) 70% (BPR)	93% (REACH/CLP) 82% (BPR)

Level of satisfaction of users with quality of ECHA Helpdesk services.	High	High
Level of satisfaction expressed in feedback from guidance users.	High	High

3. Main outputs

ECHA Helpdesk

- 7 628 questions resolved by the ECHA Helpdesk.
- 32 one-to-one sessions and a Helpdesk information stand provided at ECHA's Ninth Stakeholders' Day, 24 one-to-one sessions provided at ECHA's Second Biocides Stakeholders' Day.
- One HelpNet Steering Group meeting and three topical HelpNet workshops on BPR, CLP and REACH, respectively.
- First REACH MSCA User Administrators' workshop held.
- Q&A sessions in eight webinars providing replies to 796 topical questions.
- Three FAQ updates in written consultation and one fast-track REACH FAQ update producing altogether eight REACH, five CLP and five BPR FAQs; these FAQs having been agreed by HelpNet members.
- 26 FAQ updates for all IT tools (including invoicing and ECHA Accounts FAQs).
- IT tools training on R4BP 3 and IUCLID 5.5 for national helpdesks.
- Targeted guidelines on mixture classification developed in collaboration with national helpdesks and published on the ECHA website.
- Four webinars, five information packages, two login manuals and two quick guides for MSCAs and the setup of a collaboration platform on CIRCABC.
- The decommissioning of crypto-boxes from all MSCAs and migration to a new remote access model, necessitating all tokens to be replaced.
- Migration of biocide user accounts to enable the go-live of R4BP 3 end-to-end testing exercises for all rolled-out IT tools.
- The MSCA IT support contact form was revamped twice with the result of enabling MSCAs, national helpdesks, enforcement authorities and inter-institutional partners to approach ECHA through a single point of contact.

Guidance

- Guidance finalised with publication in 2014 (all updates unless indicated as "new"):
    - *Guidance on the preparation of of dossiers for harmonised classification and labelling* ("CLH dossiers");

- *Guidance for implementation of Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals* (Guidance for PIC - new);
- *Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA)* - Part C and Chapters R11, R7b, R7c (related to PBT assessment);
- *Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA)* - Chapter R.7a, Sections R.7.7.1 to R.7.7.7 (related to mutagenicity);
- *Guidance on the preparation of an Annex XV dossier for the identification of substances of very high concern;*
- *Guidance on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD);*
- *Guidance in a nutshell on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD)* (new, in 23 languages);
- *Guidance on the Biocidal Products Regulation, Volume V, Guidance on active substances and suppliers (Article 95 list).*
- A total of nine transitional guidance documents for the transition between the Biocidal Products Directive and Biocidal Products Regulation were also published (see: http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/transitional-guidance)
- *The Second revision to the Consultation Procedure for Guidance* (MB/2013/63 final) as endorsed at the MB meeting of 18/12/2013 was published on the ECHA website in January 2014: (http://echa.europa.eu/documents/10162/13559/mb_63_2013_consultation_procedure_for_guidance_revision_2_en.pdf)

- Corrigenda published to the following guidance documents in 2014:

  - *Guidance on the compilation of safety data sheets* (certain languages only)
  - BPR Guidance Volumes I-IV – Part A Information Requirements (to split the documents into the new structure);
  - *Guidance for downstream users;*
  - *Guidance on information requirements and chemical safety assessment,* Chapter R.7a: Endpoint specific guidance (Version 2.4) (Section R.7.1 Physicochemical properties);
  - *Guidance for identification and naming of substances under REACH and CLP.*

- Guidance projects were initiated and for which draft consultation documents were generated during 2014 (all updates, unless indicated as “new”):

  - *Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA)* - Chapter R.7a, Section R.7.6 (related to reproductive toxicity);
  - *Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA)* - Chapter R.7a, Section R.7.2 (related to corrosion/irritation);
  - *Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA)* - Chapter R.12 (use descriptor system);
  - *Guidance on the compilation of Safety Data Sheets* (fast-track update to take into account (inter alia) end of transition period for mixtures classification according to CLP);
  - *Guidance for the Biocidal Products Regulation (BPR) - Volume IV, Environment, Part B Risk Assessment (active substances)* (new);
  - *Guidance for the Biocidal Products Regulation (BPR) - Volume V, Guidance on Micro-organisms* (new);
  - *Guidance for the Biocidal Products Regulation (BPR) - Volume III, Human health, Part B Risk Assessment,* Chapter 3 on exposure assessment

1.8. Scientific IT tools (Activity 6)

ECHA develops, maintains and supports IT systems and tools which enable the Agency and its stakeholders to fulfil their regulatory obligations under the relevant regulations in an efficient and effective manner.

1. Main achievements in 2014

A technically revised major new IUCLID version, IUCLID 6, continued to be developed throughout the year. The project progressed according to established plans. After comprehensive testing, ECHA will start using the version for its internal operations. At the same time, a pre-production version will be made available for all IUCLID users, allowing them to test and familiarise themselves with the product and prepare for the final production release planned in 2016 which will replace the current IUCLID 5.

The chemical safety assessment tool Chesar was further developed and a revised Chesar 2.3 was released in June. Development of a new version Chesar 3 was commenced, based on the outcome of the internal Chemical Safety Assessment (CSA) development programme as well as the work of a group of external experts from Industry. Chesar 3 will be aligned with IUCLID 6.

The update of the REACH and CLP submission system REACH-IT started in alignment with the REACH 2018 Roadmap initiative. The new version – REACH-IT 3 – will be more modular, aligned with IUCLID 6, upgraded to recent IT technologies, revised in its user interface and will re-use the users access management component already deployed for the other submission systems (ePIC and R4BP) making users management and sign-in significantly more efficient. The externally available release of REACH-IT 3 will be in 2016 after the release of IUCLID 6.

In support for the Biocidal Products Regulation, ECHA further developed the R4BP 3 application initially released in 2013. Two versions were released during the year supporting several new application types, increasing the level of automation for the authority users, and adaptation to changes in the regulation. Remaining data from the R4BP 2 version – supporting the replaced Directive – was migrated to the new system to permit decommissioning. An editor for the Summary of Product Characteristics document (SPC Tool) was developed and released enforcing the SPC structure for the BPR applications.

ECHA released a new submission system – ePIC – as part of the transfer of the Prior Informed Consent (PIC) Regulation to ECHA, replacing and migrating data from the system operated by the Joint Research Centre under the previous regime.
As part of the ePIC go-live, extensive IT support was provided for the designated national authorities (DNA). The ePIC development phase was concluded and the system has entered into the maintenance phase in 2015.

In 2014, the restructuring of most of the externally available IT tools made significant progress, aiming for better integration and maintainability in accordance with the Enterprise Architecture renovation programme. Such a programme was also aligned with the REACH 2018 Roadmap initiative to deliver enhanced tools for registrants and, at the same time, support ECHA's efforts towards receiving better quality data.

The development of the next generation dissemination system has progressed satisfactorily, although a delay of two months on the plan could not be fully recovered. The fully revised system is planned to be released by the end of 2015.

Since the beginning of 2014, all competent authorities were able access to the Portal Dashboard for Competent Authorities – a system providing access to the relevant substance information in ECHA databases – after go-live at the end of 2013.

In other words, to consolidate and alleviate the maintenance burden of several output solutions for the competent authorities, ECHA decided to merge the REACH Portal for Enforcement Authorities (RIPE) into the Portal Dashboard. However, during the further development of the Data Integration Platform (DIP) – the back-end data repository feeding the Portal Dashboard – a drawback of several months was incurred due to architectural design issues which prevented the plans for the merge of the RIPE functionalities to be matched. Towards the end of the year, solutions for these issues were identified; they will be addressed in 2015 and some delay will be recovered.

Internally, a new case management platform called Dynamic Case was launched to support ECHA's REACH and CLP regulatory processes. The concept of the Dynamic Case consists of common functionalities to create, handle and archive records pertaining to a case, interact with source IT systems and produce content for collaboration or dissemination on a case. These common functionalities can be configured to adapt to the needs of a specific regulatory process as described in the procedures and work instructions of ECHA's Quality Management System. The fast uptake of the Dynamic Case was confirmed as 17 out of 40 identified REACH and CLP regulatory processes were already supported by the platform at the end of 2014, only a few months after go-live.

The difficulties with the software development quality affecting Odyssey (the decision support system used for dossier evaluation) were finally overcome with the successful release of two new versions as planned. The system has been enriched with functionalities and integration with other IT systems to improve the performance and efficiency of dossier evaluation. The system has also been finally fully adopted for the scientific assessment of an inquiry dossier.

The workflow system used for Evaluation (ECM-DEP) was adapted with two releases under change management, providing operational improvements and better integration with the Data Integration Platform and with Odyssey.

2. Objectives and indicators

Objectives

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

2. Well-functioning IT tools enable ECHA to receive and successfully process submissions, perform evaluations and risk assessment activities as well as to disseminate the public information, in accordance with the relevant legislation.

Performance indicators and targets

Indicator	Target in 2014	Result in 2014
Level of satisfaction of external users with the IT tools (IUCLID, REACH-IT, R4BP 3, CHESAR and Dissemination).	High	High

3. Main outputs

- The development of the new generation IT tools - IUCLID 6, REACH-IT 3, Chesar 3, new Dissemination – progressed according to the plans.
- Two new versions of R4BP were released in 2014, covering additional functionality and use cases.
- An SPC editor for preparing and editing the Summary of Product Characteristics (SPC) was developed and released supporting the authoring of structured SPCs for biocides.
- A new system supporting the PIC Regulation, ePIC, was released in time to manage notifications for 2015.
- The current dissemination system was enhanced to cover biocides and PIC data and to achieve operational efficiencies
- An update to the Chesar 2 product (version 2.3) was released in June.
- The case management platform Dynamic Case was launched, supporting 17 REACH and CLP processes by the end of the year.
- Two new versions of Odyssey were released to improve the efficiency of the scientific work in dossier evaluation and inquiry dossier processing.
- Two maintenance versions of ECM-DEP were released.

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

It is ECHA's strategic objective to become a hub for the scientific and regulatory knowledge building of the Member States, European institutions and other actors, and to use this new knowledge to improve the implementation of the chemicals legislation.

1. Main achievements in 2014

2014 was the first year of implementing the above strategic objective. As one element of this, ECHA introduced the foundation for proactive scientific capacity building for its own staff. This was done by establishing an approach for systematic competence management which was kicked off by a competence mapping among the scientific staff of the Agency.

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 and eye irritation/corrosion, skin sensitisation, genotoxicity, endocrine disrupters and aquatic and terrestrial ecotoxicity. ECHA also launched a new web section to inform registrants of new test guidelines and to promote their appropriate use in meeting the information requirements under REACH. ECHA provided expert support to the Commission in integrating the Extended-One Generation Reproduction Toxicity Study guideline in the REACH information requirements.

ECHA contributed actively to the development and use of alternatives to animal testing. This included in particular participation in the drafting of an integrated approach for testing and assessment (IATA) on skin sensitisation and to the IATA on skin irritation/corrosion within the OECD, and contributions to the development of Adverse Outcome Pathways (AoPs) development at WHO and OECD level.

As a result of a joint project between ECHA and the Joint Research Centre of the European Commission, a report was published on "Awareness of non-animal methods for the assessment of chemicals – View to promote non-animal testing and alternative methods" and ECHA arranged a follow-up workshop to deepen the collaboration and to train ECHA staff. Work to replace the *in vivo* acute oral toxicity study by a weight of evidence approach, which mainly relies on the sub-acute toxicity results, was started. A special emphasis of these activities is to help registrants avoiding unnecessary animal testing when preparing for the 2018 registration deadline.

ECHA's second report on the use of alternatives to testing on animals was published in June. The report showed that registrants have widely used alternative methods to generate information required by REACH to ensure the safe use of chemicals. Most registrants conform to the data-sharing obligations and industry has increasingly used *in vitro* methods, built categories and predicted substance properties by read-across. ECHA will use the results of the report to promote the use of alternative methods in support of registrants aiming for the 2018 registration deadline.

Furthermore, ECHA made good progress in developing a Read-across Framework (RAAF) to advise authorities and registrants on how to build and assess read-across justifications. A successful workshop on RAAF for human health was held, and work started on expanding RAAF to environmental hazards. The use of the OECD's (Quantitative) Structure-Activity Relationship (QSAR) Toolbox was promoted through web-based training to Member State authorities and stakeholders and by publishing a series of new tutorials for the Toolbox.

ECHA's Regulatory Science Strategy was finalised and published in early 2015. It steers ECHA regulatory science activities, for example, by setting priorities, by relying strongly on a demand driven approach serving operational needs, and by clarifying ECHA's role in interacting with research and development projects (such as under Horizon 2020). In the context of this work, ECHA continued to strengthen its interaction with international scientific professional societies like SETAC Europe and Eurotox.

The Topical Scientific Workshop on Nanomaterials was held on 23-24 October 2014 at ECHA bringing together close to 200 experts in the field of risk assessment of nanomaterials representing academia, authorities, industry and NGOs.
The workshop provided a unique platform for academia and regulators to discuss how to address current challenges from the regulatory perspective which can be reflected and employed in the ongoing and future research topics on nanomaterials.

ECHA increased its role at international level by accepting the chair position for the Steering Group on Testing and Assessment (SG-TA) under the Working Party for Manufactured Nanomaterials at OECD. This position has given ECHA a good opportunity to create synergies between its own activities and goals for nanomaterials and the discussions at international level e.g. on appropriateness of existing test guidelines and assessment methods of nanomaterials.

Pending the formal proposal by the European Commission on revisions of the REACH Annexes in the context of nanomaterials, ECHA has started preparatory work to update the relevant guidance documents to ensure they will be in place for the registrants in time for the 2018 deadline. ECHA's Nanomaterials Working Group (NMWG) met twice to discuss scientific and technical questions related to the implementation of REACH, CLP and the BPR, and in particular concerning environmental assessment, characterisation, structure of information in IUCLID and read-across between different forms of the same nanomaterials.

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, mixture toxicity, exposure assessment, testing methods and the use of alternative methods.

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

Performance indicators and targets

Indicator	Target in 2014	Result in 2014
Level of satisfaction with the quality of the scientific, technical and administrative support provided to the Commission and MSCAs.	High	Medium

3. Main outputs

- Systematic competence management system launched.
- A successful Topical Scientific Workshop on Regulatory Challenges in Risk Assessment of nanomaterials was organised in October 2014.
- ECHA's second report under Article 117(3) of REACH on the use of alternatives to animal testing was published.
- ECHA's two-year work plan on nanomaterials was updated.
- Two meetings of the nanomaterials working group were held.
- Participation in the annual meetings or steering groups of the most relevant research projects on nanomaterials (under FP7).
- Contributions to four OECD workshops on the development of assessment methods for NMs, and to the review of several testing guidelines regarding their applicability to NMs.
- Contributions to COM for the revision of REACH annexes regarding specific requirements for NMs.
- Promotion of improved hazard identification and risk assessment approaches through training on uncertainty methodology and mode of action/human relevancy workshops.
- ECHA and JRC report on "Awareness of non-animal methods for the assessment of chemicals – View to promote non-animal testing and alternative methods."
- Contribution to the development of OECD test guidelines and testing strategies (IATAs) especially in the areas of skin and eye irritation/corrosion, skin sensitisation, genotoxicity, endocrine disrupters, reproductive toxicity and aquatic and terrestrial ecotoxicity.
- Adverse Outcome Pathway: contributions through the OECD and WHO, and implementation through the OECD Toolbox.
- Development of Templates for Mode of Action Analysis using the WHO/IPCS MoA Framework.
- New web section to inform the registrants of new test guidelines and promotion of their use in meeting the information requirements under REACH.
- Promotion of QSAR Toolbox through training, presentations, and by providing examples (for skin sensitisation and acute aquatic toxicity) on how to use the Toolbox.
- Contribution and scientific support to the Commission in reviewing REACH Annexes on specific information requirements (reproductive toxicity, skin and eye irritation/corrosion, skin sensitisation), and in relation to 1-10 tonne per year information requirements.

2. ECHA's Bodies and Cross-cutting Activities

2.1. Committees and Forum (Activity 8)

The Committees – the Member State Committee (MSC), Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) – are an integral part of ECHA and play an essential role particularly in 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 and CLP regulations, with the aim of harmonising their approach to enforcement.

1. Main achievements in 2014

Member State Committee (MSC)

The number of cases submitted to the MSC for agreement was lower than planned. The MSC unanimously agreed on 60% of the draft compliance check decisions on registration dossiers and draft testing proposal decisions. In 33 compliance checks and 61 testing proposal cases (where two-generation reproduction toxicity testing were proposed), the MSC did not reach unanimous agreement. In accordance with the legal requirement, the full documentation was submitted to the Commission for their further decision-making.

In total, 17 substance evaluation draft decisions, as a result of evaluations carried out by Member States, were addressed by the MSC in its decision making during 2014. For 15 substances, unanimous agreement on the draft decision was reached, and this covered four substances listed in CoRAP for evaluation during 2013, the rest originating from 2012. For one substance (i.e. methanol), the MSC found unanimous agreement to terminate the decision-making procedure, and for one substance (i.e. polyhaloalkene), the MSC did not find unanimous agreement. In accordance with the legal requirement, the full documentation on the latter case was submitted to the Commission for their further decision-making. In relation to the substance evaluation process, the Committee adopted its opinion on ECHA's draft CoRAP update for 2014-2016 in February 2014.

The MSC unanimously agreed on the identification of nine substances as SVHCs that were subsequently included in the Candidate List. For one substance listed on the Candidate List previously (phthalate DEHP), the MSC identified an additional basis for its listing due to its endocrine disrupting properties. For the first time, the MSC did not reach unanimous agreement on four substances (all phthalates). The MSC opinions with the majority view on these substances, and the minority views, will be submitted to the Commission for decision-making.

The update to the prioritisation approach that ECHA is to apply from 2014 onwards was implemented for the draft sixth recommendation for inclusion of substances in Annex XIV, and after the MSC consultation ECHA included 22 substances in the public consultation. In December 2014, the MSC Rapporteur, supported by a working group, presented their workplan and first assessment. The MSC's draft opinion on ECHA's sixth draft recommendation is scheduled for adoption in June 2015.

The MSC intitiated its first request from the Executive Director for an opinion under Article 77(3)(c). It concerns an MSC opinion on the persistency and bioaccumulation of the substances D4 and D5 (octamethylcyclotetrasiloxane and decamethylcyclopentasiloxane, respectively). A draft opinion will be prepared by the rapporteur for adoption by the MSC in 2015.

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 2014, the case-owners participated in the Committees' discussions in 71% of cases.

ECHA's Executive Director appointed a new MSC Chairman in March 2014 after the retirement of its Chair who had succesfully led the MSC for 34 meetings.

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

As planned, RAC adopted a total of 51 opinions on harmonised classification and labelling in 2014, which is significantly higher than in 2013 (34) and which demonstrates the effectiveness of recent efficiency measures such as the fast track procedure for adopting CLH opinions. The ECHA Secretariat also provided extensive support to the RAC rapporteurs in developing opinions and scientific background documents. The majority of the proposals for harmonised classification and labelling concerned biocidal and plant protection products. A substantial amount of work was concluded in 2014 on complex proposals, for example, eight related anti-coagulant rodenticides and 10 inorganic copper compounds plus several industrial chemicals such as two types of glass microfibres.

RAC concluded on two requests from the Executive Director for opinions under Article 77(3)(c); one concerning consumer exposure to benzene contained in natural gas and one concerning the review of the information for setting specific (or general) concentration limits for the reproductive toxicity hazard class of tetrapropylphenol.

Opinions on five restriction proposals were adopted by RAC: to restrict the manufacturing and use of 1-methyl-2-pyrrolidone (NMP) reducing the potential effect of NMP on pregnant workers and their unborn children, to restrict nonylphenol/nonylphenol ethoxylates in textile articles that can be washed in water, to support the amendment to an existing restriction on cadmium and its compounds in paints, not to support the restriction proposal on cadmium and its compounds in artist paints, and to amend the current derogation for diaphragms in electrolysis installations in the existing restriction on chrysotile.

SEAC concluded on four restriction opinions in 2014: the proposed restriction on lead in consumer articles aiming to reduce children's exposure to lead from mouthing, and the restriction proposals on NMP, nonylphenol/nonylphenol ethoxylates in textile articles, and cadmium and its compounds in paints.

In 2014, the authorisation process gained momentum and approached maturity. RAC and SEAC were able to agree on 37 draft opinions on applications for authorisation, of which 30 were adopted as final opinions, which was 150 % of the planned numbers. These applications concerned uses of the phthalates (DEHP and DBP), lead chromate pigments, diarsenic trioxide, hexabromocyclododecane and trichloroethylene.

As part of the ongoing capacity building programme for authorisation, RAC agreed on dose-response relationships for the carcinogenicity of trichloroethylene. While RAC will use these risk estimates to evaluate applications for authorisation in a predictable and transparent manner, they are not legally binding. To date, the vast majority of applications have used such RAC reference values provided through the ECHA website.

In order to increase the efficiency of the Committees work, RAC and SEAC also agreed on a streamlined working procedure for developing and agreeing authorisation opinions.

The Secretariat made continuous efforts to support RAC and SEAC with their increasing

workload so that they are prepared for the expected peak in workload on authorisations in late 2015 and 2016. Through 2014, the results of the MSCAs committment to provide adequate support to their nominees and guarantee working time for RAC and SEAC members became increasingly apparent, although further efforts will be necessary. There was also an increase in the numbers of members appointed to the Committees: RAC rose from 42 to 45 in 2014, while SEAC rose from 32 to 37 in 2014.

ECHA staff members attended meetings of the Scientific Committee on Occupational Exposure Limits (SCOEL, DG Employment) as observers to exchange views and ensure close cooperation on issues of worker protection, in particular in relation to authorisations and restrictions. This was reciprocated by DG Employment services attending RAC as observers. Common issues impacting on the workplace were discussed, for example, the respective reference values for NMP exposure in view of addressing a potential conflict of opinion between the RAC opinion on NMP and the SCOEL opinion.

Biocidal Products Committee (BPC)

Overall, the first year of operation of the BPC is considered to have been a successful one which provides a firm foundation for the future years of operation.

The BPC prepares the opinions of the Agency in relation to several processes under the Biocidal Products Regulation (BPR). In relation to applications for the approval of new and existing active substances (Review Programme), the BPC prepares an opinion which then serves as a basis for decision-making by the European Commission and the Member States. The approval of an active substance is granted for a defined number of years, not exceeding 10 years.

During 2014, the BPC adopted opinions in relation to 34 applications for approval, mainly of existing active substances. For comparison purposes, this represents a considerable speeding up of the process compared to the previous regulatory regime. As a result of processing the first batch of these applications a revision was made to the BPC Working Procedure for handling active substance applications.

Another process for which the BPC prepares the opinion of the Agency is in relation to questions that may arise on the operation of the BPR relating to technical guidance or risks to human health, animal health or the environment from the European Commission or Member States according to Article 75(1)(g) of the BPR. During this period, the BPC adopted two opinions on these diverse questions from the European Commission.

During the year, the BPC did not receive evaluations on applications for Union authorisation (UA) of biocidal products or requests from the European Commission for an opinion in relation to a scientific or technical matter in national mutual recognition. This is significantly lower than the numbers expected.

In order to allow access to the work of the Committee and to strengthen the quality of its decision-making, ECHA accredited stakeholders and applicants have participated in the BPC plenary and BPC WG meetings as observers. By the end of 2014, 26 accredited stakeholder observers have been invited to participate in the work of the BPC, where five stakeholder organisations are regularly represented at BPC meetings.

Forum for Exchange of Information on Enforcement

In 2014, the Forum increased its focus on practical enforcement projects and sought to consolidate and improve the efficiency of a number of its other activities.

It finalised and published a report of the first phase of the third coordinated enforcement project which focused on registrations and cooperation with customs authorities. The report indicates that most duty holders are compliant with registration obligations. Where deficiencies were detected, only representatives (ORs) were found to be the group which is most frequently non-compliant. The Forum also initiated a second phase of that project, broadened by further checks along multinational supply chains focusing on ORs and decided that its fourth major project will focus on checking restrictions.

The Forum completed the preparation of its first pilot project on authorisations with inspections expected to start in early 2015 and agreed for a second authorisation pilot project to be launched in 2015. Furthermore, it agreed on two further pilot projects to be executed in 2015. The first one will check that the packaging of chemical products available to the general public have appropriate child resistant fastenings where needed. The second one will follow up specific cases where ECHA has identified deficiencies in harmonised classification and labelling. These will focus on substances with CMR or sensitising properties.

Furthermore, the Forum adopted and published its Multi-annual Work Programme 2014-2018 and a description of what enforcement of the PIC Regulation would mean.

After the successful start-up of interlinks between ECHA and NEAs related to the follow-up of ECHA's decisions by inspectors in 2013, the Forum looked to both, further specifying all aspects of the process and broadening it to cover other decisions. The Forum invested its efforts in development of the guide for interlinks that, once finished, will describe all aspects of cooperation between NEAs, MSCAs and ECHA. In order to allow for discussion between NEAs, MSCAs and ECHA, the Forum prepared its second Workshop on Interlinks to take place in early 2015.

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

Furthermore, the Forum continued its activities related to the harmonisation and support for enforcement by updating its Manual of Conclusions (MoC) and supporting the ECHA Secretariat in the development of the REACH Information Portal of Enforcement (RIPE) and its integration in the Portal Dashboard. The Forum decided to use the European Commission's ICSMS as secure communication among the enforcement authorities, after the Commission developed dedicated features for REACH and CLP inspectors.

The Forum continued to advise RAC and SEAC on the enforceability of proposals for restrictions and started considering how to improve the efficiency of its advice process. It prepared a first draft of the compendium of analytical methods listing methods related to restrictions with a limit value.

The Forum also intended to intensify its cooperation with stakeholder organisations by inviting their proposals for subjects for the fifth enforcement project and launching a discussion on how to intensify and improve cooperation between the Forum and stakeholders. To this end, the Forum Secretariat also analysed opportunities for more transparency of the Forum work.

The Forum provided input into the European Commission's project for development of enforcement indicators for REACH and CLP.

Lastly, the Secretariat provided technical, scientific and administrative support to the Forum in the organisation of its Working Group meetings, its annual stakeholder

workshop and its plenary meetings. The Forum has also agreed a number of small efficiency improvements to the operation of its plenaries and working groups.

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.

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 and solved through the sharing of information and the coordination of activities of mutual interest.

Performance indicators and targets

Indicator	Target in 2014	Results in 2014
Percentage of opinions/agreements delivered within the legal timeframe.	100%	100%
Percentage of unanimous MSC agreements.	80%	60%
Percentage of Committee opinions adopted by consensus.	80%	93%
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 (e.g. support, including training and chairing provided by ECHA, overall transparency, publication of the outcomes of Committee processes) and the Forum.	High	Not assessed in 2014, to be assessed in 2015.
Occurrence of conflicts of opinions with scientific committees of other EU bodies.	Only in well justified cases	1*

*Justified case.

3. Main outputs

Member State Committee

- Unanimous MSC agreements on 10 proposals for identification of substances of very high concern (SVHCs). Four opinions on proposals for identification of SVHC were prepared based on the majority view.
- 123 unanimous MSC agreements on draft decisions on testing proposals and compliance checks.
- Preparation of 16 unanimous agreements on draft substance evaluation decisions.
- Opinion on the second draft annual update of CoRAP.

The above was achieved through six MSC plenary meetings, active use of written procedures for agreement seeking and a high number of preparatory web conferences with the whole Committee.

Committee for Risk Assessment

- 51 RAC opinions on CLH dossiers.
- Five RAC opinions on restriction proposals.
- Nine conformity checks for restriction dossiers.
- 30 RAC opinions on applications for authorisation.
- 19 conformity checks for applications for authorisation.
- Two opinions under Article 77(3)(c) of REACH.

The above was achieved through six RAC plenary meetings.

Committee for Socio-Economic Analysis

- Four SEAC opinions on restriction proposals.
- Nine conformity checks for restriction dossiers.
- 30 SEAC opinions on applications for authorisation.
- 19 conformity checks for applications for authorisation.

The above was achieved through four plenary meetings.

Biocidal Products Committee

- 34 opinions on applications for the approval of active substances. These included two new substances, one existing substance in the Review Programme and 31 'backlog existing substances' in the Review Programme[7].

[7] Competent authority report submitted before the entry into operation of the BPR.

- Two opinions under Article 75(1)(g) of the BPR.
- Implemented the ECHA Code of Conduct for the participation of applicants and accredited stakeholder organisations in the work of the BPC.
- Completed the set of Working Procedures for the BPC and its WGs and revised the Working Procedure for processing applications for the approval of active substances in the light of experience.

The above was achieved through five plenary meetings and five meetings of each standing BPC WG.

Forum

- Three Forum plenary meetings and 13 Working Group meetings.
- Forum Multi Annual Work Programme 2014–2018.
- Description of enforcement of the PIC Regulation.
- Report on the first phase of third coordinated enforcement project, and prolongation of that project.
- Prioritisation of project proposals and decision that fourth coordinated enforcement project will focus on restrictions.
- Manual for the first pilot project on authorisation.
- Decision on two new pilot projects for 2015.
- Preparation of the Forum Interlinks workshop.
- Updated “Manual of Conclusions”.
- Nine advices of enforceability on proposed restrictions.
- First draft of compendium of analytical methods.
- One stakeholder event with discussion on improvement of cooperation.
- One training event on REACH and CLP for enforcement trainers.
- One training for National Coordinators for the first Forum pilot project on authorisation.
- Contribution to the development of enforcement indicators for REACH and CLP.

2.2. Board of Appeal (Activity 9)

The Board of Appeal (BoA) was established by the REACH Regulation to provide interested parties with the possibility of legal redress. It does this by considering, and deciding on, appeals against certain decisions of the Agency[8]. From September 2013, the BoA also became competent to consider appeals against certain Agency decisions taken under the new Biocidal Products Regulation (BPR).[9]

1. Main achievements in 2014

The number of appeals received in 2014 was broadly in line with expectations, 18 of an expected 20. The appeals received, and decisions made, in 2014 have addressed a variety of issues including SME verification, the language regime adopted by ECHA, data sharing, compliance checks and the first appeals against substance evaluation decisions. All final Board of Appeal decisions and an announcement of every appeal, made in 2014 were published on the Board of Appeal section of the ECHA website.

It should be noted that the number of appeals would have been considerably higher without measures taken by the BoA in the interests of efficiency of the BoA, the ECHA Secretariat and stakeholders to accept collective actions in the form of single appeals against substance evaluation decisions issued to many registrants. In order for such an approach to work, certain conditions have to be met to ensure legally sound decisions are made whilst protecting the rights of the parties. The six substance evaluation cases received in 2014 covered 21 appellants. This approach requires, amongst other considerations, the multiple appellants in an appeal to agree to have a single representative and that the pleas in law, arguments made, and evidence presented applies to all the appellants.

The Board of Appeal adopted a number of important final decisions in 2014. Whilst the Board of Appeal's decisions are case specific, and strictly consider the merits of each case, the findings in these decisions may have implications for both stakeholders and ECHA. The decisions made in these cases provided useful information on certain legal and scientific issues related to the interpretation and implementation of the REACH Regulation: for example, in the three decisions made in 2014 on appeals against ECHA decisions following compliance checks, the extent of the Agency's duty to state reasons (A-006-2012); the respective duties of the registrant and the Agency when proposing and assessing read-across adaptations (A-006-2012); certain issues associated with substance identity (A-008-2012); the distinction between substances and mixtures (A-008-2012); the concept of 'stabiliser' (A-001-2013); and addressing the issue of 'legitimate expectations' (A-001-2013).

Two decisions arising from the SME verification process, clarified amongst other things: the competence of the Board of Appeal to decide on a case where there is a revocation decision following an SME verification (A-002-2013); the language to be used by ECHA in communications with a registrant and in its decisions (A-002-2013); the notification of invoices (A-020-2013); the duty of registrants to act in a diligent and prudent manner in fulfilling its obligations (A-020-2013); and what constitutes an excusable error (A-020-2013).

Notably, the Board adopted two decisions regarding data-sharing issues towards the end of the year. These decisions should be of particular benefit in clarifying certain issues ahead of the 2018 registration deadline. The decision in case A-017-2013 addressed the

[8] REACH Article 91.

[9] BPR Article 77.

principle of every effort as well as addressing when costs might be potentially discriminatory. This decision should help data owners as well as those wanting to share data to better understand what is meant by every effort with regard to ensuring that costs are shared in a fair, transparent and non-discriminatory way. Amongst other things these decisions also clarified: that no decision is required by the Agency to allow a registrant to proceed with the registration of a pre-registered substance in the absence of a full data set, where the data in question are subject to a data-sharing dispute (all in A-005-2013); and the scope of the Agency's examination in data-sharing disputes (A-17-2013).

There were two consistent themes from 2013. The first was the frequency and usefulness of oral hearings. In 2014, two oral hearings were held at the request of one of the parties to an appeal; no hearings were held at the request of the Board of Appeal itself. These hearings continued to be extremely helpful in clarifying aspects of the various cases and were in several cases instrumental in the final decision of the Board of Appeal.

The second consistent theme was the participation of third parties as interveners in appeal cases. However, it should be noted that not only co-registrants or NGOs have made applications to intervene in 2014 but also Member State competent authorities who acted as the evaluating Member State in substance evaluation cases. A Member State competent authority has also applied to intervene in a dossier evaluation case where they will be the evaluating Member State for the same substance. The establishment of a direct interest in the result of the appeal has been an important element in the Board of Appeal's assessment of all applications to intervene.

During 2014, the Board of Appeal and the appeals process were firmly established as being part of the REACH regime and recognised as playing an important role in ensuring that the REACH Regulation is applied in a legally sound way as well as giving stakeholders an independent and impartial route of legal redress. The decisions made by the BoA have helped to clarify grey areas in the interpretation of REACH as well as enabling ECHA's implementation of REACH to be examined in some areas. In nine cases, appeals were withdrawn before the BoA was able to make a decision. In most of these cases, the appellant obtained the redress they sought without a final decision being needed thereby further demonstrating the value of the appeals process to stakeholders.

The Board of Appeal endeavours to make all of its decisions clear, readable and user friendly. However, the Board of Appeal recognises, despite this, that some decisions, due to their scientific and legal complexity, may be long and complex. With this in mind, and in the interest of transparency, summaries of all full and final Board of Appeal decisions are now being published. These summaries are not legally binding but should help stakeholders to understand in a short format the main elements of the decisions taken. In the interests of transparency, once an appeal case is closed, non-confidential versions of procedural decisions (for example, applications to intervene, and confidentiality requests) are also published on the Board of Appeal section of ECHA's website

Whilst no appeals against ECHA decisions made under the Biocidal Products Regulation have been made, the Board of Appeal has continued its activities to be prepared as and when such appeals are made.

In all the appeals decided and handled by the Board of Appeal in 2014, an alternate legally qualified member has been required to participate as a member of the Board cases due to the vacancy of the full time member position. A new legally qualified member was appointed to the Board of Appeal in December 2014.

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 2014	Result in 2014
Percentage of final decisions made within 90 working days of the closure of the written or oral procedure.	90%	100%

3. Main outputs

- 16 final decisions adopted and published online.
- Procedural decisions, as needed, adopted and published online.
- Summaries of closed cases published.

2.3. Communications (Activity 10)

Maintaining the good reputation of the Agency by providing accurate and timely information to duty-holders and the public at large as well as ensuring a balanced presentation of the Agency's work in the specialised and general media is an overriding goal of ECHA's communications activities. External communication is complemented by ECHA's internal communications. Keeping staff fully informed and involved is essential to the successful running of the Agency.

1. Main achievements in 2014

For the first time – and with the support of the accredited stakeholder organisations - ECHA targeted the general public with material highlighting their rights under REACH, notably to ask about dangerous substances in the products they buy. A short consumer-oriented video drove traffic to the upgraded "chemicals in our life" section of the ECHA website. With regard to the website, one of the highlights is the improvement made to the "search for chemicals" functionality, which has received favourable feedback from website users.

The Agency also supported the European Commission in their awareness raising on the deadline for the classification and labelling of mixtures in 2015. In particular, an animated video for awareness raising, an online promotional banner and a variety of online and published materials were produced.

The more than 2 000 multilingual website updates further enriched the scope of information that ECHA provides for duty-holders, with more easily navigable sections, for example, on the authorisation process. Particularly for the benefit of SMEs, the website has turned to structuring information so that it is accessed from a duty-holder's perspective. The new REACH 2018 Registration web pages launched in autumn provide an example of this approach by presenting information according to seven steps to be taken by potential registrants as well as by providing it in three levels of complexity.

ECHA also further expanded its presence in social media, gradually establishing a professional following and providing outreach to individuals who would not normally follow ECHA's news. The bimonthly Newsletter and weekly e-News (sent to over 17 500 subscribers) have continued to grow in quality and reader satisfaction, giving readers what they want and in the readable, easy to digest format that they value.

2. Objectives and indicators

Objectives

1. ECHA's external audiences are communicated with effectively, in 23 EU languages where necessary, and ECHA benefits from an accurate and proportionate media presence.

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

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

Performance indicators and targets

Indicator	Target in 2014	Result in 2014
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	Medium
Level of staff satisfaction with internal communications.	High	High

3. Main outputs

- Coordinated communication activities for specific target groups – small companies, downstream users, consumers, workers, retailers and academia – to raise awareness of their rights, responsibilities and opportunities under the legislation. Some of this work was done jointly with EU partners, Member States and accredited stakeholder organisations.
- Awareness raising for duty-holders under PIC and further targeted information to duty-holders in the biocides sector.
- Website:
    - Search for chemicals improved – made more efficient and user friendly.
    - "Information on chemicals" section revamped.
    - 2 000 updates.
- News: 21 press releases produced and 49 interviews given to journalists. 421 answers to journalists' enquiries provided. One press briefing organised.
- 61 new publications produced.
- 264 pieces of communication published in 23 languages – documents, web pages etc.
- 57 news alerts, weekly e-News bulletins and a bimonthly newsletter produced.
- 1 126 tweets, 51 Facebook posts and 38 LinkedIn posts published.
- Eight webinars and two short videos published – one for the general public and one for companies producing chemical mixtures who need to re-classify and label their products.
- Two Stakeholders' Days, one workshop for accredited stakeholder organisations and one inter-agency workshop on stakeholder engagement held.
- A bimonthly Stakeholder Update published for accredited stakeholder organisations.
- Internal information provided daily for staff on the intranet and internal

information screens. Seven all staff events organised. Corporate intranet site rebuilt and launched.

- Surveys held to gauge satisfaction and to understand stakeholder experience (e.g. stakeholder satisfaction survey, readership survey, website user survey and internal communications survey).

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 exchange with international partners creates synergies not only for authorities but also for European industry.

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

The cooperation in international organisations gives ECHA a recognised role in the field of chemical safety management at a global level, and gives the Agency an opportunity to share its learning with international partners and to learn from them in the fields in which they are more advanced. The Agency's focus is on the development of harmonised guidance, guidelines and 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.

ECHA maintains a constant dialogue with its key regulatory peer agencies in Australia, Canada, Japan and the USA, under the existing cooperation agreements.

1. Main achievements in 2014

In November, ECHA concluded its second project of capacity building on the EU chemicals legislation to beneficiaries of the Instrument for Pre-accession Assistance (IPA) and submitted the proposal of a third project for 2015-17 to the European Commission at the end of the year.

ECHA's technical dialogue on risk management approaches by means of video and telephone conferences with peer agencies, particularly with those of Australia, Canada and the USA, intensified further, enabling the sharing of relevant insights into the assessment of specific chemical substances that benefitted the Agency and its peers.

The Agency continued to explain the issues of relevance related to the EU chemicals legislation to third country audiences. In 2014, awareness raising covered, for example, the 2018 registration and 2015 classification deadline promotion as well as presentations on the SVHC Roadmap and substances in articles. In addition, ECHA shared CLP implementation experiences with Mercosur countries that are implementing the GHS system.

With the OECD, 2014 marked a big progress in specifying and testing IUCLID 6 with the OECD User Group Expert Panel (see Activity 6 for more information). Regarding the OECD QSAR Toolbox, the most recent version was released in November 2014 with new scientific features facilitating the development of justifications for forming chemical categories, thus increasing confidence in the final predictions. Moreover, usability has been improved and new QSARs have been added. Finally, the eChemPortal was also improved in 2014. A new version containing a more advanced search functionality and a major technological update was published. However, the implementation of the GHS search functionality proved more challenging than anticipated and will therefore be released early in 2015. The biocides-related work had to be deprioritised for this reason.

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 REACH and CLP, and supports EU candidate countries and potential candidates within the framework of the IPA programme in an effective and efficient way.

Performance indicators and targets

Indicator	Target in 2014	Result in 2014
Level of satisfaction of the interested parties (including the Commission) with the Agency's international cooperation activities (including scientific and administrative support to the Commission).	High	High

3. Main outputs

- OECD Projects: Endorsement of IUCLID 6 specifications. First release of the next version of the OECD QSAR Toolbox delivered to ECHA and the OECD. eChemPortal release. Publication of the OECD Guidance for characterising oleochemical substances for assessment purposes.
- Scientific and technical support provided to the European Commission in preparation of UN GHS meetings.
- ECHA's second IPA-project provided 18 capacity building activities on the REACH, CLP, Biocidal Products and PIC regulations for the EU candidate countries and potential candidates.
- Technical support was provided to the European Commission in relation to the TTIP negotiations with the USA and on existing bilateral agreements with Japan and Korea with regard to their chemicals component.
- Continued cooperation, including discussions, for example, on evaluation and risk management of chemicals, alternative methods and IT tools, with the regulatory agencies in Australia, Canada, Japan and the USA with whom ECHA has cooperation agreements.
- Four delegations from Asia, Africa and South America visited ECHA.
- ECHA delivered presentations on the EU chemicals legislation in 12 events for third country audiences.

3. Management, Organisation and Resources

3.1. Management (Activity 12)

ECHA is governed by a 36-member Management Board (MB), 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). ECHA utilises 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 2014

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, adopting the budget, and monitoring and reporting on the Agency's achievements and performance.

In 2014, 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, PIC and risk management-related tasks. Furthermore, as a regular member of the Network of EU agencies, ECHA continued to actively supporting this work, in particular in 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 Members of the European Parliament as well as the Director General from the European Commission. Regular liaison with the Parliament ENVI Committee was maintained throughout the year. An exchange of views between the Committee and the ECHA Executive Director was organised in September.

During the year, further attention was paid to strengthening the effectiveness and efficiency of the Agency through different means. The main headline for 2014 was the successful International Organisation for Standardisation (ISO) 9001 certification for "Managing and performing the technical, scientific and administrative aspects of the implementation of the REACH and CLP regulations and developing supporting IT applications". Through an independent body (Lloyd's Register LRQA), the efficiency and adequacy of its REACH and CLP processes were confirmed.

Furthermore, ECHA initiated its corporate-wide efficiency development programme which consolidated its continuous strive for improvement opportunities. The first pilot projects under this programme were successfully initiated and more dedicated activities will carry on in the following years. In addition, audits and consultancies were further performed for specific processes and activities, providing specific recommendations for correcting inefficiencies. During ECHA's annual reviewing and reporting cycle, stakeholder feedback was incorporated in these improvement initiatives. During the year, record management was further improved 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 during multiple internal workshops. The anticipated staff reductions of two percent of Temporary Agents a year until 2018 led to a decision to significantly refocus the Agency's priorities and supporting activities. As a result of these internal discussions, the outlook for ECHA's future was shaped towards a lean public organisation with effective regulatory output yet making use of fit-for-purpose horizontal and administrative support processes. These future staff reductions

risk significantly affecting ECHA's capability to proactively support SMEs and Member States as originally planned. More detailed analysis of these consequences will emerge during the coming years.

During the year, the Agency further ensured compliance with relevant regulations and internal policies, procedures and instructions by performing assurance audits, protecting personal data, 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. The Agency also provided dozens of procedural submissions in defence of its decisions in proceedings at the European General Court, the Court of Justice and the Board of Appeal.

ECHA continued to reply in a timely way to applications submitted on the basis of Regulation (EC) No 1049/2001 on public access to documents. The number of requests was stable but the number of documents and pages increased as the requests mainly concern industry-owned data of a complex scientific nature, requiring a work-intensive consultation 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 "Applications for authorisation" in 2014. Based on the results of the audit, the IAS raised five recommendations. No critical or very important recommendations were issued.

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 2014, the IAC carried out assurance audits on "Confidentiality claim verification" and "Staff training and development" as well as a consultative audit on biocides processes. 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 2014	Result in 2014
Degree of fulfilment of the ISO 9001 requirements for quality management system elements.	95 %	95%
Percentage of very important audit recommendations implemented within the deadline (IAS).	100 %	100%

3. Main outputs

- Four Management Board meetings and corresponding working groups organised to allow the Board to take all necessary decisions.
- One meeting for Member States/MSCA directors organised.
- Strong legal support provided for the drafting of ECHA decisions and for their effective defence.
- All business continuity plans for the critical processes were revised.
- Report of the Security Manager about the evolution of the Agency's security risks proposing an action plan for 2014-2018 produced.
- Efficiency project launched on two processes.
- Waste management procedure in place and an energy audit done as first steps towards implementing an environmental standard.
- The Data Protection register contained 100% of the processing operations involving personal data identified by the Data Protection Officer.
- One meeting of the Security Officers' Network organised.
- 61 initial "access to documents" requests, covering 254 documents (~3 900 pages), two confirmatory "access to documents" requests and one access to own file request answered in accordance with the applicable legislation.
- ISO 9001 certification received.
- Regulatory plans and reports produced.

3.2. Finance, Procurement and Accounting (Activity 13)

The rules governing ECHA's financial management are adopted by the Agency's Management Board after consultation with the European Commission, and must comply with the regulation on the financial rules applicable to the general budget of the Union (Financial Regulation)[10]. The funds of the REACH, Biocidal Products and PIC regulations also have to be separated in the accounts.

1. Main achievements in 2014

The revenue from ECHA's REACH/CLP activities in 2014 amounted to €27.8 million, stemming from fee income on REACH registrations, SME verification work and interest income from reserves. The REACH activities were fully self-financed during 2014.

The revenue under the Biocidal Products Regulation amounted to €7.73 million. This revenue included an EU contribution of €5.064 million, Biocidal Fee revenue of €1.265 million, an EFTA contribution of €0.152 million and a balancing contribution of €1.244 million from the Commission to cover the shortfall in fee income.

ECHA received an EU contribution for the PIC Regulation totalling €1.3 million in 2014. This contribution allowed ECHA to continue the preparatory activities to make sure that the entry into operation of this regulation on 1 March 2014 ran smoothly.

The overall budget implementation at the Agency level met the annual targets for commitments and payments.

The budget execution for REACH/CLP met the 2014 target while the payment execution significantly exceeded the target.

For biocides, execution of commitment appropriations was slightly lower than the target set, but the execution of payment appropriations exceeded the target by far.

For PIC, the execution of commitment appropriations fell slightly short of the target whereas the execution of payment appropriations was on target.

The Agency's cash reserves for the REACH/CLP activities were managed through the European Investment Bank, the Bank of Finland and term deposit accounts, with the continued objective to ensure the safeguarding of the funds and a sufficient risk diversification. At the end of 2014, all cash reserves were held with three different financial institutions. The Agreements with the European Investment Bank (EIB) and Bank of Finland expired at the end of 2014. The reserve assures that ECHA is able to fund its REACH activities well into 2015, although towards the end of 2015 ECHA is expected to enter into a mixed regime of funding with both own income and EU contributions.

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 271 companies. In addition, a further 52 verifications were completed but were put on hold due to the pending administrative charge revision. As a result of this work, a total of €2.2 million of fees and charges were collected during 2014.

In 2014, the Agency also further developed its reporting and streamlined its financial processes.

[10] REACH Article 99.

2. Objectives and indicators

Objectives

1. The Agency has correct, sound and efficient financial management while applicable financial rules and regulations are complied with.

2. Cash reserves are managed prudently and diligently.

3. The Agency has effective financial systems to manage and report on several financially segregated legal bases.

Performance indicators and targets

Indicator	Target in 2014	Result in 2014
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%	97%
Payment rate (of payment appropriations at the end of the year).	80%	87%
Carryover rate (% of committed funds carried over into 2015)	<20%	10%
Cancelled carryover payment appropriations from 2013	<5%	4%
Compliance with MB guidance on cash reserves (MB/62/2010 final).	100%	100%

3. Main outputs

- Rigorous budget and liquidity management.
- Close monitoring and management of Agency's cash reserves.
- Segregation of funds under different legislations.
- 271 verifications of registrants' SME status completed.
- Activity-based expense reporting.
- Follow-up and execution of the budget to reach the targeted commitment rate.
- Annual accounts for 2013 prepared in time.

3.3. Human Resources and Corporate Services (Activity 14)

ECHA has to conduct its activities in compliance with the EU Staff Regulations of officials and the conditions of employment of other servants of the European Communities (Staff Regulation). All ECHA staff must also act in conformity with ECHA's code of good administrative behaviour and with consideration of the public service principles for the EU civil service issued by the European Ombudsman. The ECHA management also has the responsibility to implement an ECHA social and welfare policy and related annual action plans, to safeguard staff welfare.

1. Main achievements in 2014

Human Resources (HR)

In 2014, the recruitment target of the Agency was achieved with 97% of posts filled at the end of the year (for REACH/CLP, biocides and PIC). The turnover of temporary agents remained relatively low at 4.4%. Staff planning exercise is more and more demanding due to the annual post cuts ECHA faces as well as the continuous uncertainties on the biocides area.

In the learning and development area, ECHA started the senior management development programme and continued the Head of Unit and the Team Leader development programme. By the end of 2014, 66 team leaders had been trained. The new learning and development framework was approved at the end of the year and an ECHA level learning and development plan was prepared. A total of 27 in-house scientific training courses, 158 external training missions and 22 organisational development activities were organised. 24 trainees followed the traineeship programme in ECHA during 2014.

An ECHA Corporate Day focusing on customer service was successfully organised in September 2014.

In the career development area, a new internal mobility policy was approved at the beginning of the year to enhance the possibilities for internal mobility and to make the process more dynamic. The scientific competency mapping process implementation started at the end of 2014 where a pilot project of the competency mapping was finalised. The competency mapping will continue in 2015 for all scientific staff. The job screening exercise was also launched at the end of 2014.

In November 2014, ECHA implemented the reclassification exercise for Contract Agents for the first time.

Following the implementation of the harassment prevention policy four more confidential counsellors were appointed and trained during the year.

There is also an ongoing activity on staff welfare and wellbeing including regular liaisons with the European Schooling Helsinki, parents' association of the European Schooling Helsinki and ECHA's Staff Committee.

As part of the management of conflicts of interest, staff members leaving the Agency have to sign a declaration related to post-employment duties. There were 28 staff members who left ECHA in 2014: five of them went to work for other EU institutions, bodies or agencies and one for an inter-governmental organisation. Five staff members left for the private sector. In three of these cases, the Agency saw it necessary to impose specific conditions before authorising the new employment (none of which concerned senior management posts). In the remaining cases (17), the departure was due to the end of contract, unemployment after resignation or retirement. No breach of

trust or disciplinary procedure was initiated in the area of conflict of interest management.

Corporate Services

Execution of maintenance and repair activities by the landlord according to the Refurbishment Plan agreed with ECHA continued in 2014, which included major works such as cleaning and balancing the ventilation system and replacing/renovating the kitchenettes in the different floors of ECHA's premises. Planning and preparatory works on other major activities were also conducted, specifically on the replacement of sewerage and rainwater pipes and the renovation of the façade.

Workspace planning and creation of more workstations with the acquisition of new types of furniture and more efficient use of open space premises were intensified.

In the physical security area, an audit of the current access system was conducted to assess the viability of continuing with the system. The audit report confirms that with some updates and regular maintenance, the system can continue to serve the access control requirements of ECHA within the current lease period. The annual evacuation exercise was conducted. Trainings, primarily for fire wardens, took place, one of which was an advanced course on First Aid.

Upgrades of the meeting rooms and regular maintenance of the Conference facilities were made to ensure efficient technical support of the events organised in ECHA. As in previous years, ECHA continued to host external experts. In 2014, 9 300 came to attend different meetings and events organised in ECHA's conference centre - about 16.3% more than last year's number. (Including all other visitors, the total is 11 166 visitors assisted by our reception services, a 30% increase from last year).

The increasing trend on the use of virtual conferencing and webinars was noted with 469 of those activities supported by Corporate Services, almost 22% more than in 2013 (and a 150% increase since 2010).

To ensure the delivery of good services, the performance of ECHA's travel agency is closely monitored. In this light, in April 2014 ECHA signed a contract with a new travel Agency to ensure efficient delivery of travel services and in accordance to contract.

The physical archiving project progressed considerably in 2014 with the approval of the Archiving Procedure and preparation of the archive rooms. Mail Registration services were enhanced with formalised Working Instructions and trainings for users.

ECHA's library continued to provide services primarily to the operational units with a variety of books and journals as well as access to databases and online subscriptions.

In view of the expiry of the current lease contract at the end of 2019, preparatory actions were taken to ensure a smooth launching of the Building 2020 project, formalised with the approval of the Project Initiation Document.

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 2014	Result in 2014
Percentage of establishment plan posts filled at the end of the year	95%	97%
Turnover of temporary agents.	<5%	4%
Average number of training and development days per staff member.[11]	10	10
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, seconded national experts (SNEs) and trainees (numbering approximately 600 persons overall).
- 22 selection procedures were finalised during the year (18 TA and four CA selection procedures).
- 62 recruitments were completed out of which 34 TAs and 28 CAs.
- Performance appraisal and reclassification exercise for 507 statutory staff.
- Advice and assistance delivered to staff and management on HR matters, in particular on individual rights and wellbeing.
- 2013 Staff Survey results analysed and follow-up plans developed.
- Active development of the people and performance management processes and methods.

Corporate services

- Timely purchase of equipment, materials and services through appropriate procurement procedures.
- Timely calculations and reimbursements of missions and travel reimbursements to meeting participants.
- Secure office facilities.

[11] Including on-the-job training.

- Efficient reception services.
- Good support for meetings and conferences.
- Well-functioning conference facilities with good technical support.
- Efficient mail services.
- Well-organised and correctly managed library and archives.
- Up-to-date and correct inventory of non-IT assets.

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 2014

The main achievement to increase efficiency in administrative processes was the delivery of the Human Resources management system, providing a state of the art solution to manage centrally and efficiently the core administrative functions such as personnel data, staff planning, contracts and individual rights. In 2015, the project will continue with the entry into production of the time administration module, and the training and performance appraisal modules.

The deployment of the Records Management system for the archiving of records – after a pilot was successfully completed in 2013 – was delayed as the document management policies and procedures were revised in the context of preparing for the ISO 9001 certification. The work to deploy IT support to the application of the aforementioned procedures will be resumed in 2015.

The performance and business continuity shortcomings of the legacy Document Management System based on the Microsoft SharePoint platform have been solved with the complete overhaul of the platform, taking advantage of the migration to the 2010 version. The new system includes all technical means for a rigorous implementation of the information management policies in force such as the classification of documents. The project has been a success factor for the achievement of the Integrated Quality Management System (IQMS) objectives. Due to the technical complexity and the workload required to reorganise content according to the agreed classification, few remaining workflows, applications and content still need to be migrated in 2015.

In the area of ICT infrastructure, ECHA has continued its progress on the roadmap for the outsourcing of hosting and application management services.

The management of the production environment of the ePIC submission system was outsourced from the start.

ECHA was able to undertake the previously unplanned work to successfully outsource the remaining onsite datacentre to a state-of-the-art remote datacentre, with no impact to end-users (thereby at the same time proving the resilience of the design). This has also reduced the dependency on the current premises in view of facilitating future decisions on renovations.

Several of the infrastructure services were transitioned to the outsourcer, including the managed services for the core ICT infrastructure and the backup and restore service. At the end of 2014, ECHA no longer relies on a limited pool of staff for the technical delivery of these services, thereby improving business continuity and re-focusing its resources.

An ICT Business Continuity Plan (BCP) was released in accordance with the IQMS of the Agency.

To prepare for the next outsourcing framework contract and support a strategic decision on the future model for sourcing ICT infrastructure capacity which will have to be taken in 2015, ECHA started to investigate an Infrastructure as a Service (IaaS) model which would permit sourcing capacity from a provider, on demand, relinquishing the ownership

of hardware and software. An initial feasibility study was conducted, resulting in a very useful insight into the advantages and criticalities, as well as resource implications, of a transition. Further analysis, also for comparison, will be pursued in 2015.

Ongoing optimisation activities of the existing infrastructure produced several, impactful, enhancements on a range of services:

- a new, more powerful, yet secure solution for teleworking of staff.
- a secure wireless network service (previously very limited and available only in the conference centre).
- optimisation of core infrastructure resources allocation to reclaim capacity and better cope with surging demand.
- a major upgrade of the platform used for incident management by the ECHA Helpdesk, the Helpnet and the internal ICT Helpdesk and facilities services.
- the definition of a centralised identification and users access management was commenced, with the objective to provide more efficient management of internal and external users of ECHA's IT systems and services and much improved auditability of access from the security perspective.

In the context of the asset management policies of ECHA, a secure disposal service for retired IT assets became fully operational addressing the complexity of removing sensitive data form physical devices of different nature.

2. Objectives and indicators

Objectives

1. Supporting ECHA administrative processes and management reporting with the assistance of well-functioning IT tools. 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. An IT Business Continuity Plan adequately covers the mission-critical systems for the new legislations ECHA is in charge of since 2013: biocides, PIC and the upgraded platform for internal document management and collaboration.

Performance indicators and targets

Indicator	Target in 2014	Result in 2014
Availability of mission-critical systems for external customers (i.e. uptime during service hours).	On average 98%	99%
Level of internal user satisfaction with IT services, relative to staff/ support ratio.	High	High
Level of coverage of mission-critical systems in the business continuity solution involving external data centre(s).	Extension to two mission-critical systems: R4BP 3, IT systems for PIC and the platform for	Target achieved

	internal document management and collaboration	

3. Main outputs

- The first modules of the Human Resources management system (HRMS) were launched.
- A totally refactored document management system is in use and facilitates the fulfilment of the internal policies and requirements on document management and control.
- The submission systems R4BP 3, ePIC and the internal document management systems are covered by the IT Business Continuity plan.
- Several outsourcing roadmap milestones have been achieved. The range and depth of services outsourced increased considerably. The secondary data-centre was also outsourced.
- Enhanced and optimised ICT services for staff flexibility and mobility are ready to be launched, in compliance with the internal security requirements.
- The preparation for deciding on the future ICT infrastructure sourcing was commenced and delivered an initial feasibility study.

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 five main risks relating to the Work Programme 2014. The senior management 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 2014, 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.

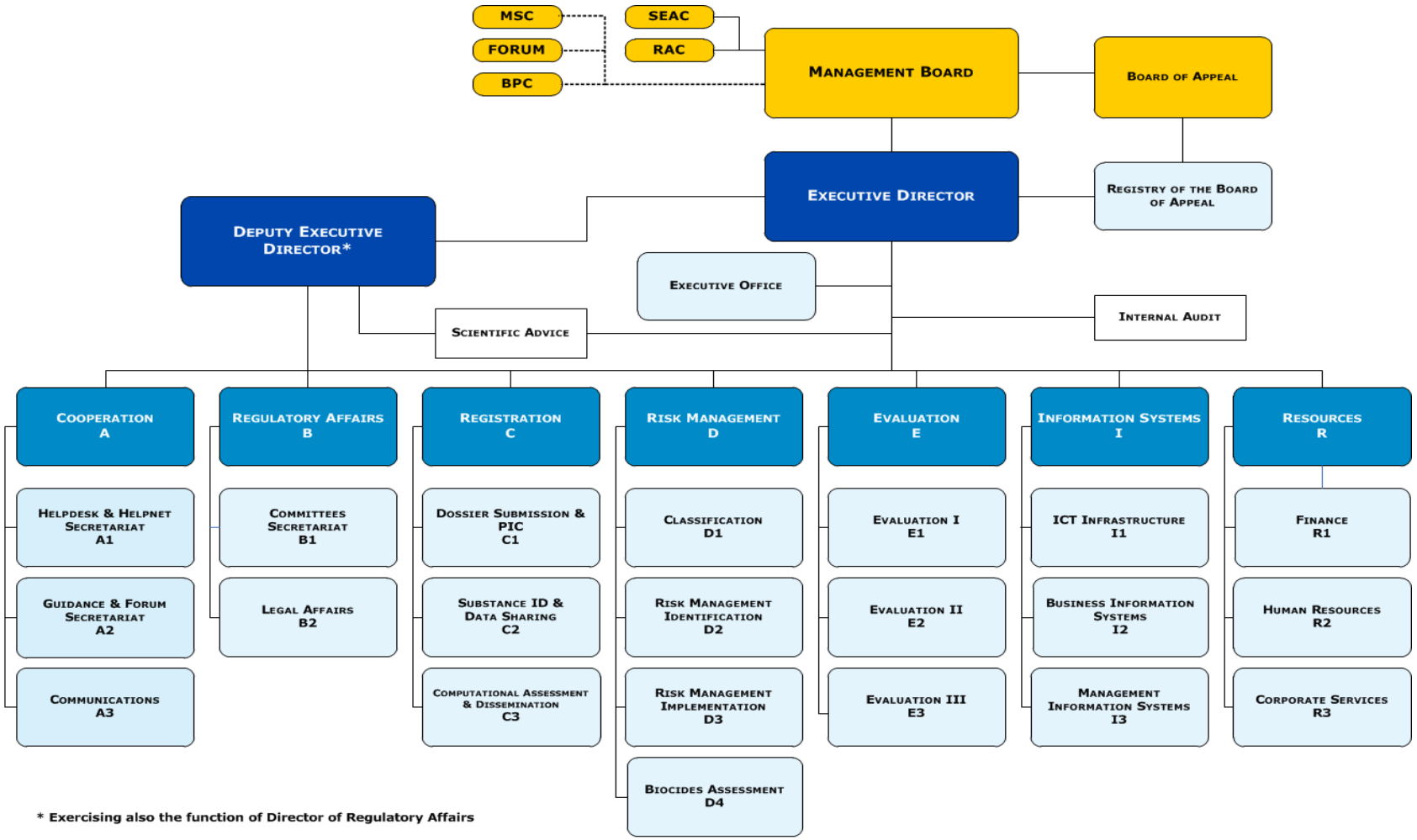
Among the most important actions completed in order to mitigate the biocides and PIC-related risks were a number of IT developments that have ensured the smooth entry into force of the PIC Regulation and smooth functioning of the biocides process. The risks with regard to balancing the uncertain biocides income with the resource needs have been tackled through scenario planning and fall-back plans, however, those still remain high for the coming years. Resource issues in the MSCAs at a time of introducing a new and complex regulation, have resulted in a lower number of adopted opinions under the Review Programme for Biocides (34 out of the initially forecasted 50 opinions were adopted in 2014).

Clear scope management, projects prioritisation and efficiency focus has been the key to handle multiple IT projects in order to avoid causing delays in implementation.

Implementation of the SVHC Roadmap 2020 has progressed in accordance with the plan due to the enhanced cooperation with MSCAs through exposure networks, expert groups and a common screening approach – 87 substances are subject to RMOAs and documented in the Public Activities Coordination Tool (PACT) on ECHA's website.

Increasing the level of security has been achieved by integrating security features into newly developed IT tools, unified solutions for ECHA and MSCAs and proper formalisation.

ANNEX 1: ECHA Organisation 2014



* Exercising also the function of Director of Regulatory Affairs

Members of the Management Board on 31 December 2014

Chair: Nina Cromnier

Member	
Thomas JAKL	Austria
Jean-Roger DREZE	Belgium
Boyko MALINOV	Bulgaria
Bojan VIDOVIĆ	Croatia
Anastassios YIANNAKI	Cyprus
Karel BLAHA	Czech Republic
Henrik Søren LARSEN	Denmark
Aive TELLING	Estonia
Pirkko KIVELÄ	Finland
Catherine MIR	France
Alexander NIES	Germany
Kassandra DIMITRIOU	Greece
Krisztina BIRÓ	Hungary
Sharon MCGUINNESS	Ireland
Antonello LAPALORCIA	Italy
Armands PLATE	Latvia
Marija TERIOSINA	Lithuania
Paul RASQUÉ	Luxembourg
Tristan CAMILLERI	Malta
Jan-Karel KWISTHOUT	Netherlands
Edyta MIĘGOĆ	Poland
Ana Teresa PEREZ	Portugal
Luminiţa TÎRCHILĂ	Romania
Edita NOVAKOVA	Slovakia
Simona FAJFAR	Slovenia
Ana FRESNO RUIZ	Spain
Nina CROMNIER	Sweden
Arwyn DAVIES	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

Krzysztof MARUSZEWSKI	Directorate General Joint Research Centre (JRC)
Hubert MANDERY	European Chemical Industry Council (CEFIC)
Gertraud LAUBER	industriAll
Martin FÜHR	University of Darmstadt

Observers from EEA / EFTA and other countries

Sigurbjörg SÆMUNDSDÓTTIR	Iceland
Henrik ERIKSEN	Norway

Members of the MSC - Member State Committee on 31 December 2014

Chair: Watze DE WOLF

Member	Nominating state
Helmut STESSEL	Austria
Kelly VANDERSTEEN	Belgium
Parvoleta Angelova LULEVA	Bulgaria
Biserka BASTIJANCIC-KOKIC	Croatia
Tasoula KYPRIANIDOU-LEONTIDOU	Cyprus
Pavlina KULHANKOVA	Czech Republic
Henrik TYLE	Denmark
Enda VESKIMÄE	Estonia
Petteri TALASNIEMI	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
Sten FLODSTRÖM	Sweden
Gary DOUGHERTY	United Kingdom

Members of RAC - Committee for Risk Assessment on 31 December 2014

Chair: Tim BOWMER

Member	Nominating state
Christine HÖLZL	Austria
Sonja KAPELARI	Austria
Safia KORATI	Belgium
Veda Marija VARNAI	Croatia
Marian RUCKI	Czech Republic
Andreas KALOGIROU	Cyprus
Frank JENSEN	Denmark
Peter Hammer SØRENSEN	Denmark
Urs SCHLÜTER	Estonia
Riitta LEINONEN	Finland
Tiina SANTONEN	Finland
Elodie PASQUIER	France
Stéphanie VIVIER	France
Norbert RUPPRICH	Germany
Ralf STAHLMANN	Germany
Nikolaos SPETSERIS	Greece
Christina TSITSIMPIKOU	Greece
Anna BIRO	Hungary
Katalin GRUIZ	Hungary
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
Michael NEUMANN	Luxembourg
Hans-Christian STOLZENBERG	Luxembourg
Betty HAKKERT	Netherlands
Marja PRONK	Netherlands
Christine BJØRGE	Norway
Boguslaw BARANSKI	Poland
Slawomir CZERCZAK	Poland
João CARVALHO	Portugal

Radu BRANISTEANU	Romania
Mihaela ILIE	Romania
Anja MENARD SRPČIČ	Slovenia
Agnes SCHULTE	Slovenia
Miguel SOGORB	Spain
José Luis TADEO	Spain
Anne-Lee GUSTAFSON	Sweden
Bert-Ove LUND	Sweden
Stephen DUNGEY	United Kingdom
Andrew SMITH	United Kingdom

Members of SEAC - Committee for Socio-economic Analysis on 31 December 2014

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
Johanna KIISKI	Finland
Jean-Marc BRIGNON	France
Karine FIORE-TARDIEU	France
Franz-Georg SIMON	Germany
Karen THIELE	Germany
Ionna ALEXANDROPOULOU	Greece
Alexandra MEXA	Greece
Endre SCHUCHTÁR	Hungary
Zoltan PALOTAI	Hungary
Marie DALTON	Ireland
Flaviano D'AMICO	Italy
Silvia GRANDI	Italy
Ivars BERGS	Latvia
Jãnis LOČS	Latvia
Ilona GOLOVACIOVA	Lithuania
Tomas SMILGIUS	Lithuania
Cees LUTTIKHUIZEN	Netherlands
Thea Marcelia SLETTEN	Norway
João ALEXANDRE	Portugal
Robert CSERGO	Romania
Janez FURLAN	Slovenia
Karmen KRAJNC	Slovenia

Adolfo NARROS	Spain
Åsa THORS	Sweden
Gary DOUGHERTY	United Kingdom
Stavros GEORGIOU	United Kingdom

Members of BPC – Biocidal Products Committee on 31 December 2014

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
Pierre-Loic BERTAGNA	France
Stefanie JAGER	Germany
Athanassios ZOUNOS	Greece
Klára Mária CZAKÓ	Hungary
John HARRISON	Ireland
Maristella RUBBIANI	Italy
Anta JANTONE	Latvia
Saulius MAJUS	Lithuania
Jeff ZIGRAND	Luxembourg
Ingrid BUSUTTIL	Malta
Maartje NELEMANS	Netherlands
Christian DONS	Norway
Barbara JAWORSKA-LUCZAK	Poland
Ines FILIPA MARTINS DE ALMEIDA	Portugal
Mihaela-Simona DRAGOIU	Romania
Denisa MIKOLASKOVA	Slovak Republic
Vesna TERNIFI	Slovenia
María Luisa GONZÁLEZ MÁRRQUEZ	Spain
Mary IAKOVIDOU	Sweden
Michael COSTIGAN	United Kingdom

Members of the Forum for Exchange of Information on Enforcement on 31 December 2014

Chair: Szilvia DEIM

Member	
Eugen ANWANDER	Austria
Paul CUYPERS	Belgium
Parvoleta LULEVA	Bulgaria
Dubravka Marija KREKOVIC	Croatia
Tasoula KYPRIANIDOU-LEONTIDOU	Cyprus
Oldřich JAROLÍM	Czech Republic
Birte Nielsen BØRGLUM	Denmark
Aljona HONGA	Estonia
Marilla LAHTINEN	Finland
Vincent DESIGNOLLE	France
Katja VOM HOFE	Germany
Eleni FOUFA	Greece
Szilvia DEIM	Hungary
Bergþóra Hlíðkvist SKÚLADÓTTIR	Iceland
Sinead MCMICKAN	Ireland
Mariano ALESSI	Italy
Parsla PALLO	Latvia
Manfred FRICK	Liechtenstein
Otilija GRINCEVIČIŪTĖ	Lithuania
Kim ENGELS	Luxembourg
Shirley MIFSUD	Malta
Jos VAN DEN BERG	Netherlands
Gro HAGEN	Norway
Marta OSÓWNIAK	Poland
Graca BRAVO	Portugal
Mihaela ALBULESCU	Romania
Dušan KOLESAR	Slovakia
Vesna NOVAK	Slovenia
Pablo SÁNCHEZ-PEÑA	Spain
Agneta WESTERBERG	Sweden
Mike POTTS	United Kingdom

ANNEX 2: Baseline assumptions

Main drivers of REACH and CLP activities	Estimate for 2014	Total in 2014	Actual %
Dossiers arriving			
Registration dossiers (including updates)	5 800	9 001	155%
Testing proposals	70	32	46%
Confidentiality requests	250	232	93%
Access to data older than 12 years	270	265	98%
PPORD notifications (including requests for extension)	300	234	78%
Inquiries	1 300	1 000	77%
Data sharing disputes	3	4	133%
Restriction proposals (Annex XV)	8	7	88%
- Out of which restriction proposals developed by ECHA	3	2	67%
Proposals for harmonised classification and labelling (Annex VI of CLP Regulation)	70	44	63%
Proposals for identification as SVHC (Annex XV)[12]	30	14	47%
Authorisation applications	20	19	95%
Alternative name requests	100	28	28%
Substances on the CoRAP to be evaluated in 2014 by Member States	50	51	102%

[12] 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.

Main drivers of REACH and CLP activities	Estimate for 2014	Total in 2014	Actual %
ECHA decisions			
Decisions on dossier and substance evaluation			
- Testing proposals	200	204	102%
- Compliance checks	150	172	115%
- Substance evaluations	35	26	74%
Decisions on data sharing	3	5	167%
Decisions on completeness check (negative, i.e. rejections)	190	59	31%
Decisions on confidentiality requests (negative)	50	67	134%
Decisions on PPORD	40	48	120%
- Requests for further information	30	40	133%
- Imposing conditions	8	1	13%
- Granting extensions	20	7	35%
Decisions on access to documents requests	100	57	57%
Revocations of registration numbers	40	33	83%
SME status rejections	300	88	29%

Main drivers of REACH and CLP activities	Estimate for 2014	Total in 2014	Actual %
Others			
Appeals submitted	20	18	90%
Appeal decisions	15	16	107%
Draft CoRAP for substances subject to evaluation	1	1	100%
Recommendations to the Commission for the Authorisation List	1	0	0%
Questions to be answered (REACH, CLP, BPR and PIC as well as respective IT tools)	6 000	8 406	140%
Dossier evaluation follow-up examinations	300	261	87%
SME status checks	600	271	45%
Management Board meetings	4	4	100%
MSC meetings	6	6	100%
RAC meetings	4	6	150%
SEAC meetings	4	4	100%
Forum meetings	3	3	100%

General enquiries by phone or email	600	2 831	472%
Press enquiries	600	421	70%
Press releases and news alerts	75	78	104%
Recruitment due to turnover	25	13	52%

Main drivers of biocides and PIC activities	Estimate for 2014	Total in 2014	Actual %
Number of active substances to be assessed under the Review Programme	50	15	30%
Number of new active substances to be assessed for applications made before entry into operation	10	2	20%
Applications for new active substance approval	5	10	200%
Applications for renewal or review of active substances	3	2	67%
Applications for Union authorisation	20	0	0%
Applications for active substance suppliers (Article 95)	300	10	3%
Applications for technical equivalence	50	6	12%
Applications for chemical similarity	100	0	0%
Overall number of applications processed	3 000	2 094	70%
SME status checks	30	5	17%
Appeals	3	0	0%
BPC meetings	5	5	100%
BPC WG meetings	26	17	65%
PIC notifications	4 000	4 678	117%
New TA/CA posts to be filled for Biocides	2	2	100%
New TA/CA posts to be filled for PIC	1	1	100%

ANNEX 3: Resources 2014

	REACH						BIOCIDES						PIC						ECHA (Total) Staff Resources 2014				Budget
	AD	AST	CA	Total	Budget	Total Committed	AD	AST	CA	Total	Budget	Total Committed	AD	AST	CA	Total	Budget	Total Committed	AD	AST	CA	Total	Budget
Implementation of the Regulatory Processes (Operational Budget)																							
Activity 1: Registration, Data-sharing and Dissemination	40	10	10	60	9 812 517	9 642 996	2	1	1	4	1 114 913	539 473		1		1	0	111 394	42	12	11	65	10 927 4
Activity 2: Evaluation	75	10	6	91	16 965 628	16 172 135				0	0	0				0	0	0	75	10	6	91	16 965 6
Activity 3: Risk Management	31	4	5	40	7 763 826	6 613 973				0	0	0				0	0	0	31	4	5	40	7 763 8
Activity 4: Classification and Labelling	12	2	2	16	2 834 611	2 493 911				0	0	0				0	0	0	12	2	2	16	2 834 6
Activity 5: Advice and Assistance through Guidance and Helpdesk	17	7	6	30	5 261 671	4 729 465	3		1	4	341 448	586 158				0	13 790	8 028	20	7	7	34	5 616 9
Activity 6: IT Support to Operations	27	8	6	41	19 533 296	18 193 681	2	1	1	4	696 538	668 868	1	1		2	565 979	542 327	30	10	7	47	20 795 8
Activity 7: Scientific Activities and Technical Advice to EU Institutions and Bodies	9	1		10	1 953 329	1 676 180				0	0	0				0	0	0	9	1	0	10	1 953 3
ECHA's Bodies and Supporting Activities				0																			
Activity 8: Committees and Forum	20	7	5	32	6 740 746	6 509 175	4	3		7	1 180 131	1 143 915				0	17 100	17 100	24	10	5	39	7 937 9
Activity 9: Board of Appeal	6	3	2	11	1 974 240	1 749 835				0	138 879	3 844					0	0	6	3	2	11	2 113 1
Activity 10: Communications	9	9	7	25	6 876 981	6 700 075		1	1	2	599 693	419 823				0	45 509	12 362	9	10	8	27	7 522 1
Activity 11: International Cooperation	3			3	856 435	1 894 663				0	0	1 364				0	0	0	3	0	0	3	856 4
Management, Organisation and Resources				0																			
Activity 12: Management	26	16	6	48	9 667 896	8 928 920			1	1	374 464	275 379				0	0	0	26	16	7	49	10 042 3
Activities 13-15: Organisation and Resources (Title II: Infrastructure)	28	44	39	111	17 648 823	16 995 253	2	1	3	6	867 154	809 209		2		2	108 589	207 109	30	47	42	119	18 624 5
Activity 16: Biocides				0		0	18	2	2	22	4 078 974	3 005 712						0	18	2	2	22	4 078 9
Activity 17: PIC				0		0	0	0	0					1	1	2	546 257	296 595	0	1	1	2	546 2
Total	**303**	**121**	**94**	**518**	**107 890 000**	**102 300 261**	**31**	**9**	**10**	**50**	**9 392 194**	**7 453 746**	**1**	**5**	**1**	**7**	**1 297 224**	**1 194 915**	**335**	**135**	**105**	**575**	**118 579 4**
In Establishment Plan:	441	98	539				48	14					6	1					495	113	608		

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

Substances added to the Candidate List in 2014

Substance Name	EC number	CAS number	Date inclusion Candidate List	SVHC scope	Candidate List Decision	Intended by
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	247-384-8	25973-55-1	17/12/2014	PBT (Article 57 d); vPvB (Article 57 e)	ED/108/2014	Germany
2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	223-346-6	3846-71-7	17/12/2014	PBT (Article 57 d); vPvB (Article 57 e)	ED/108/2014	Germany
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate; DOTE	239-622-4	15571-58-1	17/12/2014	Toxic for reproduction (Article 57 c)	ED/108/2014	
Cadmium fluoride	232-222-0	7790-79-6	17/12/2014	Carcinogenic (Article 57a); Mutagenic (Article 57b); Toxic for reproduction (Article 57 c); Equivalent level of concern having probable serious effects to human health (Article 57 f)	ED/108/2014	Sweden
Cadmium sulphate	233-331-6	10124-36-4; 31119-53-6	17/12/2014	Carcinogenic (Article 57a); Mutagenic (Article 57b); Toxic for reproduction (Article 57 c); Equivalent level of concern having probable serious effects to human health (Article 57 f)	ED/108/2014	Sweden
Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (MOTE)	-	-	17/12/2014	Toxic for reproduction (Article 57 c)	ED/108/2014	Austria
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	68515-50-4	16/06/2014	Toxic for reproduction (Article 57 c)	ED/49/2014	Sweden
Cadmium chloride	233-296-7	10108-64-2	16/06/2014	Carcinogenic (Article 57a); Mutagenic (Article 57b); Toxic for reproduction (Article 57 c); Equivalent level of concern having probable serious effects to human health (Article 57 f)	ED/49/2014	Sweden
Perboric acid, sodium salt; sodium perborate	234-390-0; 239-172-9		16/06/2014	Toxic for reproduction (Article 57 c)	ED/49/2014	Denmark
Sodium peroxometaborate	231-556-4	7632-04-4	16/06/2014	Toxic for reproduction (Article 57 c)	ED/49/2014	Denmark

ANNEX 5: Management Board Assessment of the Consolidated Annual Activity Report for 2014

MB/05/2015 final
20/03/2015

ASSESSMENT OF THE CONSOLIDATED ANNUAL ACTIVITY REPORT OF THE AUTHORISING OFFICER FOR THE YEAR 2014

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 2014 adopted by the Management Board at its meeting of September 2013,

Having regard to the Consolidated Annual Activity Report of the Authorising Officer of the European Chemicals Agency for the year 2014 as submitted to the Board on 19 March 2015.

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 45 out of the 50 performance targets set in the Work Programme 2014 were met. Satisfaction was medium in two of the 18 areas measured. Legal deadlines were missed in a handful of cases. More decisions than planned on reprotoxicity were sent for decision to the Commission due to a lack of unanimous agreements in the Member States Committee.

2. Appreciates ECHA's strategic and operational work performed in 2014 and, in particular, the achievements in:

   a. Developing the strategic vision of ECHA 2020 as a lean public organisation fully focused on delivering operational and effective regulatory work in line with its founding legislations, and demonstrating its added value to the European citizens,

   b. Starting the implementation of the first two projects under the Efficiency programme to be able to cope with staff reductions as required from all EU agencies while facing increased workload.

   c. Developing the models and implementing the first measurements of the ECHA's four strategic objectives indicating progress towards their achievement.

   d. Getting certified against ISO 9001:2008 Quality Management Standard.

   e. The smooth entry into operation of PIC in March 2014 and the successful hand over of PIC operations from the Joint Research Centre.

   f. Establishing the 2018 registration deadline roadmap based on an extensive stakeholder consultation and launching the new REACH 2018 webpages designed from a small and medium sized enterprise (SME) point of view.

   g. Continuing to make the information on the chemicals registered or notified publicly available, in particular from all dossiers registered by the 2013 deadline.

   h. Instigating the improvement of substance identification in dossiers via a letter campaign, resulting in a large number of updates, and including the substance identification checks in the Validation Assistant tool.

   i. Promoting the development of best practice on exposure scenarios and aimed at making safety data sheets clearer and understandable by downstream users.

   j. Meeting the annual targets for dossier evaluations, including the conclusion of 224 testing proposals, 283 compliance checks and 282 follow-up evaluations.

   k. Updating the Community rolling action plan for substance evaluation, including 68 new substances for 2014-2016, and preparing the draft of the next Community Rolling Action Plan update with up to 75 newly selected substances for 2015-2016.

   l. Supporting Member States in the evaluations of substances and leading to 24 decisions that received agreement in the Member States Committee and 9 conclusion documents.

   m. Adding 10 Substances of Very High Concern (SVHCs) to the Candidate List bringing the total number of substances on the Candidate List to 161 by the end of the year.

   n. Finalising the fifth recommendation for inclusion of a further five priority substances in the authorisation list and preparing the sixth recommendation.

   o. Continuing the implementation of the SVHC 2020 Roadmap Implementation Plan.

   p. Getting the authorisation process to a cruising speed and successfully processing the applications received, including pre-submission support and improved format of public consultations.

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

   r. Increasing significantly the number of opinions adopted by ECHA Committees: 5 Committee for Risk Assessment (RAC) and 4 Committee for Socio-Economic Analysis (SEAC) opinions on restriction proposals, 51 RAC opinions of on

Harmonised Classification and Labelling proposals and 30 SEAC and RAC opinions on the authorisation applications. Adopting 34 Biocidal Products Committee opinions on applications for approval of active substances under the Review Programme.

s. Maintaining up-to-date the Classification & Labelling inventory with information on 116 000 substances.

t. Supporting industry, in particular SMEs, via targeted communication tools in the form of webinars, targeted materials as well as sector-specific support for example for the essential oil and dye industries, where many SMEs are affected by the upcoming registration deadline.

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

v. Achieving a high rate of budget execution of commitment appropriations and in filling the establishment plan posts for temporary agents, both reaching 97% on average for all Regulations.

3. Notes the continued high quality of the scientific advice provided by the Agency, in particular in relation to the development of test methods, including alternatives of animal testing, chemical safety assessment, nanomaterials, Persistent, Bioaccumulative and Toxic substances, endocrine disruptors and Commission studies on REACH data requirements.

4. Welcomes the Agency's strengthened and continued efforts to improve dossier quality, including the new integrated compliance check strategy, and encouraging registrants to proactively update their dossiers.

5. Welcomes the transparency approach adopted by the Management Board (MB/61/2014), hereby also responding to the European Ombudsman's request.

6. Welcomes the work of the Secretariat in ensuring and improving the functioning of ECHA Committees, and especially in achieving an increased awareness of resource implications of the Committee membership, and concluding on the improvement actions for the restriction process from the specific task force.

7. Welcomes the work of the Forum in harmonising the approach to enforcement, which provides an improved basis for the enforcement of the provisions of REACH, CLP and PIC Regulations, including ECHA's regulatory decisions.

8. Notes the continuing efforts in verifying the SME status of registrants and the Agency's response to the Court of Justice case in this regard.

9. Notes that the appeal system, with 16 closed cases in 2014, provides effective and efficient legal redress to companies. Notes further the importance to integrate the consequences thereof in ECHA's operational activities and being transparent on that.

10. Notes that the Biocides fees were much lower than estimated, thus appreciates the efforts of the Agency to balance the lower income with its expenditure.

11. 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.

12. Notes that the revenue from fees and charges under REACH and CLP activities in 2014 amounted to 26 million euro thus exceeding the forecasts.

13. Congratulates the Agency on reducing its carry-over rate to below 10% on the average for all Regulations and encourages the Agency to continue its efforts to reduce the carry over where possible.

14. Notes 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.

15. Notes the further progress made in implementing risk management 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.
16. Notes the further progress made in the area of fraud prevention by developing the Agency's strategy and action plan as well as in refining its practices on avoiding conflicts of interest.
17. Welcomes that ECHA has taken action on the recommendations of the MB in last year's assessment of the annual report:
    a. New structure for the annual Work Programme 2016 was introduced with a closer link to the Multi-Annual Work Programme.
    b. RAC and SEAC agreed on a streamlined working procedure for developing and agreeing authorisation opinions.
    c. REACH and CLP processes have now been documented and audited. The initiation of the Efficiency programme permitted to identify efficiency and synergy gains.
    d. A simplified guidance in a nutshell document on Scientific Research and Development and Product and Process Orientated Research and Development to support innovation was published.
    e. User-friendliness of dissemination website was improved.
    f. Multi-language approach towards SMEs was initiated.
    g. A proposal made to the Management Board on how to improve substance identity assessment in the completeness check.
    h. Variety of online material relating to the CLP deadline and 2018 registration section was published, benefitting in particular the SMEs.
    i. Using the experience gained in data sharing ECHA reinforced advice to companies in particular SMEs, and released guiding documents on cost sharing and Substance Information Exchange Forum management, and supported the Commission in preparing an implementing act on data sharing under REACH and practical guides on data sharing for Biocides.
    j. Active contribution to the work of the Task Force on simplified approach for special cases by developing simplified formats for the Chemical Safety Report, Analysis of Alternatives and Socio-Economic Analysis thus making the submission of authorisation applications less expensive and lighter for the industry.
18. Recommends that ECHA, while facing resource constraints, in 2015:
    a. Continues active follow up of the implementation of the audit recommendations.
    b. Further promotes the use of multilingual communication in its communication with companies in particular SMEs.
    c. Continues identifying synergies within its activities to support companies to promote competitiveness and innovation, within the Agency's remit.
    d. Continues to support industry to meet their obligations so that substances are safely handled, in particular along the supply chain.
    e. Continues and strengthens its own work to ensure high dossier quality in a cost efficient and effective manner.
    f. Reflects, which further actions would be necessary to contribute to achieving the "REACH 2020 goals".
    g. Supports Member States and encourages them to take up their roles under the legislations and provide adequate resources and expertise.

h. Continues implementation of the efficiency programme.

For the Management Board

The Chair

signed
Nina CROMNIER

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ED-AH-13-101-EN-N - ISBN 978-92-9244-413-6 - ISSN: 1831-7340- doi: 10.2823/80524

Publications Office