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General Report 2013

33rd Meeting of the Management Board 19-20 March 2014

Item	7
Action	For adoption
Status	Final - public

Action requested

The Management Board is invited

- to adopt the General Report of the Agency for 2013, and
- to instruct the Executive Director to submit the document to the Member States, the European Parliament, the Council, the Commission, the European Economic and Social Committee and the Court of Auditors, and to have it published.

Background

1. The Management Board adopts by 30 April each year a report of the Agency for the previous year.[1] To this end, the Executive Director submits each year a draft report covering the activities of the Agency to the Board.

2. This report should include information about the number of registration dossiers received, the number of substances evaluated, the number of applications for authorisation received, the number of proposals for restriction received by the Agency and opined upon, the time taken for completion of the associated procedures, and the substances authorised, dossiers rejected, substances restricted; complaints received and the action taken; an overview of the activities of the Forum.[2]

3. The General Report provides information on achievement of the objectives of the Agency, set in the Work Programme 2013. The results of the Work Programme indicators are presented as well as the main outputs of the Agency. The General Report is prepared in accordance with the principles of Activity Based Management and provides information on the actual allocation of resources for the Activities.

Matters for consideration

The report describes that the Agency achieved to a very high extent the objectives, priorities, and outputs set out in the Work Programme 2013.

In particular, ECHA achieved the following:

- ECHA pursued the four strategic aims set in the 2013-2015 Multi-Annual Work Programme through different Activities.

[1] Article 78(a) of the REACH Regulation (EC) No 1907/2006
[2] Article 83(3) of REACH

- The registration deadline for phase-in substances of 100-1000 tonnes per year passed successfully and about 3000 new substances were registered.
- Special attention was given to Small and Medium-sized Enterprises (SMEs) including proactive phone calls from ECHA staff to help them with the registration process and tools.
- ECHA disseminated all the 2013 deadline relevant dossiers, with the exception of the limited number of those undergoing assessment of confidentiality requests.
- ECHA exceeded the target of checking at least 5% of the highest tonnage bands for compliance.
- The first update to the Community Rolling Action Plan was published with 62 new substances.
- The evaluation of 36 substances included in the first year of the CoRAP (2012-2014) was concluded by the respective evaluating Member States and resulted in draft decisions requesting further information for 32 substances.
- ECHA developed its implementation plan for the EU SVHC Roadmap 2020.
- ECHA received the first eight applications for authorisation covering two different substances (DEHP, DBP) and 17 different specific uses.
- ECHA managed successfully the entry into operation of the Biocidal Product Regulation (BPR) on 1 September.

The Work Programme 2013 contained 55 performance indicators, and the target was met for 44 indicators, exceeded for 8 of them, while for three indicators the target was not met:

- Biocides (activity 16): Project success rate for critical preparatory activities in terms of availability of end products – target 100%, result 90%.
- Percentage of unanimous MSC agreements – target 80 %, result 65 %.
- Degree of fulfilment of the ISO 9001:2008 requirements for quality management system elements – target 80 %, result 75 %.

Attachment:

- Draft ECHA General Report for the year 2013

ECHA
EUROPEAN CHEMICALS AGENCY

General Report 2013

General Report 2013

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European Chemicals Agency

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List of Acronyms

AD	Administrator
AST	Assistant
BPC	Biocidal Products Committee
BPR	Biocidal Products Regulation
C & L	Classification and Labelling
CA	Contract Agent
Chesar	Chemical Safety Assessment and Reporting tool
CLH	Harmonised classification and labelling
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, mutagenic or toxic to reproduction
COM	European Commission
CoRAP	Community rolling action plan
CSA	Chemical safety assessment
CSR	Chemical safety report
DCG	Directors' Contact Group
DNA	Designated national authorities
DNEL	Derived no-effect level
DQA	Dossier Quality Assistant
eChemPortal	OECD Global portal to information on chemical substances
EC	European Commission
ECHA	European Chemicals Agency
EDEXIM	European Database of Export and Import of Dangerous Chemicals
EEA	European Economic Area
EEN	European Enterprise Network
EFSA	European Food Safety Authority
ENES	ECHA-Stakeholder Exchange Network on Exposure Scenarios
ES	Exposure scenario
EU	European Union
FAQ	Frequently asked questions
Forum	Forum for Exchange of Information on Enforcement
HelpNet	REACH and CLP Helpdesk Network
HR	Human Resources
HRMS	Human Resources management system
IPA	Instrument for Pre-Accession Assistance
IQMS	Integrated Quality Management System
ISO	International Organization 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
MB	Management Board
MS	Member State
MSC	Member State Committee
MSCA	Member State competent authority
NEA	National enforcement authority
NGO	Non-governmental organisation
NONS	Notification of new substances
OECD	Organisation for Economic Cooperation and Development
Odyssey	ECHA's tool to support evaluation tasks
PBT	Persistent, bioaccumulative and toxic
PIC	Rotterdam Convention on the Prior Informed Consent Procedure

PPORD	Product and Process Oriented Research and Development
PPP	Plant protection product
PSIS	Pre-submission information session
QObL	Quality Observation Letter
(Q)SAR	(Quantitative) Structure-Activity Relationship
R4BP	Register for Biocidal Products
RAC	Risk Assessment Committee
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REACH-IT	The central IT system providing support for REACH
RIPE	REACH Information Portal for Enforcement
RMOA	Risk Management Option Analysis
SEAC	Socio-Economic Analysis Committee
SME	Small and medium-sized enterprises
SNE	Seconded National Expert
SVHC	Substance of very high concern
TA	Temporary Agent
TP	Testing proposals
UN	United Nations
UN GHS	United Nations Global Harmonised System of classification and labelling of chemicals.
vPvB	Very persistent and very bioaccumulative
WP	Work Programme

FOREWORD BY THE EXECUTIVE DIRECTOR

"The year of data quality"

This report provides information on the work and achievements of ECHA in 2013. It is a lengthy document that follows exactly the structure and content of the Annual Work Programme 2013 reporting what was achieved, which targets were met and the reasons for any shortcomings. It gives a clear picture of all that has been done with the considerable resources that we have at our disposal to impact on the safety of chemicals within the EU. You will find a wealth of information here.

In this foreword, I want to highlight just one specific issue – data quality. The quality of the information provided by companies on the chemical substances they manufacture and import is an essential factor in making sure the objectives of REACH and the other regulations we manage are achieved to protect human health and the environment. ECHA has been critical of the quality of the data provided by companies – from a lack of clarity about the actual chemical identity of the substance in question, through to poorly explained and justified 'read-across' predictions of substance properties from analogue chemicals to reduce costs and animal testing.

My message from 2013 is a positive one, that step-by-step we are seeing improvements in the quality of data. Our initial screening of dossiers submitted for the 2013 registration deadline suggests that these dossiers seem to be of higher quality, in areas that have been subject to targeted actions such as intermediates or substance identity, than the ones submitted in 2010 for the first deadline. I am pleased that the efforts made by ECHA have contributed to this improvement – by improved guidance, workshops for lead registrants, webinars, online materials as well as assistance through our Helpdesk, phone calls, and face-to-face discussions in our Stakeholders' Days. Nevertheless, in the end it is the ever-increasing number of registrants who produce and submit the good-quality dossers that deserve our congratulations.

Moreover, many of the previous registrations submitted for the 2010 deadline have already been improved and will further improve in response to the dossier evaluation decisions sent to registrants. ECHA's newest Evaluation Report shows that after receiving ECHA's evaluation decisions, companies successfully updated two thirds of the dossiers concerned and brought them into compliance. Where companies have failed to do so, national enforcement authorities are stepping in to enforce the decisions.

There is no room for complacency however. By focusing our compliance check capacity on key endpoints and other essential information relevant for the safety of substances and addressing other shortcomings through a variety of other means, we will ultimately be able to ensure the good data quality of the vast majority of registered substances. Note that we have already undertaken compliance checks, partly or completely, for *one third* of the substances registered for the 2010 deadline.

As good quality data is the first strategic objective of ECHA's strategic plan for the coming five years, we want to work together with industry to bring the registration data to a level that instils confidence in all our stakeholders to the benefit of downstream users, workers, consumers and all EU citizens.

I wish you a successful 2014.

Geert Dancet
Executive Director

Presentation of the European Chemicals Agency

Established on 1 June 2007, the European Chemicals Agency (ECHA) is at the centre of the regulatory system for chemicals in the European Union (EU), set out in Regulation (EC) No 1907/2006 of the European Parliament and the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). At the beginning of 2009, REACH was complemented 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). These legislative acts are applicable in all EU Member States without the need for transposition into national law.

The purpose of the REACH system is to ensure a high level of protection of human health and of the environment; to promote alternative methods to animal testing to assess the hazards of chemicals; to facilitate the free circulation of substances within the single market; and to enhance competitiveness and innovation. In practical terms, the new regime is expected to close a knowledge gap in relation to so called “phase-in” substances placed on the European market; to speed up the placing of safe and innovative chemicals on the market; and to make the risk management of these substances more efficient – in particular by shifting the burden of proof for identifying and controlling risks from authorities to companies. The successful implementation of REACH requires a well-functioning Agency, capable of delivering independent and high-quality science-based opinions within strict legal deadlines, as well as ensuring that the operational aspects of the legislation function smoothly. However, the efficient operation of REACH also depends on ECHA’s institutional partners, in particular the Member States of the EU, the European Parliament and the European Commission (“Commission”) on the one hand, and on industry to implement the regulation properly, on the other.

The purpose of the CLP Regulation is to ensure a high level of protection of human health and of the environment, as well as the free movement of substances, mixtures and certain articles, by harmonising the criteria for the classification of substances and mixtures, and the rules on labelling and packaging. The hazardous properties of chemicals include physical hazards as well as hazards to human health and to the environment, including hazards to the ozone layer. Furthermore, the CLP Regulation constitutes an EU contribution to the global harmonisation of criteria for classification and labelling, the latter having been developed within the United Nations (UN GHS).

Both regulations should contribute to the fulfilment of the Strategic Approach to International Chemicals Management (SAICM) adopted on 6 February 2006 in Dubai.

The Regulation (EU) No 528/2012 of the European Parliament and the Council concerning the making available on the market and use of biocidal products (“Biocidal Products Regulation”), which entered into force in July 2012, aims to harmonise the European market for biocidal products and their active substances while providing a high level of protection for humans, animals and the environment. The application of the regulation started in September 2013 and provided new tasks for ECHA in the evaluation of active substance and the authorisation of biocidal products.

The recast PIC Regulation[1], which concerns the export and import of dangerous chemicals, will bring new tasks to ECHA in 2014.

[1] Regulation (EU) 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals (recast).

ECHA's Mission

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

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

ECHA's Vision

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

ECHA's Values

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

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

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

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

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

Main Achievements 2013 – Summary

ECHA pursued the four strategic aims set in the 2013-2015 Multi-Annual Work Programme, and developed further in the 2014-2018 Multi-Annual Work Programme, through a large number of actions under its different activities. The year contained several important milestones namely the second registration deadline under REACH, reaching the first 5 % target for the compliance checks and the entry into operation of the Biocidal Products Regulation.

The registration deadline for phase-in substances manufactured or imported in amounts of 100-1 000 tonnes per year and not previously registered passed successfully and about 3000 new substances were registered. This matched the intentions of the industry even though around 900 of the intended substances were not registered while an additional 800 substances that were not originally intended were registered. ECHA supported the companies in several ways enabling them to submit their registration dossiers in time. Special attention was given to small and medium-sized enterprises (SMEs) including proactive phone calls from ECHA staff to help them with the registration process and tools. Dissemination of information on registered substances remained a high priority for ECHA. In 2013, the Agency managed to disseminate all of the 2013 deadline-relevant dossiers, with the exception of a limited number of those undergoing assessment of confidentiality requests.

The main focus in dossier evaluation was on the compliance check of REACH registrations above 100 tonnes that were submitted for the 2010 registration deadline. ECHA exceeded the target of checking at least 5 % of the highest two tonnage bands for compliance. The vast majority of the dossiers were selected with intelligent IT screening tools for examination of the endpoints that matter most for the safe use of substances. This serves not only to instil confidence in REACH by ensuring coverage of a representative proportion of all registrations, it also contributes to achieving ECHA's strategic objective of maximising the availability of high-quality data enabling the safe manufacture and use of chemicals.

The first update to the Community rolling action plan was published with 62 new substances. The evaluation of 36 substances included in the first year of the CoRAP (2012-2014) was concluded by the respective evaluating Member States and resulted in draft decisions requesting further information for 32 substances.

Based on the EU Roadmap for SVHC identification and implementation of REACH risk management measures to 2020 that was finalised by the Commission, ECHA developed its implementation plan. ECHA redirected existing activities to be in line with the implementation work and initiated some new activities in the field of risk management. ECHA received the first eight applications for authorisation covering two different substances (DEHP and DBP) and 17 different specific uses. The number of restriction proposals and proposals for harmonised classification and labelling, reaching the Committee stage in the process and requiring a scientific opinion, also increased stretching the capacity of RAC and SEAC very much. The Management Board consequently agreed on a set of measures to increase their capacity further so that they would not constitute a bottleneck.

ECHA managed the entry into operation of the Biocidal Products Regulation (BPR) on 1 September successfully, despite the severe constraints in staff resources. The IT tools for Member States and industry were ready as planned. ECHA Helpdesk launched its support in April and the first set of Guidance documents was published. Overall, on the basis of the number of applications received, the start of the BPR has been smooth but

the interest to apply for EU authorisation has been lower than originally estimated.

ECHA has also incorporated most of the recommendations addressed to the Agency in the Commission's "REACH Review"[1] Report into its multi-annual planning. The Agency in particular stepped up its actions vis-à-vis SMEs and has nominated an SME Ambassador as the point of contact for all SME matters. ECHA has also stepped up its scientific and regulatory knowledge building in support of the Commission in particular to further regulate the identification and risk management of nanomaterials and endocrine disruptors.

The austerity measures relating to the EU budget resulted in a first reduction of 1 % of its establishment posts for REACH and CLP activities. In 2013, the reduction was compensated by increasing the number of contract agents. As work volume is expected to increase while further staff reductions are looming in the coming years, ECHA has set up a comprehensive efficiency development programme for 2014-2016.

[1] General Report on REACH, COM (2013)49 final

1. Implementation of the Regulatory Processes

Activity 1: Registration, Data-sharing and Dissemination

Registration is one of the cornerstones of REACH being the first step for ensuring the safe use of chemicals. For registration, companies share data, document the properties and uses of their chemicals and demonstrate that they can be used safely. This work is recorded in the registration dossier submitted to ECHA. The Agency verifies the completeness of the information provided and the payment of the registration fee, before assigning a registration number. Most of the information is then disseminated to the public through ECHA's website and analysed in order to trigger further regulatory action whenever appropriate.

1. Main Achievements in 2013

Registration and dossier submissions

Registration

The year 2013 marked one of the REACH milestones, namely the second registration deadline at the end of May concerning phase-in substances[2] in quantities over 100 tonnes per year. ECHA had carefully prepared for several scenarios based on experience gained in 2010 and feedback received from potential registrants in 2012, and managed to handle the elevated level of activity around the registration deadline smoothly. Altogether, 9 030 registrations were successfully submitted by the 2013 deadline, of which 3 000 dossiers were already received before 2013 (see Table 1.1).

Unlike in 2010, the registration dossiers arrived more steadily towards the final run-up in the last two weeks of May, and the expected peak in March for the lead registrant dossiers did not take place. These registration dossiers covered about 3 000 additional substances, together with around 700 substances that had already been registered by other companies for the previous deadline in 2010. This means that over 7 500 substances have now been registered under REACH, broadly in line with the original estimates of the European Commission. On top of the first-time submissions of registrations, around 7 000 registration updates were received during 2013.

During the run-up to the 2013 registration deadline, ECHA gathered information from pre-registrants in order to gain an understanding on what substances would be registered. This information was published on the ECHA website to provide downstream users with information on the registration of their critical substances. The feedback received from industry indicated that around 3 000 additional substances would be registered by May 2013. Although the final number of registered substances matched with the intentions, around 900 of the intended substances were not registered while an additional 800 substances not originally intended were finally registered. ECHA has not received any concern from industry in relation to those substances not registered. Feedback from lead registrants showed that the main reasons for substances not being registered were, in order of importance, the decision to postpone the registration to the 2018 deadline, the decision to register the substance with a different chemical identifier, and the decision to discontinue supply due to market reasons.

[2] Substances that have been produced and/or placed on the market and not notified under the Directive 67/548/EEC. For an exact definition please refer to Article 3(20) of REACH.

ECHA supported the companies in several ways enabling them to submit their registration dossiers in time. In order to help registrants proactively prepare better quality dossiers, ECHA released a new tool, the Dossier Quality Assistant (DQA) in February 2013. This tool, which is included in the IUCLID Technical Completeness Check (TCC) plug-in – now renamed the Validation Assistant plug-in, is designed to help registrants to detect potential inconsistencies in their registration dossiers and correct their dossiers before submitting or updating them. After the release of the Dossier Quality Assistant, ECHA contacted the known lead registrants of 2013 and urged them to proactively use the tool to improve their substance identification information. In some cases, it could be done in time for the deadline. In addition, two comprehensive webinars on the registration process were given in early 2013, and individual support to 425 companies was provided in the last weeks of May. Special attention was given to small and medium-sized enterprises (SMEs) including proactive phone calls from ECHA staff to help them with the registration process and tools.

ECHA also opened the solutions designed in 2010 by the Directors' Contact Group (DCG)[3] for diligent companies facing unexpected difficulties in their registration. For example, member registrants whose lead registrant was not submitting their dossier in time could present their situation to ECHA. Eighteen companies made initial contact to ECHA on the DCG-related issues, but finally only 10 provided the necessary documentation to support their case. In order to keep the downstream users of chemicals well informed on the registration progress, ECHA regularly published information on the known lead registrants, and also indicated whether a registration dossier had been received for substances intended to be registered.

The verification of the status of companies that had registered as SMEs continued and led to the revocation of registration decisions in 37 cases (cf. Activity 13). This concerned registrants who had incorrectly claimed to be entitled to a fee reduction and did not pay the remaining fee and administrative charge despite reminders. The decisions were replaced with rejections. Considering the particular needs of SMEs, ECHA offered all potential SMEs the possibility to provide further evidence on their size, and many of the lodged appeal cases could be closed because an agreement was reached between ECHA and the companies (see Activity 9). Learning from these cases, ECHA has also taken further precautionary steps to avoid real SMEs facing a revocation of their registrations by a lack of timely reaction to our requests.

In 2013, ECHA continued with the verification of intermediate dossiers with the aim to ensure that these dossiers only cover uses which fulfil the definition for intermediate use and take place under strictly controlled conditions. Priority was given to dossiers of substances of very high concern recommended for inclusion in Annex XIV of REACH or already in Annex XIV. During the calendar year, ECHA sent 25 letters requesting further information (so-called Article 36 letters) and completed the verification process for a number of cases from previous years. ECHA initiated a compliance check, which resulted in a draft decision sent to the registrant, for one case related to a substance in Annex XIV. Lessons learnt from the intermediate verification process are being used to develop a practical guide on registration of intermediates which will be published in 2014.

In relation to the Croatian accession to the European Union in July 2013, in order to ease the Croatian duty-holders' tight submission deadlines, ECHA familiarised them with the IT dossier submission system (REACH-IT) and the dossier preparation tool (IUCLID) by holding two workshops for industry and authorities. By the end of the Croatian pre-

[3] The Directors' Contact Group is composed of Directors of the Commission, ECHA, and industry associations. It was established in early 2010 as a structure to monitor industry's preparedness towards the first registration deadline and to identify solutions when needed to practical problems faced by registrants.

registration period, 24 Croatian companies had managed to pre-register 206 substances. They also submitted 55 registration dossiers.[4]

Computational tools and methods

ECHA increased its capacity to analyse and utilise the databases on substances that it has gathered from registrations and other submissions, such as C&L notifications. This led to the development of algorithms that could be used in the context of both dossier and substance evaluation, as well as in the screening of substances of very high concern. In practice this means that ECHA now has tools in its use for identifying substances for the Community rolling action plan (CoRAP) and the 2020 SVHC Roadmap, and for conducting targeted compliance checks of registration dossiers over the whole database for the areas where risks arising from insufficient information are the greatest (so-called areas of concern). For more information, please refer to Activities 2 and 3 within this Report.

One of the main challenges was to follow-up on the letters sent to registrants of intermediate dossiers with shortcomings, identified through the large-scale screening in autumn 2012. The ECHA action already had a desirable effect in 2012, as more than 90% of the nearly 2400 dossiers found deficient were updated. ECHA screened these updates in 2013, and to a large extent the issues that had triggered ECHA's concerns had been addressed. Furthermore, in 2013 around a hundred of the dossiers were updated to full dossiers, also including non-intermediate uses as revealed by the screening. In other dossiers, the non-intermediate uses were removed to bring the dossiers in line with the legal requirements of REACH. Finally, ECHA conducted the preliminary check of intermediate dossiers submitted for the 2013 deadline, indicating fewer problems than in 2010.

In recognition of the importance of clear and unambiguous substance identity as a starting point for all REACH and CLP processes, algorithms were also developed to screen the registration dossiers for anomalies in substance identity information. These algorithms will be fully capitalised in the upgraded version of the Dossier Quality Assistant to be released in early 2014, and the subsequent screenings of the database. ECHA also made progress in its ability to analyse the chemical safety reports (CSRs) received in text format.

Other types of dossier submissions

With regard to other types of dossiers received under the REACH and CLP Regulation, a steady moderate flow of other submissions were also received for substances in articles notifications (Article 7(2)) and downstream user reports (Article 38). The first applications for authorisation were also received (for more, see Activity 3).

ECHA continued to make efforts to promote the possibility of applying for registration exemptions for substances used in product and process oriented research and development (PPORD), and enhanced the PPORD web section to better support the duty holders. Exemptions are granted for five years, but can be extended by ECHA's decision upon request, provided that adequate justification is given, including why the R&D programme could not be completed within the initial five-year period. The year 2013 saw the first requests for extension corresponding to PPORD exemptions granted in the early months of the REACH operations in 2008. The work performed by ECHA to assess the notifications received since 2008 helped make informed decisions on these requests. Eight requests for PPORD extension were received in 2013. Four resulted in a positive decision and four are still under assessment or consultation with the relevant Member

[4] Of these, 48 were registrations of a substance at or above 1 000 tonnes, two registrations of a substance between 10 and 100 tonnes, and five registrations of an on-site isolated intermediate at or above 10 tonnes.

States.

Another major date of 2013 was the entry into operation of the Biocidal Product Regulation (BPR) on 1 September. In the first half of the year, the preparatory activities for setting the procedures and developing and validating the tools for receiving and processing the biocides dossiers were run in parallel with the registration peak. With a careful planning, this did not create any disruption in either process and ECHA opened access to the Registry for Biocidal Products (R4BP 3) for Member States and the Commission in late August, and the submission portal for industry on 1 September as planned. After that, altogether 1 274 biocides dossiers were received and forwarded to evaluating authorities, demonstrating the successful first steps on implementing the BPR (for more, see Activity 16).

Chemical Safety Assessment (CSA) Development Programme

The year 2013 saw the consolidation for the CSA Development Programme. The programme coordination was enhanced leading to more cohesion between the numerous activities under the programme as well as ECHA's other work. The most visible achievement of the CSA Development Programme was the publication of the CSR/ES Roadmap[5], prepared together with Member State and industry stakeholders. The roadmap reflects the current state-of-the-art in the area of CSRs and exposure scenarios, and sets clear targets for improving them by 2018. The CSR/ES Roadmap will therefore provide an important guideline and conceptual framework in the area of improving information on the safe use of chemicals in the next five years.

In order to enhance the future submission and utilisation of improved use and exposure information by the registrants, ECHA organised a workshop with the Member State authorities to collect input on their needs regarding such information in the context of their regulatory tasks. It was also discussed which of this information should be available for authorities (Member States and ECHA) in a structured format in the IUCLID dossier in order to support mass screening and better use of this information. This work will continue in 2014. ECHA also gained some systematic experience in evaluating CSRs (see Activity 2) leading to the identification of a number of typical shortcomings in dossiers submitted in 2010. This experience can now be fed into updating and expanding the Chemical Safety Assessment and Reporting (Chesar) tool.

ECHA also supported industry-led activities concerning methodologies for converting REACH exposure scenario information into safety advice on mixtures, building harmonised short titles for exposure scenarios, and on developing harmonised formats for improving the information input to consumer exposure assessment under REACH. Two ECHA-Stakeholder Exchange Network on Exposure Scenarios (ENES) plenary meetings were organised over the year (one by ECHA and one by industry) to take stock of the progress made between the meetings. The ENES discussions were consolidated under the CSA Development Programme into a major input for the update of the Guidance for Downstream users (see Activity 5). In addition to the Guidance update, the support for downstream users intensified in the form of regular webinars and the redesign of the downstream user support web section on the ECHA website. Finally, responding to the findings on the formulators of mixtures by the Forum (see Activity 8), ECHA started preparations to provide more support on compiling and understanding (extended) safety data sheets.

All the work done in 2013 to align the different key elements of the chemical safety report (CSR) and exposure scenario (ES) will be used in 2014 to further develop tools

[5] The cross-stakeholder roadmap towards good quality information on the safe use of chemicals in the REACH chemical safety report and the extended safety data sheet. See http://echa.europa.eu/csr-es-roadmap.

such as IUCLID, Chesar, or the ESCom XML, as well as expanding the good practice advice, templates and examples of exposure scenarios in new areas such as the service life of articles.

Data sharing and substance identification

Similar to the 2010 deadline, activities related to data sharing disputes remained relatively low in 2013: ECHA received only 18 disputes for arbitration under REACH; 17 within substance information exchange forums (SIEFs) and one following an inquiry. ECHA issued 11 decisions.[6] Based on its experience of two registration deadlines, ECHA was able to draw conclusions on this process and these learnings will help communicate more targeted advice, especially from the SME perspective. They will also be fed into the preparatory activities for the last registration deadline of the 2018 registration roadmap, which will start in 2014. Concerning data sharing on biocidal dossiers, please refer to Activity 16.

Also similar to 2010, the registration deadline put pressure on the inquiry process aiming to put potential and existing registrants in contact with each other, and there was a clear peak in the second quarter of the year. However, the recent developments in enhancing the process proved to be successful, and ECHA managed to process the received inquiries within its own internal targets.

Discussions on substance identity continued either as part of the above mentioned processes, or with individual duty holders and sectorial organisations throughout the year. These discussions were held with a view to approaching a common understanding on substance identity and substance sameness elements. These issues were also discussed with Member State authorities. Some tangible outcomes are expected in 2014.

Overall, the substance identity activity remained at a very high level due to the inquiry and evaluation activities, where around 2 500 substance identity checks were conducted.

The feasibility study on giving solid regulatory status (i.e. official EC numbers) to chemicals for which ECHA has assigned list numbers was postponed, as resources were targeted at the evaluation activity. The need for this work will be further assessed in 2014.

Dissemination – electronic public access to information

Dissemination of information on registered substances remains a high priority for ECHA. In 2013, the Agency managed to disseminate all the 2013 deadline-relevant dossiers, with the exception of the limited number of those undergoing assessment of confidentiality requests. This means that ECHA now has information on more than 10 000 substances from over 40 000 dossiers online, including an increasing amount of information from dossiers notified under the previous legislation (NONS). With the entry into operation of the BPR, ECHA complemented the dissemination website with information on approved biocidal active substances (53) and authorisations for biocidal products (2 763). In order to help navigation through this vast database, ECHA enhanced its search function. Access via the Organisation for Economic Cooperation and Development (OECD) global portal to information on chemical substances (eChemPortal)

[6] Six decisions in favour of potential registrants and five decisions in favour of the existing registrant. Two disputes were closed without ECHA decision (inadmissible or withdrawn). Five disputes are still being processed and the decisions are due in early 2014. It should be noted that even though some of these disputes were relevant for the 2013 deadline they were submitted only towards the end of the year.

to ECHA's dissemination portal as well as synchronisation between the two was also maintained.

The assessment of confidentiality requests, which are found only in a small portion of dossiers, was enhanced in 2013 by stabilising the process documentation and reviewing the IT workflow. Altogether, ECHA was able to assess nearly 900 requests, including 271 cases where further information supporting the request had been requested from the registrant. All requests submitted in 2012 have been assessed. Overall, 20 % were rejected. The main reasons for rejection were that either the information was already available in the public domain or the justification provided was insufficient. For 160 cases, ECHA has requested further information from the registrant. These cases will be concluded in 2014. All requests submitted in 2013 will be assessed in 2014.

In response to the stakeholder concerns on the dissemination portal, ECHA conducted a comprehensive survey to better understand the existing perception of shortcomings and to collect ideas for improvement. Based on the results, the initial specifications and scoping was done for the development towards the "single point of access" concept to be implemented in the revamped dissemination portal in 2015 (see Activity 6). ECHA also made the first design of the so called "substance brief profile" concept, which compiles key information concerning one substance, including whether it will or has been evaluated or whether it is subject to authorisation or restriction, and displays it in an easily understandable way. The concept was discussed with the industry and non-governmental organisation (NGO) stakeholders in a workshop in December, and the conceptualisation work will continue in 2014.

2. Objectives and Indicators

Objectives

1. All dossiers, inquiries and data sharing disputes undergo the required checks and the respective decisions are given, and confidentiality claims assessed, according to the standard procedures, ensuring 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 an easy access to information from all dossiers of registered substances and C&L notifications within a reasonable time after the registration/submission of notification.

Performance Indicators and Targets

Indicator	Target in 2013	Result in 2013
Percentage of registrations, PPORD notifications processed within the legal timeframe.	100 %	100 %
Percentage of inquiries processed within the internal timeframe (20 working days).	80 %	86 %
Percentage of data sharing disputes	100 %	100 %

processed within the legal/internal timeframe.		
Extent of publication of registration dossiers successfully submitted by the registration deadline of 31 May 2013.	90 %	99 %
Level of satisfaction of interested parties with dissemination, data sharing and dossier submission processes of ECHA.	High	High

3. Main Outputs

Registration and dossier submissions

- 14 839 registration dossiers (including updates) and 299 PPORD notifications (including updates and requests for extension) underwent the decision making process and assigned a registration or PPORD notification number, where relevant.
- 54 decisions on PPORDs.
- Two webinars and individual support for both lead and member registrants.
- Submission tool and internal procedures in place to receive and process biocides dossiers by the end of August.

CSA Programme

- CSR/ES Roadmap published on 17 July 2013. Progress made in the areas of exposure scenario short titles, Specific Consumer Exposure Determinants (SCEDs) and advice on safe use of mixtures as foreseen in the first implementation plan. Two ENES events organised.

Data sharing and substance identification

- 1020 inquiry numbers given. The inquirer has been put in contact with the previous registrant(s) where relevant.
- 13 data sharing disputes resolved (five still on-going).

Dissemination

- 589 new confidentiality requests underwent initial assessment and 271 cases from 2012 underwent final assessment.
- Information from the registration dossiers was published on the ECHA website and linked to the OECD eChemPortal (information from 11 225 dossiers published for the first time).

Table 1.1: Outcome of the 2013 registration deadline

Summary for the 2013 deadline	
Number of registrations (dossiers)	9 030
Registrations received in 2013	*6 421*
Number of registrants (companies)	3 188
SME registrants	1 077

The tables below relate solely to the dossiers (initial or updates) received in 2013.

Table 1.2: Number of dossiers (including updates) submitted (input) in 2013 as compared to the workload estimates in the Work Programme 2013

Dossier type	Actual	WP 2013 estimates
Registrations	14 839	15 200
Full registrations	12 353	-
Transported Isolated Intermediates	1 936	-
Onsite Isolated Intermediates	550	-
Other types of dossiers		
PPORD notifications	299	400
Inquiries (including updates)	1 903	1 200*
Notifications under Article 7(2)	62	70
DU reports under Article 38	78	400
Alternative chemical names requests under CLP Article 24	38	150
Applications for Authorisation	13	20

*The estimate was made for initial inquiries only.

Table 1.3: Dossier types of **new** registrations in 2013

	Total	Non Phase-in	Phase-in	
			Total	*For 2013 deadline*
Registrations	8 457	323	8 152	5 476
Transported Isolated Intermediates	1 298	176	1 122	776
Onsite Isolated Intermediates	296	74	222	169
Total	10 069	573	9 496	6 421

Table 1.4: Company sizes of the registrants submitting **new** registrations in 2013

Total	Large	Medium	Small	Micro
10 069	79.2 %	11.8 %	5.6 %	3.4 %

Table 1.5: Dossier types of registration updates in 2013

	Total	Non Phase-in	Phase-in	NONS
Full registrations	3 881	214	3 368	299
Transported Isolated Intermediates	997	94	832	71
Onsite Isolated Intermediates	419	13	404	2
Total	5 297	321	4 604	372

Table 1.6: Update types of registration dossiers updated in 2013

	Total	REACH	NONS
Updates following regulatory communication*	6 %	6 %	0 %
Spontaneous updates**	94 %	87 %	7 %
Total	100 %	93 %	7 %

***Regulatory communication includes evaluation decisions and communication further to a confidentiality request assessment

****This includes updates further to the screening of intermediate dossiers

Table 1.7: Main reasons identified for spontaneous updates in 2013

	REACH	NONS
Change in classification and labelling	8 %	14 %
Change in composition of the substance	3 %	2 %
Change in the access granted to information	1 %	1 %
Change in tonnage band	12 %	34 %
New identified uses	7 %	7 %
New knowledge of the risks for human health and/or environment	4 %	4 %
New or update of CSR and guidance on safe use	20 %	4 %
Other	45 %	34 %

Activity 2: Evaluation

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

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

1. Main Achievements in 2013

Dossier evaluation

In 2013, the main focus of dossier evaluation was on the compliance check of REACH registrations that were submitted by the 2010 registration deadline. ECHA had committed itself to check at least 5% of those highest tonnage band dossiers for compliance by the end of the year. This target was fully met and even exceeded. The 5 % target - as prescribed in Article 41(5) of REACH - serves not only to instil confidence in REACH by ensuring coverage of a proportion of all registrations, it also contributes to achieving ECHA's strategic objective of maximising the availability of high-quality data enabling safe manufacture and use of chemicals.

ECHA selected dossiers for overall compliance checks that cover elements necessary for safe use throughout a dossier. For these extensive checks, ECHA either picked dossiers randomly or through concern-driven criteria. Furthermore, ECHA also performed targeted compliance checks. For this targeting, ECHA used intelligent selection strategies to screen its database of registration dossiers, with the focus on those aspects of the dossier that are most relevant for the safe use. Examples of dossiers that were selected for particular concerns are those that contain a large number of adaptations to the standard testing regime or that apply many read-across approaches for higher-tier endpoints. In targeted compliance checks, ECHA focused on specific parts of the selected dossiers, for example, on substance identity issues, on endpoints that were considered highly relevant to risk management and chemical safety, or on substances that may be subject to substance evaluation soon (CoRAP substances, see under 'Substance evaluation' in the section below).

In 2013 ECHA significantly increased the overall efficiency of the evaluation process as can be seen from Table 2.1 providing an overview of the main dossier evaluation output. A total of 928 compliance checks were concluded in 2013, leading to 566 draft decisions. In 2013 39% of all compliance checks were concluded without requests for further information while 61% triggered ECHA to send a draft decision to the registrant. The high percentage of cases requiring action is largely explained by the fact that 90% of the dossiers were selected for compliance check based on already identified concern.

Altogether, by the end of 2013 ECHA had checked at least partially 1 130 dossiers submitted for the 2010 registration deadline for compliance. Over a third of substances registered for that deadline were covered by these checks.

Furthermore, ECHA concluded 55 new testing proposal examinations: a total of 46 draft decisions were sent to the registrants whereas nine testing proposals examinations were terminated. At the same time, ECHA further processed draft decisions on those testing proposals that were sent to registrants by the end of 2012 and of the on-going compliance checks. The decision making process involved interactions with registrants, Member State competent authorities and – in the case of proposals for amendments to the draft decision – the Member State Committee. In total, 111 final decisions on testing proposals as well as 159 final decisions on compliance checks were processed through the decision making process and sent to the registrants. Concerning 61 dossiers registered by the 2010 deadline, decisions on testing proposals could not be adopted due to either pending issues on substance identity or the registrants' significantly revised testing plans for large categories of substances which in some cases also involved substances registered only in 2013. The new testing proposals stemming from the 2013 registration deadline were analysed and grouped for efficient processing in 2014-2016.

Follow-up to Dossier evaluation

In 2013, ECHA implemented the approach for the follow-up of dossier evaluation decisions developed in 2012. The objective of the follow-up is to evaluate whether the new information provided by the registrant complies with the requirements imposed in ECHA's decision. In 76 % of the cases where the deadline in the decision passed in 2013, the follow-up evaluation was concluded within six months after the deadline. ECHA conducted 222 follow-up evaluations on dossier evaluation decisions. In total 147 'Art 42(2) notifications' were sent stating that the dossier evaluation for the respective decisions had been completed, i.e. the information requested was received. In 32 cases the Member States were informed that the information requested had not been received by the decision deadline and that enforcement measures may have to be considered by the national enforcement authorities. Six of these cases are now considered to be complete after a new update has been received and evaluated. For 43 cases, the information requested was received, but the updated dossiers caused other concerns regarding the same information requirement and ECHA initiated a new dossier evaluation decision pursuant to Article 42(1) of REACH. In addition, ECHA conducted follow-up evaluations on 80 Quality Observation Letters (QObLs). In 57 cases, the QObLs resulted in an improvement of the dossier quality either by fully (38 cases) or partly (19 cases) addressing the quality observation; in 17 cases the quality observations were not addressed at all. In six cases the registrants ceased manufacture.

Further general advice to registrants regarding evaluation issues was provided in 2013 through i.e. webinars supporting the targeted compliance checks and lead registrant workshops. In the annual progress report on REACH evaluation for 2012, published on ECHA's website in February 2013, detailed recommendations were provided to registrants, mainly focusing on substance identity and justifications for adaptation of information requirements. The report and its layman's version also serve as a general communication to industry and other stakeholders on evaluation findings. ECHA also initiated the statistical data analysis in view of the publication of the second report under Article 117(3) on the use of alternative methods for vertebrate testing.

Substance evaluation Community rolling action plan

In March 2013, ECHA published the first update to the Community rolling action plan covering 2013–2015, with an amendment later in the year to include one substance that should be urgently evaluated. The CoRAP (2013-2015) contains 115 substances: 53 substances already included in the first CoRAP (2012–2014) and 62 newly allocated substances. The substances were distributed for evaluation in 2013, 2014 and 2015 among 22 Member States

The Member States and ECHA screened registration dossiers to select substances to be included in the draft CoRAP update for 2014-2016. The focus was 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. This draft CoRAP (2014-2016) was submitted to the Member States and the ECHA Member State Committee and published in November 2013 with a view to having the update of the CoRAP adopted in March 2014.

Substance evaluation process

The evaluation of 36 substances included in the first year of the CoRAP (2012-2014) was concluded by the respective evaluating Member States by 28 February 2013 and resulted in draft decisions requesting further information for 32 substances. The evaluation of four substances was concluded without a need to request further information. ECHA screened the draft decisions for consistency to ensure a harmonised approach in requesting further information among the evaluating Member States. After receipt of the registrants' comments draft decisions of 23 substances were notified to all other Member State competent authorities and ECHA for consultation.

By the end of 2013, draft decisions were agreed at the Member State Committee for 14 substances. Two agreed decisions were sent by ECHA to the registrants concerned, decisions for the remaining 12 substances were under finalisation by evaluating Member State or ECHA at the end of the year. On its website, ECHA also published the conclusion documents prepared by the evaluating Member State for the four substances for which there was no draft decision.

In parallel to the decision making process for the substances listed for 2012 in CoRAP (2012-2104), 47 substances on CoRAP (2013-2015) were subject to evaluation in 2013. For those substances, ECHA provided aggregated datasets on the dossiers to be evaluated, templates of outcome documents, a checklist to ensure adherence to the procedure and instructions on drafting substance evaluation decisions.

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. As a result of the workshop, a working group including participants from the Member States, industry associations, the European Commission and ECHA was formed to discuss and propose best practice for evaluating MSCAs and registrants to interact. The MSCAs discussed the proposal in November 2013 with a view to publishing it on ECHA's website at the beginning of 2014.

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.

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

3. All substance evaluations are planned in the CoRAP, prepared and processed

with a high degree of scientific, technical and legal quality according to agreed standard approaches and procedures and within the legal deadlines.

Performance Indicators and Targets

Indicator	Target in 2013	Result in 2013
Percentage of dossier and substance evaluations treated within the legal timeframe.	100 %	100 %
Proportion of compliance checks concluded to reach the 5 % target for the highest tonnage band dossiers submitted by the 2010 deadline.	100 %	114 %
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 %	76 %
Level of satisfaction of MSCAs with ECHA's support for substance evaluation.	High	High

3. Main Outputs

- 928 compliance checks concluded, leading to 566 draft decisions. From the draft decisions prepared in 2012 and 2013, 159 were adopted in 2013 and 121 were terminated after the registrant had successfully updated the dossier.
- 23 non-phase-in testing proposal examinations concluded (nine at draft decision stage).
- 222 follow-up evaluations performed (against minimum 120 planned).
- The first annual update of the CoRAP in March 2013 including 62 new substances. The second draft CoRAP (2014-2016) update submitted to the Member State Committee in October 2013. It included 56 candidate CoRAP substances identified (of which 39 based on ECHA coordinated screening and 17 based on Member States priorities (Article 45(5)).
- Supporting activities for MSCAs performing substance evaluation according to 2013 programme.
- All the service contracts with MSCAs in place by the publication of the first CoRAP update.
- Under substance evaluation: Draft decisions requesting further information on 32 substances produced by the MSCAs and submitted to the decision making process, of which two already concluded in ECHA final decisions. In addition, four conclusions without request for further information.

- Annual evaluation report (Article 54) and related communications.

Table 2.1: Compliance checks (CCH) and testing proposal examinations (TPE) completed or concluded in 2013.

Output	TPEs	CCH
Final decisions issued in 2013	**111**	**159**
Concluded testing proposal examinations / compliance checks	**55**	**928**
Draft decisions sent to the registrants	46	566
Quality observation letters	n/a	1
Termination of testing proposals examination / Compliance check concluded without action	9	361

Activity 3: Risk Management

ECHA's tasks relating to risk management include providing support to the Commission and the Member States in identifying substances for further regulatory risk management, 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 Socio-Economic Analysis Committee (SEAC) for opinion making.

1. Main Achievements in 2013

Screening for Risk Management

The EU Roadmap for SVHC identification and implementation of REACH risk management measures to 2020 was finalised by the Commission in early 2013 and found widespread support at the Competitiveness and Environmental Councils. Based on the outcome of a workshop for Member States and the Commission organised in April, ECHA developed an implementation plan for this roadmap.

This implementation plan sets out:

i) how to identify those substances that raise potential serious concerns to human health or the environment by IT screening of REACH and CLP databases for further scrutiny,
ii) how to generate further information where needed, and
iii) how to identify the most appropriate regulatory action to address the identified concerns by using the risk management option analysis (RMOA).

In addition, the plan includes a commitment for early communication on the roadmap implementation and on the substance-specific activities with the aim to ensure the transparency and predictability of the authorities' work.

Parallel to the finalisation of the SVHC Roadmap implementation plan, ECHA redirected existing activities to be in line with the implementation work and initiated some new activities. These actions include, for instance, developing common screening approaches to serve different REACH and CLP processes, setting up new coordination groups for substance-specific activities and further development of the tools to support the RMO approach. Furthermore, the communication on the roadmap was initiated through a dedicated section on the website and by presenting the implementation plan in a stakeholder workshop organised by the Commission. The practical implementation work carried out by ECHA in 2013 included support to the Commission for the development of RMOAs for the 37 substances which were included in the Candidate List in 2012 at the request of the Commission.

ECHA continued to facilitate the sharing of information between Member States to enhance coordination and cooperation in regulatory risk management. ECHA organised three risk management expert meetings in cooperation with volunteering Member States to enhance the common understanding and information exchange across the regulatory risk management activities and to get the roadmap implementation started. Another example of cooperation is the work of the PBT expert group supporting the screening and assessment of substances with potential PBT properties and developing methods and

guidance for such assessments. A similar expert group has been set up to address substances with endocrine disruption properties and its first meeting will be in early 2014. Moreover, ECHA further developed and kept up-to-date technical tools to share substance specific information.

Identification of SVHCs and Annex XIV recommendations

Based on proposals submitted by the Member States, a total of 13 substances of very high concern were added to the Candidate List in June and December 2013. These included four substances which were identified because there is scientific evidence of probable serious effects to the environment: one on the basis that it degrades to an endocrine disruptor already identified as an SVHC and three due to adverse effects on multiple organs after repeated exposure, in particular on kidney and bone. Furthermore, these new SVHCs included two PBT and/or vPvB (very persistent and very bioaccumulative) substances. By the end of 2013, the total number of SVHC substances included in the Candidate List was 151.

ECHA provided the fourth recommendation for inclusion of priority substances in the Authorisation List to the Commission in January and developed its fifth recommendation on which the Member State Committee (MSC) provided its opinion in December. Inclusion of five substances from the Candidate List was recommended and suggestions for the application and sunset dates were made. The recommendation was supported by the majority of the MSC and takes account, as relevant, of the comments received from interested parties during the public consultation, which took place earlier in the year. ECHA's recommendation, the MSC opinion, including the minority opinion, and all background documentation are publicly available on ECHA's website.

Authorisation applications

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, technical) questions. In total, nine PSISs were held in 2013. ECHA has received very positive feedback on the usefulness of these sessions.

In 2013 ECHA received the first applications for authorisation. A total of eight applications, covering two different substances (DEHP and DBP) and 17 different specific uses were received. All of the received applications passed the business rules and conformity checks. This demonstrates that the applicants have understood and utilised ECHA's instructions well. ECHA successfully launched two public consultations to collect information on the alternatives to the phthalates for which applications were received. In December 2013 RAC and SEAC adopted their opinions on the first application (DEHP, Rolls-Royce plc), well in advance of the legal deadline.

In order to further increase the awareness of the authorisation requirements, ECHA held two seminars for potential applicants in February and June 2013. 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, a successful cooperation was established with the European Aviation Safety Agency (EASA) and the aviation industry on airworthiness and REACH authorisation. ECHA has also collaborated with the European Maritime 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 over 40 new questions and answers on its website.

In 2013, ECHA finalised and adopted all necessary internal quality documents to ensure

the efficient processing of applications. ECHA also increased the capacity of its staff by organising training courses on how to best support the opinion-making process and on the use of the necessary tools to receive and process applications.

Capacity building of ECHA's Committees for Risk Assessment and Socio-economic Analysis, started in 2012, and was continued in 2013. The aim was to clarify some key issues, such as how to assess economic feasibility of alternatives and how to establish the recommendation on the length of a review period. ECHA also set up a working group on how SEAC could better analyse the costs and risk reduction relating to non-threshold substances, such as PBTs and vPvBs. To improve the efficiency of RAC's work and provide guidance for applicants in a transparent manner, RAC has derived "reference derived no-effect levels (DNELs)" for three phthalates (DEHP, DBP and BBP) and has agreed on dose-response relationships for the carcinogenicity of hexavalent chromium substances and inorganic arsenic substances. All this information is available on the dedicated support section on ECHA's website.

Restrictions

Following different requests by the Commission, ECHA worked on the preparation of various new restriction proposals and developed review reports for existing restrictions. A proposal to amend the existing Annex XVII entry for cadmium in paints was submitted in November 2013 and the proposals for amending the chrysotile asbestos entry was prepared with the aim to submit it in January 2014. 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. Work to prepare a restriction for the flame retardant, Decabromodiphenylether (DecaBDE) is ongoing. ECHA also submitted a report (September 2013) to the Commission in advance of a possible request to prepare a restriction on various uses of five cobalt salts.

At the request of the Commission, ECHA reviewed the restriction of the phthalates DINP and DIDP in toys and childcare articles in 2012. This review report was subject to a 12-month long public consultation. Furthermore, ECHA requested a scientific review of its report from RAC which it received in March 2013. Based on this opinion and an extensive consultation with industry and other stakeholders, ECHA finalised its report in August 2013 and sent it to Commission. The report concluded that a risk of mouthing of toys and childcare articles with DINP and DIDP cannot be excluded if the existing restriction were lifted. The Commission and the Members States concluded accordingly in late 2013 and congratulated ECHA for a thorough and transparent scientific review.

In 2013, the Commission proposed a decision on the restriction dossier for chromium (VI) compounds in leather articles and on 1,4-dichlorobenzene in toilet blocks and air fresheners. RAC and SEAC had given opinions on these restrictions and ECHA had forwarded them to the Commission in 2012 and 2013. ECHA provided technical support to the Commission during this adoption process.

In summer 2013, ECHA published the Annex XVII entries in a user-friendly table format on its website which allows interested parties to quickly check if their substance is included in the annex, provides links to the consolidated text and annexes of the regulation as well as to the respective Q&As that have been developed for specific entries. In addition, together with the Forum for Exchange of Information on Enforcement (Forum) and Helpdesk, ECHA identified some further needs to clarify the restriction entries.

Together with the Commission, ECHA initiated a project on how to improve the efficiency

of the restriction process in late 2013. The work started with a survey of MSs, RAC and SEAC and stakeholders to identify the possibilities for further improving efficiency.

Other activities related to risk management

ECHA continued to raise awareness of importers and producers of articles on their obligations to notify to ECHA the presence of Candidate List substances in their articles to ECHA. Furthermore, ECHA performed a survey to summarise the activities Member States have carried out and plan to initiate with regard to the obligations on substances in articles with the aim to support the identification and initiation of any complementary or joint activities. The survey demonstrated that the level of activity and types of activities vary among the Member States and that the available resources currently do not allow further joint activities.

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 states has progressed, although delays were experienced so that results will only be available in 2014. A report on the costs of substitution was published (May 2013) and the results were presented and discussed at SEAC. A small survey of applicants for authorisation was undertaken (summer 2013) to obtain the first estimates of the costs of preparing applications, and this survey is being developed to become a routine part of the application for authorisation process. ECHA also co-founded the Network of REACH SEA and Analysis of Alternatives Practitioners (NeRSAP), an informal network for those involved in undertaking practical SEA work to come together and discuss methodological and practical issues and problems. The first meeting was held in Brussels in April 2013.

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 2013	Result in 2013
Percentage of registered substances preliminary screened for further	25 %	>25 %[7]

[7] This percentage is calculated based on the numbers of substances in the following lists: screening of the full registration database (excluding 2013 registration deadline) and identification of potential CMRs (cat1A/1B) for further regulatory risk management. In addition the registration status of a list of potential SVHCs (endocrine disrupters, substances classified as respiratory and skin sensitisers listed in Annex VI to the CLP) have been investigated for potential further regulatory risk management.

regulatory risk management.		
Percentage of SVHC dossiers treated within the legal timeframe.	100 %	100 %
Percentage of restriction dossiers treated within the legal timeframe.	100 %	100 %
Percentage of applications for authorisation treated within the legal timeframe.	100 %	100 %
Level of satisfaction of the Commission, MSCAs, ECHA Committees and other interested parties with the quality of the scientific, technical and administrative support provided.	High	High

3. Main Outputs

- SVHC Roadmap implementation plan finalised.
- Provided the Commission and Member States several analyses of the registered substances to support the identification of substances that need further information gathering and/or regulatory risk management.
- Three meetings of risk management experts organised in cooperation with Member States.
- Three meetings of the PBT Expert Group organised.
- Established two updates of the Candidate List with new SVHCs in June and December 2013, now including 151 entries.
- Prepared ECHA's fifth recommendation to include five SVHCs from the Candidate List in Annex XIV (Authorisation List).
- Provided timely support, of a high scientific quality, to the RAC and SEAC and its rapporteurs for their development of opinions on restriction proposals and applications for authorisation.
- Provided a proposal for the definition of "prolonged contact with the skin" in relation to nickel restriction to the Commission.
- Provided a preliminary investigation into the conditions of use of five cobalt salts to the Commission.
- Two seminars organised on applications for authorisation for industry and other interested parties.
- Finalised and adopted internal quality documents on applications for authorisation.
- Published over 40 questions and answers on authorisation and two notes to clarify the assessment of economic feasibility and the duration of a review period on the ECHA website.
- Published "reference DNELs" for three phthalates (DEHP, DBP and BBP) and dose-response relationships for the carcinogenicity of hexavalent chromium substances and of inorganic arsenic substances on the ECHA website.

Table: Key statistics on applications for authorisation

	Received notifications	Pre-submission information sessions held	Received[1] applications	'Uses applied for'	RAC-SEAC opinions[2]
Total	11	9	8	17	1

*) Situation as of 8 January 2014.

[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.

Activity 4: Classification and Labelling (C&L)

Classification reflects the hazards of chemicals and labelling helps ensure that substances and mixtures are manufactured, used, transported and disposed of safely. Classification defines the first level of risk management measures that companies need to implement and therefore plays an important role in developing the exposure scenarios which need to be communicated down the supply chain. Classification for several hazards may have legal consequences in the context of several directives and regulations.

1. Main Achievements in 2013

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 2013, Member State competent authorities submitted 28 CLH proposals and additionally one proposal from industry was received. For 40 substances, a public consultation was completed. The number of proposals in the process however is considerable larger (about 100). About 40 % concerns dossiers to be resubmitted to ECHA after failing an accordance check due to shortcomings in the proposal. ECHA organised a workshop for dossier submitters with the aim to establish how the Agency could best support Member States and industry to draft high quality proposals for CLH. Based on the results of this workshop, the support to dossier submitters was increased. The number of dossiers being reworked by Member States reduced from 59 in 2012 to 42 by the end of 2013.

ECHA provided extensive support to the RAC rapporteurs in developing opinions and scientific background documents on 34 proposals for a harmonised classification and three opinions following requests according to REACH, Article 77(3)(c). With the support of ECHA dossier managers, a review of an earlier classification of gallium arsenide requested by the Commission could be concluded.

With the increasing workload of the RAC and its rapporteurs, the support of the scientific dossier managers (SDMs) is becoming more important for the quality and consistency of opinions. Not only the number of dossiers is growing, but the focus is also increasingly on complex hazard classes (such as carcinogenicity, mutagenicity, reproductive toxicity, and respiratory sensitisation). 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. As about 70 % of the proposals for CLH concern such active substances, this has a major impact on the overall opinion development work for both ECHA and RAC. In cooperation with the European Food Safety Authority (EFSA), ECHA adjusted the process of opinion development on classification for PPPs, so that the RAC opinion would be available within the regulatory timeframe for the approval or renewal of PPPs. By using the flexibility in the opinion development process for CLH, alignment of timelines and scientific content was possible.

In 2013, the first RAC opinion on a CLH dossier for a PPP under Regulation (EC) No 1107/2009 was issued.

ECHA took further steps to streamline the process of opinion development by RAC, among others by implementing a policy where handling information becomes available after the public consultation.

Classification and Labelling Inventory (C&L Inventory)

ECHA is required to establish and manage a C&L inventory based on C&L notifications from industry, and it 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).

By the end of 2013, ECHA received over 6.1 million notifications covering about 125 000 distinct substances, of which almost 116 000 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. Every month, roughly 300 new substances are added in the database and, since the launch of the C&L Inventory, an average of about 15 000 updates per month are done. In a workshop with Member States and industry stakeholders, ways to analyse and use these data for identifying substances that could merit a harmonised classification and labelling were discussed.

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. It is to be noted that for about half of the notified substances there is only one notification, which implies that for substances with more notifiers the actual divergence is higher. More uniform self-classifications, explicitly agreed self-classification and clear reasons for any deviating classification, will improve the usefulness of the C&L Inventory, in particular for downstream users and SMEs.

The 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 and registrants on the classification for a particular substance without revealing their identity. However, with only a few communications per month, the current usage of the platform is very low and further actions will need to be taken to enhance the use by the industry actors.

Evaluating requests for the use of 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.

In total, 28 requests were accepted for processing and 26 decisions were completed leading to 11 requests being rejected and 15 accepted.

2. Objectives and Indicators

Objectives

1. All dossiers related to the harmonised C&L process are 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. Any request for the use of an alternative chemical name is processed 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 2013	Result in 2013
Percentage of proposals for Harmonised C&L processed within legal timeframe.	100 %	100 %
Percentage of requests for use of alternative chemical name processed within legal timeframe.	100 %	100 %
Level of satisfaction of the Commission, MSCAs and RAC with the quality of the scientific, technical and administrative support provided.	High	High

3. Main Outputs

- Carried out 31 accordance checks of dossiers containing proposals for harmonised classification and labelling.
- Provided timely support, of a high scientific quality, to the RAC and its rapporteurs for their development of 34 opinions and additionally two opinions on Article 77(c) requests, and of scientific background documents for such proposals.
- Provided support to dossier submitters with the effect of a steep decrease of number of dossiers being reworked by dossier submitters.
- Implemented a process for developing CLH opinions in line with the approval process for active substances in PPPs.
- Included all notifications and updates in the classification and labelling database, with the public C&L Inventory updated accordingly.
- Launched the C&L Platform.
- Concluded 28 dossiers with requests for an alternative name.
- Two successful workshops on improving the CLH proposals and the use of the Inventory.
- Scientific and technical advice for updated guidance on application of CLP criteria and for implementing the fifth GHS revision into the CLP Regulation provided to the Commission.

Activity 5: Advice and assistance through Guidance and Helpdesk

The ECHA Helpdesk gives advice to companies in order for them to prepare high quality dossiers; it clarifies obligations under the REACH, CLP, and Biocidal Products Regulations and provides support to users of the ECHA IT tools, which includes assistance with the submission of dossiers. The network of national REACH, CLP and BPR helpdesks (HelpNet) aims to foster a common understanding of the obligations under these regulations among national helpdesks and thereby harmonise their responses to questions from industry. ECHA manages the HelpNet and chairs the Steering Group. The common objective of the ECHA Helpdesk and the national helpdesks is to support registrants to successfully register and submit their registration dossier.

REACH, CLP and BPR require ECHA to provide technical and scientific guidance and tools for the operation of those regulations for industry, especially SMEs and other interested parties. Furthermore, ECHA must provide assistance to registrants and explanatory information on REACH to other interested parties.

1. Main Achievements in 2013

ECHA Helpdesk and HelpNet

In 2013, the ECHA Helpdesk replied to around 6 000 questions related to BPR, CLP and REACH submitted by individual duty holders (companies). It launched its support on BPR-related issues on 15 April. The ECHA Helpdesk also responded to hundreds of enquiries arising in other contexts, such as from the national helpdesks, webinar Q&A sessions and one-to-one sessions with individual stakeholders at ECHA's Eighth Stakeholders' Day.

One of the big achievements of the year was supporting registrants in meeting the REACH 2013 registration deadline. During the last three months before the deadline, the ECHA Helpdesk provided a special service to duty holders. As the common objective of the ECHA Helpdesk and of national helpdesks was to support registrants to successfully register by submitting their registration dossiers, support to companies in meeting the registration deadline was the predominant topic of the Seventh HelpNet Steering Group meeting in March. Also starting in that month, the ECHA Helpdesk organised regular conference calls with the seven national helpdesks with the highest numbers of expected registrants, keeping them updated with the latest developments and discussing issues related to the deadline.

Managing the network of national REACH and CLP helpdesks (HelpNet) remained a core activity of the ECHA Helpdesk in 2013. This work aimed to ensure that national helpdesks provide harmonised replies to companies and that they remain up-to-date on issues so that they can act effectively as a first point of contact for companies. Through this, the advice and assistance provided to duty holders in all 31 EU and European Economic Area (EEA) countries in which REACH and CLP apply is duly streamlined. To enhance collaboration and the exchange of best practice, the Helpdesk undertook 13 visits to national helpdesks and organised two HelpNet Steering Group meetings.

With regard to the upcoming mixture classification deadline of 2015, a HelpNet Working Group on mixture classification was established in order to identify and provide simpler guidelines to industry. The Eighth HelpNet Steering Group meeting in November focused on exchanging experience and views on supporting small and medium-sized enterprises (SMEs), with various national helpdesk correspondents presenting the outcome of recent related events or of national surveys with SME specificities. One session of this meeting was held together with representatives of the European Enterprise Network (EEN) to

stimulate the outreach of ECHA's and the national helpdesks' support to wider SME audiences.

In accordance with the Biocidal Product Regulation, ECHA is to support national BPR helpdesks. At the Eighth HelpNet Steering Group meeting, helpdesk correspondents agreed to integrate the national BPR helpdesks and other national authorities into its work. Thus, the scope of the HelpNet was expanded to cover the BPR helpdesks, the BPR competent authorities nominated helpdesk correspondents. Over the course of the year, ECHA provided targeted support (namely a workshop and a webinar) to support national helpdesks in their tasks under the BPR, and also kicked off the use of the HelpEx tool for this purpose, so that they could align their responses to difficult BPR questions. The Helpdesk kept the biocides competent authorities up-to-date on these support activities for national BPR helpdesks. New frequently asked questions (FAQs), commonly agreed by the national organisations providing helpdesk support, the European Commission and ECHA were published for CLP, REACH and the BPR.

During the summer, ECHA Helpdesk established a single point of contact and to coordinate the deployment of ECHA's IT systems for biocides. It thus became instrumental in the successful build-up of the prerequisite capacity in the MSCAs to use the ECHA IT systems to implement the BPR. As this work was widely appreciated, in mid-November, the ECHA Helpdesk extended the scope of its activities to provide the support for handling the IT tools delivered to MSCAs, mandated national institutes, designated national authorities and to the services of the European Commission.

Guidance

During the first half of the year, with a view to the 31 May 2013 REACH registration deadline, ECHA – as already for the 2010 deadline – maintained a moratorium on the release of registration-relevant guidance to provide a stable regulatory environment for duty holders to prepare and submit their dossiers. After the end of the moratorium (and already in preparation for the needs of SMEs in particular with a view already to the 2018 Registration deadline), ECHA published several Guidance and quasi-guidance documents on REACH. The Agency continued to provide selected SME-relevant guidance publications in 23 EU languages (since 2013 including Croatian). In particular, ECHA published Guidance on the compilation of Safety Sheets and for Downstream Users, together with related Guidance in a Nutshell pieces, both of which are of particular relevance to SMEs.

ECHA continued to improve the accessibility of guidance for all interested parties by producing and maintaining supportive documentation (Question and Answer pairs i.e. on authorisation, REACH Fact Sheet on the Toll manufacturer, web pages for specific REACH and CLP processes, the REACH Navigator tool, and the REACH terminology database (ECHA-term), guidance documents (i.e. Annex V, Part D of the Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA) and on exposure scenario format in Part D and F of the IR&CSA and several minor corrigenda to other REACH guidance)).

ECHA also addressed urgent needs for major updates of existing CLP guidance. During 2013, the internal preparations for consulting updated PPORD Guidance and new PIC (Prior Informed Consent) Guidance matured to the extent that the respective draft guidance documents could be published at the outset of the following year.

By the end of the year and supported by the Commission, ECHA finalised the first set of guidance documents for the Biocidal Products Regulation (BPR) that entered into operation on 1 September 2013.

A further focus of guidance activities during 2013, beyond the core REACH guidance, was to initiate activities to integrate ECHA's new responsibilities for guidance on BPR and PIC Regulation into ECHA's Consultation Procedure for Guidance.
A second revision to the Consultation Procedure for Guidance (MB/63/2013 final) was endorsed by the ECHA Management Board at its December 2013 meeting. It, *inter alia,* addressed needs to:

- address specific needs with respect to guidance on the BPR and PIC Regulation;
- better distinguish procedures for updates to guidance which is aimed at Member State competent authorities and at ECHA itself from that aimed at industry;
- improve flexibility when replacing guidance documents with web-based information sources – especially for the benefit of small and medium-sized enterprises (SMEs);
- add a formal and transparent procedure for making guidance documents obsolete;
- increase flexibility to allow faster (and/or more efficient and effective) updates to guidance.

2. Objectives and Indicators

Objectives

1. Industry and the Member States receive timely and efficient support from the ECHA Helpdesk, and through high quality guidance documents, to fulfil its obligations under REACH and CLP.

2. Support is provided for the implementation of REACH and CLP in EU/EEA Member States via the training of trainers.

Performance Indicators and Targets

Indicator	Target in 2013	Result in 2013
Percentage of ECHA Helpdesk questions answered within the established timeframe (15 working days).	80 %	94 %
Level of satisfaction of users with quality of ECHA Helpdesk services.	High	High
Percentage of feedback replies provided by ECHA to questions submitted to HelpEx by national helpdesks, within the timeframe set by the originator of the question.	80 %	98 %
Level of satisfaction expressed in feedback from guidance users.	High	High

3. Main Outputs

ECHA Helpdesk

- 5 975 questions dealt with by the ECHA Helpdesk, including questions raised during webinars and one-to-one sessions at ECHA's Stakeholders' Days.
- The national helpdesks posted 85 questions on HelpEx on BPR, CLP and REACH, and the ECHA Helpdesk provided 187 comments to all questions posted.
- The revamp of ECHA's Q&A website to have all Q&As and FAQs available in one site to allow easy access and search functions to industry.
- HelpNet: two meetings of the HelpNet Steering Group, updates of BPR, CLP and REACH FAQs and training events for national BPR, CLP and REACH helpdesks (such as hands-on training, webinars, workshops).
- Support to MSCAs: ECHA provided hands-on training for authorities during the summer, published an MSCA support webinar in October and trained MSCA user administrators on the R4BP3 tool that was being deployed.
- Support to SMEs:
    - Calling companies ahead of the 2013 REACH registration deadline which appeared as SMEs, adapting the Helpdesk's answering strategy by signing replies with staff members' names to enhance the proximity and accessibility by companies;
    - Preparing answers to registered mail letters addressed to the Helpdesk or to some of those addressed to ECHA's SME Ambassador.

Guidance

Finalisation of guidance activities initiated in 2012 (all updates, unless indicated as "new"):

- Guidance on the application of the CLP criteria (second and fourth Adaptation to Technical Progress (ATP) including sensitisation hazards);
- Guidance for Downstream Users;
- Guidance on the compilation of Safety Data Sheets;
- Navigator tool;
- Nutshell Guidance(s):
    - Compilation of Safety Data Sheets;
    - Downstream users;
    - Registration;
- REACH fact sheet on "Toll manufacturer under the REACH regulation";
- Guidance on the Biocidal Product Regulation:
    - Guidance on information requirements (new);
    - Guidance on applications for technical equivalence (new);
    - Regulatory guidance on the Biocidal Products applications (new);
    - Guidance on active substance suppliers (new);
    - Vol. III Human Health, Part B Risk Assessment (new).

Guidance projects that have been initiated and for which draft consultation documents were produced during 2013 (updates, unless indicated as “new”):

- Guidance on the preparation of CLH dossiers (specifications for industry dossier submitters);
- Chapter R.11 (PBT assessment) of the Guidance on information requirements and chemical safety assessment (IR&CSA);
- Part C (PBT assessment) of the Guidance on IR&CSA;
- Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern;
- Chapter R7a of the IR&CSA guidance (section R.7.7.1 related to mutagenicity only).

Corrigenda to the following guidance documents were published during 2013:

- IR&CSA Guidance Chapter R7a (Endpoint specific guidance);
- IR&CSA Guidance Chapter R.20 (Table of Terms);
- Guidance on Registration.

Activity 6: Scientific IT tools

The REACH, CLP and Biocidal Products Regulations impact a significant number of companies – more than 70 000 legal entities are registered in REACH-IT – and require submission, processing and the sharing of enormous amounts of data between industry and authorities. Therefore, ECHA has to be an IT-based agency and timely delivery of fully functional IT systems for industry, Member States and the Agency's own use are the key to ECHA's success.

1. Main Achievements in 2013

Supporting the 2013 REACH deadline

Respecting the six-month moratorium for the changes to the IT systems to be used by industry for submission before the REACH registration deadline in May, some efficiency improvements were implemented in REACH-IT by March for ECHA internal use but this did not have any impact on registrants.

In addition to general business continuity improvements, the operation of REACH-IT was outsourced before the deadline, to secure the necessary IT services also outside of normal ECHA working hours. The application was open for submissions for 24 hours every day from 20 May to 31 May.

Deadline preparations were successful and registrants were able to submit their applications without technical issues.

Pursuing the data integration project towards integrated data and a single point of access for MSCAs

At the end of 2013, ECHA released the final version of a data integration project, launched in 2011, with a view to better integrating data and business applications based on a data integration platform. Using the portal dashboard, competent authority users are able to search and access chemical substances and related information pertaining to all REACH processes through one combined view. The data integration platform will be progressively utilised by several applications, including the new ECHA dissemination portal.

A comprehensive redesign and development of the IUCLID platform – IUCLID 6 – was started in 2013. IUCLID 6 will greatly enhance the functional and non-functional properties of the current IUCLID 5 system, including support for different organisation sizes, improved security, integration with other applications, performance and scalability. The core set of functionality will be delivered at the beginning of 2014, followed by extensive testing, also involving external stakeholders. The release of IUCLID 6 to users outside ECHA is foreseen for early 2016.

Due to the demanding targets set for the delivery of a production ready Register for Biocidal Products (R4BP 3), the work on the new generation of REACH-IT was delayed. ECHA has nevertheless started a major revision of the REACH-IT architecture through analysis and feasibility studies. REACH-IT will be redesigned for faster and more cost effective maintenance through structural changes. Needs for improved usability, especially considering the SMEs, for the 2018 REACH deadline will be taken into account during the development. The improved integration abilities of IUCLID 6 will be utilised in the redesign work. The first components of REACH-IT 3 will be developed in 2014.

CHESAR was further developed during 2013 by releasing a new version in March with an easier generation of exposure scenarios for communication in the supply chain.

Implementing the dissemination roadmap

The dissemination portal was maintained throughout the year by releasing several enhancements and additions to the data provided according to the roadmap. These enhancements include company names, publishing more information from NONS dossiers, search by uses, and publishing of biocidal substances and products. In parallel, an architecture study was conducted and an analysis study started on the redesign of the dissemination system which will enable an integrated view of all the data and information around a chemical substance available in ECHA and not confidential. The revised system will build on the basis of the data integration platform capabilities and utilise the IUCLID 6 integration possibilities.

The C&L Inventory was updated to also cover the Dangerous Substance Directive and Seveso II classifications and translation of the substance names available for CLP Annex VI entries, including in Croatian. A C&L Platform was published in January for registrants and notifiers to help them agree on their C&L entries.

Extending the IT support to ECHA's workflows

The dossier evaluation workflow (DEP) was enhanced with three new releases providing better integration with other IT systems. DEP proved to be a valuable tool to support the evaluation work, enabling the achievement of the 5 % target on the compliance checks for the highest tonnage bands dossiers.

Odyssey, the scientific decision support tool supporting the evaluation work, was improved with two new releases improving the integration with other systems and increasing the scope of application to also support the inquiry assessment. However, the repeated delays and deficient quality of the software received from the contractor led to delays and the need to apply contractual remedies. Further versions have been postponed until 2014.

The Enterprise Content Management (ECM) Programme was pursued with the approval of a new roadmap for the programme including two major initiatives. Firstly, the Records Management project was implemented and is ready to start in production from January 2014. Secondly, a generic case management solution called Dynamic Case V1.0 was designed and progressively developed to provide support for all REACH and CLP related processes. The entry in production for the first processes will be rolled-out in 2014. The integration of ECHA's workflows systems with the external collaboration platform was put on hold. In fact, ECHA analysed several options, among which the reinforcement of the security of the CIRCA-BC currently used platform (owned and maintained by the Commission IT services) and a market tool delivered as a service on the internet offering adequate security features. Before taking a final decision ECHA decided to perform a pilot project initiated in 2013 and spanning into 2014. In fact moving away from CIRCA-BC has implications for the end users and for the Secretariat normally managing the collaboration groups.

Implementing IT systems for Biocides and PIC

For the new Biocidal Product Regulation, ECHA developed R4BP 3, a fully revised version of the R4BP submission system, updated the IUCLID 5 system with the necessary changes for the BPR, migrated 2 396 closed cases from the previous R4BP system, and established security requirements and technical implementation for the remote connectivity of the designated national authorities. In addition, the ECHA dissemination portal was updated to cover the active substances, the biocidal product authorisations and the so-called Article 95 list by the date of entry into operation.

ECHA was able to successfully receive applications under the Biocidal Products Regulation and the national authorities could immediately carry out their tasks in the new system.

The recast PIC Regulation will enter into operation on March 2014. In preparation for this, ECHA has been developing a new system, ePIC, to replace the currently used European Database of Export and Import of Dangerous Chemicals (EDEXIM) submission tool and database. Due to overlapping resource needs for the preparations for the BPR and PIC Regulation, the release of ePIC is scheduled for autumn 2014. Until then, the current EDEXIM system will be used. This approach was agreed with the European Commission and the designated national authorities, and ECHA has been progressing according to this plan in 2013.

Work of the REACH enforcement authorities was supported by three releases (in March, October and December) of the REACH Information Portal for Enforcement (RIPE) portal for enforcement authorities.

2. Objectives and Indicators

Objectives

1. IT systems (particularly IUCLID, CHESAR, REACH-IT and dissemination) adequately support industry and ECHA in processing dossiers for the 2013 REACH deadline and in disseminating the public information.

2. IT systems are adequate to support the first tasks foreseen for ECHA by the entry into operation of the Biocidal Products Regulation.

Performance Indicators and Targets

Indicator	Target in 2013	Result in 2013
Level of satisfaction of external users with the IT tools (IUCLID, REACH-IT, CHESAR and Dissemination).	High	High

3. Main Outputs

- First version of the portal dashboard for MSCAs was released.
- IUCLID 6 architecture design finished and development has progressed according to the project plan.
- REACH-IT redesign started with architecture and analysis studies.
- IT systems and functionalities of R4BP 3, IUCLID and dissemination were in place and operational for the entry into operation of the Biocidal Products Regulation.
- RIPE portal was further developed and three new versions released.
- REACH-IT registration deadline was successfully supported by the appropriate tools: REACH-IT, IUCLID, Chesar and dissemination.
- Preparations for PIC entry into operation in 2014 were progressing according to the plans.
- Compliance check target was successfully supported by appropriate tools: DEP and three new versions of DEP released, as well as two new versions of Odyssey.

- Dynamic Case V1.0 was successfully designed and development has progressed according to the project plan.
- One new version of SVHC workflow tool released.
- Business information systems in production were maintained.

Activity 7: Scientific activities and technical advice to EU Institutions and Bodies

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

1. Main Achievements in 2013

The Agency continued its preparations to implement it third strategic objective, to become a hub for the scientific and regulatory capacity building of Member States, European institutions and other actors, and to use this knowledge to improve the implementation of the chemicals legislation.

ECHA provided scientific input to the development of new OECD test guidelines as well as for alternative testing and assessment methods. ECHA trained both the MSCAs and its own staff on the use and possibilities of the OECD Quantitative Structure-Activity Relationship (QSAR) Toolbox, thus building the capacity of the authorities in the area of QSAR. ECHA also contributed to the OECD Guidance on grouping of chemicals. Internally, ECHA organised itself to efficiently discuss and analyse non-test method approaches as submitted by the registrants, and as presented in the scientific literature. The first trainings on specific software designed for non-test methods were also organised for the staff.

In 2013, ECHA continued to support the Commission on their work on regulatory aspects of nanomaterials and played a catalyst and pro-active role in implementing the various actions on nanomaterials stemming from REACH and CLP. ECHA continued to organise extensive training, for ECHA staff as well as for stakeholders, in the field of nanomaterials. In addition, ECHA started interactions with relevant FP7 research projects, in order to follow the most recent developments in the nanomaterials research.

ECHA participated in the last stages of the NANOSUPPORT project with the Joint Research Centre. The outcome of this project was further used by the Commission in the ongoing impact assessment of possible amendments to the REACH Annexes in relation to nanomaterials. The ECHA Nanomaterials Working Group dealt with recent findings and developments especially in the area of nanomaterials characterisation as well as read across and grouping of nanomaterials. ECHA organised the two final meetings of the Group Assessing Already Registered Nanomaterials (GAARN). The main outcome of GAARN meetings was formulated as best practice recommendations for registrants that were published on the ECHA nanomaterial web page and disseminated through a webinar. Furthermore, ECHA followed the OECD work by active participation in several expert meetings of the Working Party on Manufactured Nanomaterials.

ECHA continued to contribute to ongoing Commission initiatives in relation to endocrine disruptors including the development of horizontal criteria for these substances. ECHA participated and provided expert advice in the *adhoc* meeting of Commission services, EU Agencies and Member States, the Endocrine Disruptors Expert Advisory Group (ED EAG), and the EFSA Scientific Committee Working group on Endocrine Active Substances.

ECHA strengthened its cooperation with the Commission Joint Research Centre through a cooperation agreement, implemented through a collaboration programme. This included

e.g. reports and briefings on selected hazard endpoints on using non-standard data, and cooperation on REACH-relevant integrated approaches to testing and assessment, in particular concerning skin sensitisation.

Furthermore, ECHA analysed the recommendations addressed to ECHA in the Commission Communication following the review of certain elements of REACH. As most of the recommendations were in line with ECHA's own findings in its report on the functioning of REACH and CLP (July 2011), implementation of ECHA's Work Programme 2013 already encompassed many of the actions recommended by the Commission. Where appropriate, ECHA integrated additional follow-up actions when preparing its Multi-Annual Work Programme 2014-2018.

As a new way of working, in May 2013 ECHA organised the first topical scientific workshop to foster dialogue between research and regulatory actors. The theme of this workshop was risk assessment for the sediment compartment. In addition, ECHA was engaged in a newly established sub-group of scientific advisors under the network of EU agencies (involving eight EU agencies and the Chief Scientific Adviser to Commission President Barroso), and prepared for a Memorandum of Understanding between ECHA and European Medicines Agency (with a view to signing the memorandum in 2014).

2. Objectives and Indicators

Objectives

1. ECHA has good capacity to provide scientific and technical advice on the safety of chemicals, including nanomaterials and endocrine disruptors, mixture toxicity, exposure assessment, testing methods and the use of alternative methods.

Performance Indicators and Targets

Indicator	Target in 2013	Result in 2013
Level of satisfaction with the quality of the scientific, technical and administrative support provided to the Commission and MSCAs.	High	High

3. Main Outputs

- Contributions provided for the development of new test methods, mainly through the OECD Test Guidelines Programme.
- Software on non-test methods procured and made accessible, expert knowledge built up by training, practical experience and active exchange with experts outside ECHA. Trainings organised in the field of alternatives to testing for in-house and external experts.
- Webinar on "How to ensure the safe use of nanomaterials under REACH - Part II: Current best practices for human health and environmental hazard assessment for NM".
- Assessing human health and environmental hazards of nanomaterials - Best practice for REACH Registrants published.

- ECHA input to the establishment of a baseline for the purposes of an impact assessment of possible modifications of REACH Annexes for nanomaterials.

- Summary of the main outcomes of the discussions of the Topical Scientific Workshop on Risk Assessment for the Sediment Compartment.

Activity 16: Biocides

The activity 'biocides' covers ECHA's operations under the Biocidal Products Regulation related to the evaluation of active substances, product applications for Union authorisation, as well as the scientific assessments to be performed by the Agency itself under the regulation (applications for technical equivalence, active substance supplier and classification of changes). ECHA not only supports the Biocidal Products Committee to arrive at approvals of substances and products at EU level but also provides the Secretariat for the Coordination Group that deals with disagreements within the mutual recognition process of national authorisations.

1. Main Achievements in 2013

Regulation (EU) No 528/2012 of 22 May 2012 concerning the making available on the market and the use of biocidal products ('the Biocidal Products Regulation' – BPR) entered into operation on 1 September 2013.

During this year preparatory work has continued through the nine biocide implementation projects (BIPs) described below.

Biocide implementation project	Description
BIP 1	Active substance approval
BIP 2	Product authorisations
BIP 3	Technical equivalence and alternative suppliers
BIP 4	Data sharing and dissemination
BIP 5	Biocidal Products Committee and Coordination Group
BIP 6	Guidance, Helpdesk and communication
BIP 7	Finance and HR
BIP 8	Governance and accounting
BIP 9	Biocides IT (including data submissions and invoicing).

The Agency was operational on 1 September 2013 to carry out all tasks conferred on it by the Biocidal Products Regulation (BPR). Due to constraints in human and financial resources ECHA did not manage to finalise all the planned preparatory work which is also reflected in the performance indicator result (90% instead of 100%). However, the necessary procedures, IT systems (IUCLID 5.5 and R4BP 3) and workflows were in place and operational for submission, handling of dossiers, applications for technical equivalence, active substance suppliers and inquiries to share data. In addition, the Biocidal Products Committee with several permanent and *adhoc* working groups was established to start working in 2014. Finalisation of the remaining critical preparatory activities, such as further development of internal procedures, workflows, and additional functionalities for R4BP 3, will be carried out in the first semester of 2014.

The Coordination Group met for the first time in September 2013 and started its actual work in December 2013 following the appointment of contact points, election of an interim Chair and establishment of draft rules of procedure and working procedures.

The handover of the review programme of active substances from the European Commission's Joint Research Centre (JRC) has been completed.

From the entry into operation, the dissemination obligations defined by the BPR have been met with the publication of the following three lists: approved active substances, granted product authorisations by MSCAs as of entry into operation (based on the

information contained in R4BP 2), and the provisional list of active substance suppliers.

Contacts and networks with competent authorities and interested parties have been established in the first Biocides Stakeholders' Day held in ECHA in June. The first dedicated visit to a biocides competent authority took place in December 2013.

Between the entry into operation and the end of the year, one application for the renewal of active substances, four applications for technical equivalence and six applications for active substance suppliers (Article 95) were received. The deadline for reaching a technical equivalence decision being 90 days with the possibility to extend it by the time taken by the applicant to address requests for additional information, the decisions should thus be expected in Q1 or Q2 of 2014. There is no deadline defined in the BPR for the decisions on applications for active substance suppliers; the first decisions can be expected in Q1 or Q2 2014. During the same period, 1 208 applications for the national authorisation of biocidal products (new applications, renewals and mutual recognitions) have been received and forwarded to the relevant competent authorities. Overall, on the basis of the number of applications received, the start of the BPR seems to have been slower than originally estimated but the period since the entry into operations has been too short to be representative and the reliability of the estimates was known to be low.

2. Objectives and Indicators

Objectives

1. Agency is prepared and operational by 1 September 2013 to carry out all tasks conferred on it by the Biocidal Products Regulation.

2. From 1 September 2013, all dossiers are processed according to the standard procedures adopted by ECHA and within the legal deadlines or targets set.

Performance Indicators and Targets

Indicator	Target in 2013	Result in 2013
Project success rate for critical preparatory activities in terms of availability of end products.	100 %	90 %
Percentage of dossiers handled according to standard procedures and legal deadlines.	100 %	100 %
Level of satisfaction with the quality of scientific, technical, and administrative support provided to the members of BPC, Coordination Group (CG), and to the Commission and MSCA's. (also during preparations).	High	High

3. Main Outputs

- The Coordination Group had two meetings since the entry into operation and has started its actual work with the discussion of two mutual recognition disagreements in December 2013.
- The handover of the review programme of active substances from the JRC has been completed.
- Since the entry into operation, ECHA also processed 24 inquiries for data sharing for biocides.
- One data sharing dispute was received towards the end of the year and is under processing, with a decision due early in 2014.

Activity 17: PIC

The Prior Informed Consent procedure (PIC) Regulation implements the international Rotterdam Convention in the EU. It applies to banned or severely restricted chemicals and provides for information exchange mechanisms regarding the export and import of those chemicals. ECHA will manage the practical functioning of the PIC mechanisms and will provide the Commission, upon request, with technical and scientific input and assistance.

1. Main Achievements in 2013

The year 2013 was crucial for getting ready for the entry into operation of the recast PIC Regulation on 1 March 2014. To this end, a project plan was established at the beginning of 2013, addressing recruitment and staff training aspects, procedures and IT development, as well as handover from the Joint Research Centre (JRC).

All stakeholders were kept aware of ECHA's progress and were involved in the decision-making concerning the implementation of the new IT tool (ePIC). Several stakeholders' workshops were organised with representatives from the Commission, designated national authorities (DNAs) and industry. This was to ensure a smooth switch from the existing EDIXIM system to ePIC in late 2014.

ECHA also attended the DNA meetings and reported on progress there. Further handover discussions with the JRC and the Commission were finalised, and at the end of 2013 a set of staff were trained on the PIC Regulation and the submission system at the JRC by working on real cases.

2. Objectives and Indicators

Objectives

1. Preparations well underway to start implementing the new PIC tasks from entry into operation, in an effective and successful way.

Performance Indicators and Targets

Indicator	Target in 2013	Result in 2013
Project success rate for the preparatory activities in terms of time, scope and resources.	80 %	80 %
Level of satisfaction with the quality of scientific, technical, and administrative support provided to the Commission and MS DNA's.	High	High

3. Main Outputs

- Significant progress in designing the necessary procedures, workflows and IT systems for submission and handling of notifications.
- Contacts and networks with DNAs and interested parties established.

2. ECHA's Bodies and Cross-cutting Activities

Activity 8: Committees and Forum

The Committees – the Member State Committee (MSC), Committee for Risk Assessment (RAC), Committee for Socio-economic Analysis (SEAC) and Biocidal Products Committee (BPR) - are an integral part of ECHA and play an essential role particularly in providing valuable scientific and technical advice (i.e. agreements and opinions) as a basis for ECHA and Commission decision making.

The Forum for Exchange of Information on Enforcement provides a network of Member State authorities responsible for the enforcement of the REACH, CLP and PIC Regulations, with the aim of harmonising their approach to enforcement. Its role is also to closely cooperate with national enforcement authorities (NEAs) and MSCAs to ensure an appropriate coordination between their tasks.

1. Main Achievements in 2013

The Member State Committee (MSC)

The MSC unanimously agreed on the identification of eight substances as SVHCs that were later included in the Candidate List. For four other substances, the MSC agreed unanimously that it was not possible to conclude on their identification as SVHCs.

In December 2013, the MSC adopted its opinion on ECHA's fifth draft recommendation for prioritisation of five more substances for inclusion in Annex XIV. For one of the substances, the MSC opinion included a minority view about the prioritisation. Update of the prioritisation approach to be applied from 2014 onwards was discussed and endorsed by the MSC.

The MSC unanimously agreed on 18 ECHA draft compliance check decisions on registration dossiers and on 109 testing proposal draft decisions. In 82 testing proposal cases (where two-generation reproduction toxicity testing were proposed), the MSC did not reach unanimous agreement due to pending conclusion at policy level about how to apply the newest test method for reproductive toxicity. In accordance with the legal requirement, the full documentation was or is to be submitted to the Commission for their further decision making. Consequently, the performance indicator concerning the level of unanimity of MSC agreements was at 65 % instead of the minimum target of 80 %.

The first substance evaluation draft decisions (in total 16 draft decisions), as a result from substance evaluations carried out by Member States, were agreed upon by the MSC during 2013. This covered 14 substances listed in the CoRAP for evaluation during 2012. This marked the start of the final decision making in the substance evaluation process under REACH. In relation to the substance evaluation process, the Committee adopted its opinion on ECHA's draft CoRAP update in February 2013 and also provided its opinion on the addition of one substance to the CoRAP during the year.

The regular stakeholder observers of the MSC and case owners (registrants) have been able to follow the MSC discussions on dossier evaluation since 2011. During 2013, in case-owners participated in the Committees' discussions in 66 % of cases.

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

RAC adopted with consensus a total of 34 opinions on harmonised classification and labelling in 2013, of which, the majority concerned plant protection products (PPPs). The first dossier on an active substance under the PPP Regulation (EC) No. 1107/2009, for which the EFSA and ECHA processes needed to be aligned to avoid differing opinions, was concluded in December. A substantial amount of work performed in 2013 on complex proposals for harmonised classification and labelling, e.g. the opinion development of eight anticoagulant rodenticides, was carried over to 2014 for finalisation.

RAC concluded on three requests from the Executive Director for opinions under Article 77(3)(c); one concerning the toxicity to reproduction of gallium arsenide, a review of ECHA's report on the restriction of the non-classified phthalates DINP and DIDP and one related to the specific target organ toxicity of two phenolic benzotriazoles.

Opinions on two restrictions proposals were adopted by RAC; one on 1,4-dichlorobenzene in air fresheners and toilet blocks and one on the restriction of lead in consumer articles that can be placed in the mouth by small children.

SEAC concluded on two opinions in 2013, namely the proposal to restrict chromium VI in leather articles and the proposal to restrict 1,4- dichlorobenzene in air fresheners and toilet blocks. The opinion making in SEAC on the restriction of lead in consumer articles is expected to be finalised in 2014. Out of six conformity checks carried out for new restriction dossiers one was found to be in non-conformity by both RAC and SEAC.

To streamline the restriction process the Committee procedures for restrictions on conformity check and opinion development process were reviewed in 2013. The opinion development review is to be agreed upon in 2014.

RAC and SEAC agreed on the first application for authorisation concerning the use of DEHP in the processing of a stop-off formulation used during the diffusion bonding and manufacture of aero engine fan blades. Discussion on seven further applications started in late 2013 and will be finalised in 2014. In total, eight applications passed the conformity check by RAC and SEAC in 2013 (one was withdrawn, and four will be concluded in early 2014.

SEAC agreed on how they will evaluate economic feasibility within the context of the application for authorisation procedure. In addition, RAC and SEAC have jointly agreed on a recommendation on the length of the review period in the authorisation process.

As part of the ongoing capacity building programme for authorisation, RAC agreed on dose-response relationships for the carcinogenicity of hexavalent chromium substances and of inorganic arsenic substances. RAC will use these risk estimates to evaluate applications for authorisation in a predictable and transparent manner.

In 2013, SEAC established a working group to examine ways of evaluating PBTs and vPvBs in the context of restrictions and applications for authorisation.

In 2013, the Secretariat made additional efforts to support RAC and SEAC with their increasing workload. The functioning of the ECHA Committees and the additional challenges of the increased workload, in particular the need for rapporteurs in RAC and SEAC, was discussed on three occasions in the ECHA Management Board and also in the

MSCA Directors' meeting and has been signalled as an important issue affecting the successful implementation of REACH. As a result, MSCAs are requested to commit a minimum of 50 % work time for new or re-nominated members and to provide adequate support to the Committee members that will face an increasing workload in the coming years. There was an increase in the number of members appointed to the Committees with the Management Board appointments in December: RAC rose from 39 to 42, while SEAC rose from 25 to 32.

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. This was reciprocated by DG Employment attending RAC. Common issues impacting on the workplace were discussed, e.g. the respective reference values with some difference for 1,4- dichlorobenzene exposure.

Biocidal Products Committee (BPC)

The Biocidal Products Committee has been established and is fully operational to start working in 2014. The Committee established the Rules of Procedure that were adopted by the Management Board, and developed key working procedures and opinion templates. The approach for engaging stakeholder and applicants into the work of the Committee was also developed. Several permanent and *adhoc* working groups of the BPC have been established to support the work of the Committee from January 2014.

Forum for Exchange of Information on Enforcement

In 2013, the Forum directed substantial efforts towards its coordinated enforcement projects. It finalised and published the final report on its second coordinated enforcement project which focused on formulators of mixtures. The report highlighted significant deficiencies in safety data sheets and a need for further awareness-raising among duty holders. The Forum has also concluded the first inspection phase of the third Forum coordinated REACH enforcement project on registration obligations, the verification of the registrations by Only Representatives and cooperation with the customs authorities.

In order to further strengthen its project-related capabilities, the Forum developed a harmonised methodology for selecting, prioritising, conducting and evaluating its coordinated enforcement projects.

In addition to these large-scale coordinated projects, the Forum has also concluded and published reports from two pilot projects. The first project focused on intermediates, with national authorities verifying the status of intermediates by checking the application of strictly controlled conditions (SCCs) onsite. The other project was intended to test interlinks by enforcing obligations of Only Representatives and those related to PPORDs.

The operational interlinks between ECHA and NEAs related to the follow-up of ECHA's decisions by inspectors further intensified, particularly with regard to the follow up of Statements of Non Compliance resulting from dossier evaluation decisions. The cooperation between ECHA and NEAs, facilitated by a network of focal points in all Member States, became fully functional, a prerequisite of enforcement to help ECHA achieve its strategic aim of improving the quality of data submitted in registration dossiers. The Forum started deliberating the expansion of this cooperation to further decision types in 2014.

In order to build enforcement capacity at the national level, the Forum prepared and conducted its 'training for trainers' events, focusing on the control of exposure scenarios,

inspection of intermediates, substance identity and obligations for substances in articles.

Furthermore, the Forum continued its activities related to the harmonisation and support for enforcement by updating its Manual of Conclusions (MoC) in 23 languages and supporting the ECHA Secretariat in the development of the REACH Information Portal of Enforcement (RIPE). It also discussed and agreed with the Commission, the changes needed to the European Commission's ICSMS system in order to ensure that it is suitable for secure communication among the enforcement authorities.

The Forum Secretariat supported study visits and provided dedicated training programmes for inspectors to the Croatian enforcement authority to prepare them for their new responsibilities under REACH and CLP. Additionally, 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 also continued to advise RAC, SEAC and the ECHA Secretariat on the enforceability of proposals for restrictions. It set out to prepare a compendium of analytical methods and adopted a methodology for collecting information on these methods from various stakeholders.

The Forum also discussed its comprehensive Multi-annual Work Programme 2014-2018 as well as its role in enforcing the PIC Regulation, paving the way for further actions on PIC after its entry into operation.

Lastly, the Forum made its cooperation with stakeholder organisations more practical by inviting their proposals for subjects for the fourth enforcement project and contributions to the collection of information on analytical methods.

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 opinions and agreements that support the final decision making in a transparent manner while ensuring the necessary confidentiality.

2. The Secretariat will drive, support and facilitate the work of the Forum efficiently and effectively and in a transparent manner so that it will have been able:
   - to further strengthen and harmonise the enforcement of the REACH and CLP regulations in the EU/EEA Member States, while ensuring the necessary confidentiality, and
   - to promote harmonised enforcement by coordinating joint enforcement projects and sharing best practice.

3. Conflicts of opinion with scientific committees of other Community 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 2013	Result in 2013
Percentage of opinions/ agreements delivered within the legal timeframe.	100 %	100 %
Percentage of unanimous MSC agreements.	80 %	65 %
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	High
Occurrence of conflicts of opinions with scientific committees of other EU bodies.	Only in well justified cases	One

3. Main Outputs

Member State Committee

- Unanimous MSC agreements on 12 proposals for identification of substances of very high concern (SVHCs).
- 127 unanimous MSC agreements on draft decisions on testing proposals and compliance checks.
- Preparation of 16 unanimous agreements on draft substance evaluation decisions.
- Opinion on ECHA's draft recommendation for Annex XIV.
- Opinion on the first draft update of CoRAP and opinion on addition of one substance to CoRAP.

The above was achieved through:

- Six plenary meetings and seven working group meetings and four preparatory meetings.
- Participation in workshops on dossier and/or substance evaluation and/or the authorisation process.

Committee for Risk Assessment

- 34 RAC opinions on CLH dossiers.
- Two RAC opinions on restriction proposals.
- Six conformity checks for restrictions dossiers (five positive, one negative).
- Three opinions under Article 77(3)(c) of REACH.
- One RAC opinion on applications for authorisation.
- Eight conformity checks for applications for authorisation (all positive).

The above was achieved through four plenary meetings.

Committee for Socio-economic Analysis

- Two SEAC opinions on restriction proposals.
- Six conformity checks for restrictions dossiers (five positive, one negative).
- One opinion on applications for authorisation.
- Eight conformity checks for applications for authorisation (all positive).

The above was achieved through four plenary meetings.

Biocidal Products Committee

- Committee established.
- Rules of procedure approved.
- Main working procedures and opinion templates agreed.
- Work Programme for 2014-2016.
- A code of conduct for the participation of applicants in the BPC.

The above was achieved through three preparatory meetings.

Coordination Group

- Focal points appointed, Chair appointed.
- Regular meetings established.
- Draft rules of procedure and main working practices and principles established.
- First mutual recognition disagreements discussed.

Forum

- Three Forum plenary meetings and twelve Working Group meetings.
- Final report on the second Forum enforcement project on compliance of formulators with REACH and CLP.
- Final report of pilot project on intermediates.
- Final report of pilot project on interlinks when controlling PPORD and OR obligations.
- Updated “Manual of Conclusions”.
- Adopted harmonised methodology for selecting, prioritising, conducting and evaluating of Forum coordinated projects.
- Functioning ECHA-NEA cooperation on follow up of ECHA decisions (Statements of non-compliance).
- Adopted final list of changes needed in the Commission-owned ICSMS system.
- One stakeholder event, one training event on REACH and CLP for enforcement trainers with experts from ECHA and MSCAs.
- Six advices of enforceability on proposed restrictions.
- Adopted the first version of the methodology to recommend analytical methods for the enforcement of Annex XVII restrictions.

Activity 9: Board of Appeal

The Board of Appeal was established by the REACH Regulation to provide interested parties with the possibility of legal redress. It does this by considering and making decisions on appeals against certain decisions of the Agency (see Article 91 of the REACH Regulation).

1. Main Achievements in 2013

The number of appeals lodged in 2013 (22) is in line with expectations based on the rate of appeals against appealable ECHA decisions (registrations, data sharing, dossier evaluation, and substance evaluation). In other words, the number of appeals is less than anticipated in Work Programme (WP) 2013 (36) but the number of appealable decisions taken by ECHA in the first nine months of the year was also less than anticipated. A large number of appealable decisions were taken by ECHA in the last quarter of 2013 which may lead to a higher number of appeals than expected in the first quarter of 2014.

More appeals in 2013 were made by SMEs (small and medium-sized enterprises) than was previously the case. In particular, 16 new appeals were lodged contesting revocation of registration numbers, largely by smaller companies which appear to be less experienced with REACH and ECHA processes. The main reason for these appeals was the revocation of registration numbers due to disputes on the company size status of the registrant. Challenges to ECHA's language regime have also been a factor in some cases. In several of these 'company size'-related appeals (12), the parties (i.e. the Appellant and ECHA) agreed to discuss their particular cases outside the appeals process and the Board of Appeal consequently stayed the appeal proceedings to allow negotiations and discussions between the parties to take place. In most of these cases, the parties have reached an agreement to settle the case to their mutual satisfaction and the appeals have subsequently been withdrawn. Whilst the Board of Appeal has not needed to conclude its deliberations in these cases, the very existence of the appeals process has enabled Appellants to obtain legal redress and the Agency had the opportunity to adapt its practices to help SMEs.

In addition, two appeals relating to a data sharing dispute, one appeal contesting the registration of another company, and three appeals relating to compliance checks were lodged in 2013. These appeals, except one in which the Executive Director rectified the contested decision, are currently under consideration by the Board of Appeal.

During 2013, five Board of Appeal decisions on appeals relating to ECHA decisions following compliance checks were adopted. Whilst the Board of Appeal decisions are decided strictly on the merits of each case, the findings in these decisions may have wider applicability and 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, the Agency's obligations under Article 25 when requesting non-standard tests (the 'last resort' principle); the application of the proportionality principle when the Agency requests further information; considerations on OECD test guidelines (A-005-2011); ECHA's margin of discretion in considering proposals for read-across (A-001-2012); clarification of the Article 42 follow-up procedure to dossier evaluation decisions; interpretation of ECHA guidance in relation to dossier updates, specifically whether the Agency adequately informed the Appellant about the deadline for making updates to be considered in the decision making process (A-003-2012); interpretation of the information requirements in Annex X of REACH; assessment of waiving statements; late update of a registration dossier; ECHA's duty to state reasons for its decisions (A-004-2012); scope and lawfulness of rectifications by ECHA's Executive Director; admissibility of new information submitted during appeal proceedings (A-007-2012); and the principle

of good administration (A-003-2012 and A-007-2012). In addition, a decision regarding the rejection of a registration (A-005-2012) clarified the registrant's obligation to keep its REACH-IT account information up-to-date and the requirements for a valid notification to registrants from ECHA via REACH-IT.

It should also be noted that in 2013 the opportunity to intervene in appeal cases was granted in one case where the applicant established an interest in the final decision. Two applications to intervene were rejected; one because the applicant had not demonstrated its interest in the result of the specific case and another one as the applicant did not establish its legal personality. One procedural decision on a request for confidentiality was adopted by the Chairman. All significant procedural decisions are published online once the case in question has been closed.

The Board of Appeal has gone to great lengths to give the parties ample opportunities to explain their views, defend their arguments, and respond to the arguments of the other party and, if relevant, interveners. In the same vein, it should be noted that five oral hearings and a meeting via teleconference (pursuant to Article 15 of the Rules of Procedure) were also organised in 2013. The hearings, normally over a full working-day, gave the parties and interveners the opportunity to make their case directly to the Board of Appeal and for the Board to directly pose questions to the parties and interveners to clarify any issues needed to enable the Board to make its final decision.

Preparations for future appeals arising from the implementation of the BPR were started with staff training in cooperation with ECHA operational units and by attending appropriate seminars and conferences. The appeals section of the ECHA website has also been updated with information relating to appeals under the BPR and translated into all languages.

2. Objectives and Indicators

Objectives

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

Performance Indicators and Targets

Indicator	Target in 2013	Result in 2013
Percentage of final decisions made within 90 working days of the closure of the written or oral procedure.	90 %	100 %

3. Main Outputs

- 22 new cases lodged and processed.
- Eight final decisions adopted (of which two were withdrawal decisions).
- 16 procedural decisions (one confidentiality request, three applications to intervene, two joining of cases, six stay of proceedings, one request to change

the language, one rectification, one request to submit new evidence and one request to hear experts) adopted.

- Five oral hearings and one meeting pursuant to Article 15 of the Rules of Procedure with the parties were conducted.
- All final decisions published, as well as certain procedural decisions related to intervention applications and confidentiality requests, published online. A new leaflet on the appeals process was also published.

Activity 10: Communications

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

1. Main Achievements in 2013

Under a "REACH 2013" banner, ECHA conducted a major coordinated effort to publicise the 2013 registration deadline. Activities in the run up to the deadline focused on urging companies to register in time, followed by activities to promote the results of the deadline and their implications for the safer use of chemicals. The Agency held its first ever press conference in Brussels, attended by Brussels-based journalists, to inform on the results of the registration. Over 14 000 unique visits to the results online and a total of 77 significant articles more than doubled the volume of ECHA's other most covered pieces of news. Around 18 000 Twitter accounts were reached on that occasion. Using respective partner platforms, such as the European Enterprise Network (EEN), this campaign also sought to reach SMEs.

In collaboration with the services of the European Commission, ECHA also engaged in a number of other high-profile communications activities: the entry into operation of the Biocidal Products Regulation and providing an exhibition on the benefits of REACH.

Apart from these time-bound events, the numerous achievements of the Agency were accompanied by communications activities addressed to duty holders, interested parties and the general public. Communication – mainly by means of ECHA's newsletter and its web-based publications – complemented and supported the regulatory work of the Agency. It provided an indispensable tool to inform stakeholders and the public of ECHA's actions to implement the EU chemicals safety legislation, not least by highlighting the four strategic goals that ECHA adopted as a foundation of its work after the initial period of establishing all regulatory processes.

Various joint communication actions with EU partners and accredited stakeholder organisations supported industry, especially SMEs, in understanding their duties and the benefits of implementing the EU chemicals safety legislation: new web sections were prepared for workers and the general public, and a communicators' network was established. Training was arranged for Enterprise Europe Network members. The Agency informed accredited stakeholder organisations by means of dedicated e-bulletins.

ECHA made its first entry to social media as an Agency: news was published on Twitter from January 2013 to extend the reach of ECHA's news and to expand the Agency's online presence. 503 Tweets were made. A social media strategy for the Agency was established to reach out to new and specific audiences in a resource efficient manner.

In the course of the year, ECHA achieved greater levels of engagement with Stakeholders – record numbers participated in two ECHA Stakeholders' Days for REACH/ CLP and BPR respectively (3 500 participants at the events and online); 1 000 additional readers subscribed to the ECHA Newsletter and e-News; 10 further accredited stakeholder organisations were accepted; and the ECHA Secretariat launched a new stakeholder discussion platform for civil society accredited stakeholder organisations. This intensified stakeholder work was met with a high level of appreciation.

The Agency also enjoyed a high level of media interest in its activities. It organised over 50 interviews for journalists and provided two media briefings.

By providing a total of 250 products in translation of the original ECHA documents and information items into 22 other official EU languages the Agency delivered at a rate of more than 25 % above target to satisfy the multilingual information needs of its audiences.

Together with the services and the European Commission as well as other communications' partners, the Agency started its preparations for awareness-raising activities for the CLP notification obligations for mixtures that will take effect in 2015. In this regard, the follow-up to the recommendations of the Commission's Article 34(2) CLP Report on the Communication of the safe use of chemicals was postponed until 2014.

A planned new publishing tool to facilitate the timely issuing and revision of ECHA's publications was postponed until 2014, due to a revision of some communications processes to improve efficiency.

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 & Targets

Indicator	Target in 2013	Result in 2013
Level of reader satisfaction with ECHA's written output, including languages available, (website, e-News, Newsletter, Press Releases, News Alerts). This to be measured in terms of timeliness, content and usability.	High	High e-News - High ECHA Newsletter - High
Level of accredited stakeholder satisfaction with the information they receive and their engagement with ECHA.	High	High
Level of staff satisfaction with internal communications.	High	High

3. Main Outputs

- Around 250 products (online and offline content) published in the 23 official EU languages (including Croatian).
- Coordinated communication activities on the REACH 2013 deadline; the entry into operation of the BPR and the SVHC Roadmap. Planned activities on applications for authorisation and PIC were postponed until in 2014.
- Biocides communications activities, including 12 press releases/news alerts, 15 Newsletter articles, 28 topics in ECHA's stakeholder updates, 60 new web pages, one dedicated Stakeholders' Day, one strategic discussion with accredited stakeholders, information material and internal communications activities.
- 44 press releases produced and two press briefings organised for the media. Over 50 spontaneously requested interviews were given to the media.
- 50 news alerts, 51 weekly e-News bulletins and a bimonthly newsletter produced for interested parties.
- Two Stakeholders' Days, one recurrent workshop for accredited stakeholder organisations and an additional briefing day for newly accredited stakeholders were held.
- A Europe Day event for the general public was held, attracting 3 500 visitors.
- ECHA's online presence further improved, by creating new sections (e.g. on Biocides) and further disseminating information on chemicals. Around 1 800 updates performed on the website.
- Editorial and layout support was provided to 45 ECHA Publications, and eight leaflets were published to raise awareness on ECHA's work. ECHA's first e-book was published on the website (Multi-Annual Work Programme 2014-2018).
- Internal information was provided daily on the intranet and internal information screens, with 449 news items published. 50 weekly internal news summaries (ECHAnet Exchange) produced, four quarterly Staff Assemblies organised as well as three breakfast meetings with ECHA staff and the Executive Director.
- 10 surveys to gauge satisfaction or to understand stakeholder experiences were undertaken.
- Launch of a tool for a more efficient internal handling of translation-related workload.

Activity 11: International Cooperation

As a leading regulatory agency worldwide, ECHA manages the advanced EU chemicals safety regime. This entails interaction with actors beyond the European Union. ECHA shares experience with an increasing number of regulatory authorities in countries adopting chemicals safety legislation and carries out awareness raising with industry in countries exporting to the EU. This contributes to the effective implementation of the legislation to the extent that it depends on foreign actors contributing to compliance within the EU. ECHA's work within the OECD as well as in support of the EU's adherence to international conventions represents an important element of this activity.

1. Main Achievements in 2013

The main field of ECHA's international cooperation continued to be the Agency's involvement in numerous OECD activities, its contribution to the preparation of the candidate countries for accession to the EU, as well as its contacts with individual OECD Member States.

In the OECD, ECHA maintained its active contribution towards harmonising the tools for chemicals management. 2013 and 2014 are crucial for collecting information requirements for IUCLID 6, in order to ensure a public release in 2016, and this work was kicked off in 2013 with a large consultation on stakeholders' requirements. To enable reporting properties of nanomaterials, specific OECD-harmonised templates, which had been developed in previous years, were implemented into IUCLID in 2013. In collaboration with the JRC, an OECD Harmonised Template to capture intermediate effects of toxicological studies was drafted. This template is designed to support the Adverse Outcome Pathway activity at the OECD, and to serve as a first step to establish a way of capturing this type of data.

To disseminate registration information from ECHA's database as broadly and efficiently as possible, the link to the OECD eChemPortal was regularly updated. Furthermore, during 2013, a new logo for the portal was agreed and the portal development and maintenance was further secured.

ECHA also continued its active contribution to the QSAR Toolbox development with a view to making it a practically useful tool for the 2018 registrants who want to explore the potential for read-across for their substances. The technical review of the software code was finalised and a scientific review was initiated. In collaboration with the OECD, a future strategy for the foreseen major developments was put together. To support this, a new tender was launched to support the improvement of the tool. The main aim is not only to further enhance the scientific validity of the QSAR toolbox but also to significantly improve its user friendliness.

Throughout the year, the Agency continued its work in support of candidate countries and potential candidates, focusing on Croatia in the immediate run-up to the country's accession to the European Union on 1 July 2013. With the support provided under the European Union's Instrument for Pre-Accession Assistance (IPA) programme, the Agency realised study visits, workshops and other capacity building activities on REACH, CLP and the Biocidal Products Regulation, focusing on the knowledge the beneficiaries needed to participate in ECHA's work.

Based upon the cooperation agreements established with peer agencies in Australia, Canada, Japan and the USA a number of (overwhelmingly audio-visual) meetings were held between regulatory scientists focusing on exchanging information on technical topics ranging from individual substances to work on substances in articles and

regulatory developments on nanomaterials. Efforts to review the cooperation and to enhance its implementation were also initiated.

The worldwide interest in the EU chemicals legislations continued at a high level as shown by the demand for explanatory meetings with authorities and industry from several countries visiting the Agency to gain a better understanding of the status and lessons learnt during its implementation. These presentations also served the aim of raising awareness and knowledge of foreign manufacturers who account for nearly half of all dossier submissions through their Only Representatives or importers, and thus contributed to pursuing the goal of improving the quality of dossiers.

2. Objectives and Indicators

Objectives

1. The Commission receives high-quality scientific and technical support for its international activities, especially in multilateral bodies.

2. ECHA, within the scope of its responsibilities, 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 2013	Result in 2013
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

- In total, 23 new and 15 updated harmonised templates were/are under review with the OECD, including specific templates for nanomaterials.
- An updated version of the OECD QSAR Toolbox version 3, bringing more functionality and databases was released in December 2013.
- Specifications for IUCLID 6 architecture accepted in the OECD IUCLID User Group Expert Panel.
- Hosting and further enhancing the eChemPortal according to the priority on possible improvements endorsed by the Joint Meeting in 2012
- 17 activities were carried out under the second IPA-project for candidate countries and potential candidates for the EU.

- Technical support was provided to the European Commission in relation to bilateral agreements with a chemicals component with Japan and the Russian Federation.
- Technical input to the European Commission in relation to the June and November UN GHS meetings.
- Close to 20 (mainly virtual) meetings with Australian, Canadian, Japanese and US peer agencies.
- Six delegations from Europe, Africa, Asia and South America visited ECHA, as well as one delegation from regional international organisation grouping countries in Central Asia.
- ECHA participated in 15 workshops and seminars for third country audiences.
- Provision of scientific and technical support to the Commission on UN GHS, including participation and input to the work at OECD and UN level.
- Continued cooperation with the regulatory agencies in the four countries outside the European Union with whom ECHA has concluded cooperation agreements.
- Capacity building activities targeted at EU candidate countries and potential candidates under the IPA programme and possibly targeted cooperation with the European Union's European Neighbourhood Policy (ENP) partner countries under the European Neighbourhood and Partnership Instrument (ENPI) programme.
- Presentations at seminars/workshops/conferences in key third countries (either in person or by video conference) and hosting of visits by representatives of such countries.

3. Management, Organisation and Resources

Activity 12: Management

The Agency strives to ensure a modern corporate identity and management that complies with the highest EU standards, so that it can efficiently integrate new activities to its organisation.

1. Main Achievements in 2013

The Management Board, ECHA's governing body, met quarterly during the year. Over the year, the Board duly discharged all its statutory obligations as set out in the legislation, 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. The multi-annual planning of the Agency was developed to a more strategic level and a five-year Multi-Annual Work Programme was adopted by the Management Board in September.

As part of the preparatory activities for ECHA's tasks under the BPR, the Management Board closely monitored the progress and put appropriate implementing decisions in place. The Board took due account of the Commission "REACH review" communication and took appropriate actions to address the findings related to ECHA. Furthermore, the Management Board reviewed the functioning of the ECHA Committees and the availability of resources at national level. Similarly, the structure of the Board of Appeal was reviewed and confirmed.

The Management Board meeting in the first quarter was organised as part of the Irish EU Presidency and was combined with a REACH conference focusing in particular on SMEs. With regard to institutional developments, the Management Board was kept duly informed, in particular of the Common Approach on decentralised agencies and the implementation roadmap, including a meeting organised by the Commission with the Chairs of governing boards of agencies. The meetings and decisions of the Management Board were prepared by working groups, especially in the field of planning and reporting, audit, dissemination and matters related to the Board of Appeal. Six written procedures were organised in 2013.

The policy concerning the management of potential conflicts of interest, adopted by the Management Board in September 2011, has been further implemented with specific decisions of the Executive Director, further integrated in the ECHA processes and largely communicated within the Agency. The Conflict of Interest Advisory Committee provided input to the Management Board in the context of the finalisation of eligibility criteria for members of ECHA's bodies. Compulsory trainings and workshops on conflicts of interest and ethics have been organised for all staff and managers. In preparation of a review of the policy in 2014, an external audit was organised to review the implementation status against the 2012 findings of the Court of Auditors.

The Agency received several high-level visits over the course of the year, for example by Members of the European Parliament. Regular liaison with the Parliament ENVI Committee was maintained throughout 2013. An exchange of views between the Committee and the ECHA Executive Director focused on the Commission's "REACH Review".

ECHAs term as part of the Troika coordinating the Network of EU agencies ended in February 2013. As a regular member, ECHA continued to actively supporting the work of

the network, in particular in the implementation of the Common Approach on decentralised agencies. The Network submitted a comprehensive report on the work accomplished in this field to the institutions in December 2013.

In 2013, the Agency further developed its contacts with Member States through Executive Director visits and by organising a meeting with MSCA Directors to further improve the joint planning of substance evaluation and risk management-related tasks. The building up of relations with new partner competent authorities responsible for the BPR received specific attention, for example in the annual planning meeting with MSCA directors. In July, a meeting with the competent authorities responsible for REACH and CLP was organised in Helsinki.

The Agency has continued to use the development of its integrated Quality Management System to improve its management and internal processes. In 2013, the focus has been the preparation for the 2014 certification exercise, in line with the approved roadmap leading towards ISO 9001 certification. In addition, a project has been implemented to prepare an efficiency programme for 2014-2016, in order to be able to face the staff reduction announced for EU agencies and implement the new Multi-Annual Work Programme. The Agency has also worked to implement a better internal information management, and a project to improve records management is ongoing.

ECHA's Management Board adopted a unified security model based on REACH and CLP information systems to also cover the exchange of information with Biocides MSCAs. The model was prepared by the Security Officers' Network taking into account the fact that MSCAs are directly involved in many processes under the BPR and therefore need more extensive and flexible access to the Agency's information systems. In addition, the IT continuity technical preparedness plan has been established.

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 seems quite stable but the number of documents and pages increase 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).

During the course of 2013, within the framework of the Quality system, a new system to record and solve external complaints received by the Agency was put in place. The Agency received nine external complaints, almost all of which related to SME issues and one to the dissemination of a dossier evaluation. All those complaints have been appropriately solved and corrective action has been taken when needed. A conclusion that can be drawn from this exercise is that, taking into account the limited number of flagged complaints, more awareness among ECHA staff still needs to be raised.

With a view to the need to shift the focus of attention in implementing the REACH Regulation towards involving small and medium-sized enterprises (SMEs) and to support them in fulfilling their obligations as downstream users and in preparing for submitting dossiers for the 2018 REACH registration deadline, the Agency appointed an "SME Ambassador". ECHA chose the Director of Cooperation Andreas Herdina to exercise this function and thus to anchor it in the Agency's senior management. This function comprises an internal role of raising awareness of ECHA staff for SME needs and concerns as well as catalysing appropriate responses, and an external role of harvesting

and analysing such needs from interacting with SME representatives and companies as well as presenting ECHA's approach towards SMEs to various audiences.

According to ECHA's Financial Regulation, the Internal Auditor for ECHA is the Internal Auditor of the European Commission (IAS). The IAS performed an audit on "Committees Management in the European Chemicals Agency" in 2013. Based on the results of the audit, the IAS raised seven recommendations, including one very important recommendation to review its interpretation of the timeframe for completion of RAC opinions on substances proposed for harmonised classification, labelling and packaging under the CLP Regulation.

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, adds value by providing the Executive Director with additional assurance and consulting activities. In 2013, the IAC carried out assurance audits on video-surveillance implementation at ECHA premises; Forum secretariat; and document and record management.

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 2013	Result in 2013
Degree of fulfilment of the ISO 9001:2008 requirements for quality management system elements.	80 %	75 %
Percentage of very important audit recommendations implemented within the deadline (IAS).	100 %	100 %
Percentage of annual declarations of interest filled in by the members of the Management Board, the Committees and the Forum.	100 %	100 %

3. Main Outputs

- Four Management Board meetings and 14 meetings involving Management Board members organised.
- All regulatory plans and reports produced.
- The Quality Management System was further developed and implemented following the roadmap leading towards ISO 9001 certification.

- Strong legal support provided to ensure that ECHA's decisions are in line with legal requirements.
- Effective defence provided through dozens of legal documents in 42 legal proceedings before the Court and/or the Board of Appeal.
- 70 initial and three confirmatory "access to documents" requests, covering about 650 documents, answered in accordance with the applicable legislation.
- The Data Protection register contained 100% of the processing operations involving personal data identified by the Data Protection Officer.
- One MSCA Directors' planning meeting organised.
- One Security Officer's Network meeting organised.
- 29 framework agreements for the transfer of fees to the Member States in place.

Activity 13: Finance, Procurement and Accounting

1. Main Achievements in 2013

The revenue from ECHA's REACH/CLP activities in 2013 amounted to €89 million, stemming from fee income on REACH registrations, SME verification work and interest income from reserves. The second REACH deadline occurred on 31 May 2013 and as a result of higher than initially predicted fee revenue, and a positive budget result from 2012, the budget for 2013 was amended by increasing the reserve by €55.1 million. The REACH activities were fully self-financed during 2013.

The Biocidal Product Regulation entered into operation on 1 September 2013. The revenue under this regulation amounted to €7.48 million. This revenue included an EU contribution of €6.07 million, Biocidal Fee revenue of €0.31 million, a voluntary contribution from an EEA Member State of €0.18 million and a balancing contribution of €0.92 million from the Commission to cover the shortfall in fee income.

ECHA received an EU contribution for the PIC Regulation totalling €1.56 million in 2013. This contribution allowed ECHA to continue the preparatory activities to ensure the smooth entry into operation of this regulation on 1 March 2014.

The budget execution for REACH amounted to 98.7% for the commitment appropriations and 88.3% for the payment appropriations. The 98.7% marginally exceeds the 2013 target of 97%, while the 88.3% payment execution significantly exceeds the target of 75%.

For Biocides and PIC, despite the fact that they were both in their start-up phase as defined by the Commission, in fact in their first full year of budget implementation the commitment rates were at a high level of 98.2% and 98.7% respectively. On the contrary, the payment rates of these regulations were highly impacted by the start-up phase and by the multi-annual nature of the IT developments and were therefore limited to 69.5% and 29.6% respectively.

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. The reserve assures that ECHA is able to fund its REACH activities until 2015, after which it is expected for ECHA to enter into a mixed regime of funding with both own income and EU contribution. At the end of 2013, ECHA launched calls for tender for banking services including current and deposit bank accounts.

The Agency continued its systematic verification of the status of companies that had registered as SMEs and had consequently benefited from SME reductions. The verification was completed on a total of 516 companies. As a result from this work, a total of €8.2 million of fees and charges were invoiced during 2013.

The initial target for 2013 was set at 300 verifications. During the year, an option to rectify an incorrectly declared size category directly after ECHA has initiated verification was introduced. This option allowed the companies to benefit from an administrative charge reduced by 50%. A significant number of companies chose this option and the managerial decision to process these cases as a priority resulted in the high number of verifications concluded compared to the target. However, while exceeding the target significantly in 2013, this prioritisation decision will reduce the expected output compared to the planned target for 2014.

In 2013, the Agency further developed its reporting systems. The main emphasis has been in the streamlining of reporting at activity level and taking into account the need to segregate funds between the REACH/CLP, Biocidal Products and PIC regulations.

Finally, during 2013 ECHA procured scientific, IT and administrative services under its existing Framework Contracts; successfully concluded open calls for tender for the establishment of new Framework Contracts for a Human Resources integrated management system, phase 3 of the QSAR toolbox, travel and medical services, as well as an audit to increase efficiency in its procurement and contract management processes that resulted in planned actions to be implemented in 2014.

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 2013	Result in 2013
Number of reservations in the annual report on financial and accounting issues of the European Court of Auditors.	0	0
Commitment rate (of commitment appropriations at the end of the year).*	97 %	98.7 %
Payment rate (of payment appropriations at the end of the year).*	75 % (*)	88.3 %
Carry over rate (% of committed funds carried over in 2013).*	< 12 %	10.4 %
Compliance with MB guidance on cash reserves (MB/62/2010 final).	100 %	100 %

* for activities related to REACH/CLP.

3. Main Outputs

- Rigorous budget and liquidity management.
- Complete asset inventory.
- Mechanism for managing and investing the Agency's cash reserves in operation and under close monitoring.

- Reporting established to ensure segregation of funds under different legislations.
- Further systematic verification of registrants' SME status and collection of revenue related to false declarations.
- Activity-based expense reporting in implementation, separating REACH/CLP from BPR and PIC respectively.
- Annual accounts for 2012 prepared in time.
- Establishment of new Framework Contracts for Human Resources management system (HRMS), QSAR toolbox (Phase 3), travel services and medical services.

Activity 14: Human Resources and Corporate Services

1. Main Achievements in 2013

Human Resources

In the selection and recruitment area, the recruitment target for REACH/CLP (97%) was achieved. The recruitment target for Biocides/PIC was also reached, despite the fact that recruitment for the whole establishment plan could only start in September 2013 due to budgetary uncertainties. ECHA engaged a large number of interim workers on an exceptional basis mainly to cope with the peak workload in certain key areas, such as the registration process and the important preparatory work for the Biocidal Products and Prior Informed Consent regulations. The turnover of Temporary Agents for 2013 was 3.1%.

In the policy and regulations area, the preparatory work for and implementation of the new Staff Regulation was conducted, including a comprehensive information campaign for staff. The transition to a new medical service provider was successful and the process for the administration of medical files was improved to ensure a high level of data protection. The Extranet services were revamped, with particular focus on enhancing the information and assistance provided to newcomers. Contacts with the Finnish authorities were fostered to support staff integration into Finland. Furthermore, the Agency closely collaborated with the European Schooling Helsinki to offer high quality European education in Helsinki. An automated tool was also developed for the management of conflict of interest process.

In the learning and development area, ECHA's first Team Leader Development Programme was launched (53 Team Leaders completed the programme) and the preparatory work for the Senior Management Development Programme was completed.

An ECHA Corporate Day focusing on "Organisational Efficiency" was organised successfully in June 2013. All-staff training sessions in harassment prevention were organised towards the end of 2013. 63 staff members achieved the required ability to work in a third language. A total of 23 in-house scientific training courses, 114 external training missions and 25 organisational development activities were organised. 16 trainees started their traineeships at ECHA in 2013.

In the career development area, a staff retention policy was developed and an outplacement service was developed to support staff members whose contracts were not renewed. The career development team promoted internal mobility and the use of the Inter-agency Job Market by launching several vacancies for this type of recruitment.

Corporate Services

Following the identified need for a wider scope for building renovation and maintenance projects, ECHA has received a general action plan from the landlord (Varma) covering both short-term and long-term actions. Some have been initiated in 2013 and larger ones are expected in the coming two years. To ensure business continuity, a new Uninterruptible Power Supply (UPS) in Data Center 1 was installed and need for further cabling was investigated. A study on the proposed electrical upgrade project was completed and is ready for implementation in 2014.

Office space planning was in focus in response to the reorganisation and the new recruitments for the Biocidal Products and PIC regulations. ECHA managed to incorporate the new staff through the creation of more workstations with the acquisition of new

furniture and more efficient use of open space premises.

Reinforcement of the physical security continued, with the improved closed-circuit television (CCTV) becoming operational in early 2013. Upon recommendation from a fire safety assessment, the renewal of the Agency's evacuation maps was completed and general evacuation drills were conducted.

Meetings and other events were organised in ECHA's conference centre and attended by a total of about 7 600 external participants (+8 % from last year). As anticipated, the number of virtual conferencing and webinars continued to rise with an increase by 22% from the previous year. To ensure well-functioning and effective meeting facilities, new equipment was installed in some meeting rooms.

A new Travel Agency contract was signed to serve the travel needs of both external meeting participants and ECHA staff. Major updates on the Mission Management tool were introduced with the aim for a more efficient workflow and reporting. Furthermore, to provide a more stable solution to the Agency's courier services, a longer term service contract was put in place.

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.

2. Objectives and Indicators

Objectives

1. The Agency has a sufficient number of skilled staff to ensure the implementation of the Work Plan and offer 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 2013	Result in 2013
Percentage of establishment plan posts filled at the end of the year for REACH/CLP.	97 %	97%
Percentage of establishment plan posts filled at the end of the year for Biocides/PIC.	90 %	90 %
Turnover of Temporary Agents.	< 5 %	3.1 %
Average number of training and development days per staff member.	7.5	10.7
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 office facilities and logistics services.	High	High

3. Main Outputs

Human Resources

- Payroll for statutory staff and other payments to staff, Seconded National Experts (SNEs) and trainees (616 persons).
- 28 selection procedures launched out of which 27 were concluded.
- 87 recruitments completed (including 26 new contracts for staff already in house).
- An average of 10.7 training days per staff member achieved.
- Performance appraisal (503 staff) and reclassification (425 staff) exercise organised for statutory staff.
- Administration of rights and obligations, working conditions, emoluments and social security for more than 600 members of ECHA's statutory staff.
- Advice and assistance rendered to more than 600 members of ECHA's statutory staff and management on HR matters pertaining to individual rights and obligations, staff policy and wellbeing.
- Staff Survey 2013 response rate: 82% - increase of 10% in overall ECHA Staff Survey Index; analysis and follow-up to be conducted in Q1 2014.
- Promoted Internal Mobility and Inter-agency Job Market by having 20 vacancies open for this type of recruitment.

Corporate services

- Timely purchase of equipment, materials and services through appropriate procurement procedures.
- Timely calculations and reimbursements of staff mission (717) and travel reimbursements for external meeting participants (1 480).
- Secure office facilities.
- Supported 956 events (285 official meetings, 334 video and web conferences, 337 other meetings/workshops.
- Well-functioning audio-visual equipment (upgraded 26 meeting rooms with new equipment).
- Efficient mail services.
- Well-organised and correctly managed library and archives.
- Up-to-date and correct inventory of non-IT assets.

Activity 15: Information and Communication Technology

1. Main Achievements in 2013

In line with the strategic decision taken by ECHA, several areas of IT have been outsourced successfully. The drivers for outsourcing can be varied. Management of REACH-IT was outsourced before the REACH registration deadline to ensure 24/7 monitoring and support. The management of other systems such as the email platform MS Exchange and the document management platform SharePoint have been outsourced to provide improved support and coverage. Both these projects were outsourced in conjunction with upgrades thereby providing improved functionality to the users of the application, something ECHA would not have had the capacity to do alone. External computing capacity was procured in Q4 to outsource the management of non-production infrastructure (used for development and testing purposes). This is a ground-breaking move for ECHA as it means that ECHA is not only using its own infrastructure to provide computing services. The external capacity will supplement the internal one without additional investment in hardware. Although ECHA is very much on a learning curve in this area, further use of this concept is planned in the future. ECHA will retain the service management for the outsourced services.

During 2013, the requirement for additional storage capacity was identified, particularly to support any potential surge in data requirements for the REACH registration deadline. ECHA was able to take advantage of the highly available (HA) systems and the duplicate data centres, implemented to support the IT-BCP, and was able to migrate all processing capacity from one data centre to the other so that the upgrade took part largely during working hours, and with no impact to end-users.

A significant effort was made to support the rollout of the ECHA IT tools for the MSCAs to support biocides (IUCLID, R4BP 3). A cross directorate team was created to address not only the installation of IT systems and token distribution but also the administrative side and immediate implementation of ongoing support. Taking advantage of the R4BP 3 rollout and the use of tokens, ECHA was able to start the decommission project of the old legacy and complex “cryptobox” solution for remote access to REACH-IT.

An ongoing problem in Information Communications Technology (ICT) is to ensure the supply of the infrastructure is in line with the demand, particularly as infrastructure upgrades are costly and budget planning is required. To this end, much work has been carried out to setup a capacity management process, which captures demand from the projects, giving a medium to long-term capacity growth forecast. This in turns allows us to ensure capacity is available.

A significant progress has been made to provide a more efficient, integrated and powerful system for the Human Resources administrative processes (HRMS). After the tender and award of the system, the work for the hosting and implementation was initiated as planned before the end of the year and the supporting implementing contracts signed. The support of administrative processes was also further improved with the revamp of the mission management application in line with the new Mission Handbook, Remedy was reshaped to support the new ICT catalogue and NC CAPA, new applications were developed for the purpose of the Declaration of Conflicts of Interest (DoI) and the Quality Management System (IQMS) and will be brought to production in early January.

In 2013, the internal platform for document management in the Agency was re-engineering to provide much improved support to the handling of documents and administrative workflows. The new platform is supported by an upgraded and outsourced SharePoint platform and applies the adopted procedures on information management,

classification, process ownership, common nomenclature and metadata.

The Identity Data Management (IDM) ensures a higher level of consistency across the IT systems, applications and processes, automating the identity lifecycle management across the Human Resources system, Active Directory, Corporate Mail and ECAS systems. It is based on business rules and reduces the cost and risk involved in manual identity and credential management.

2. Objectives and Indicators

Objectives

1. The technical ICT infrastructure of the Agency is operated at a high service level and continuity, efficiency, and security is maximised for all supported business operations.

2. An IT Business Continuity Plan adequately covers the mission-critical systems.

Performance Indicators and Targets

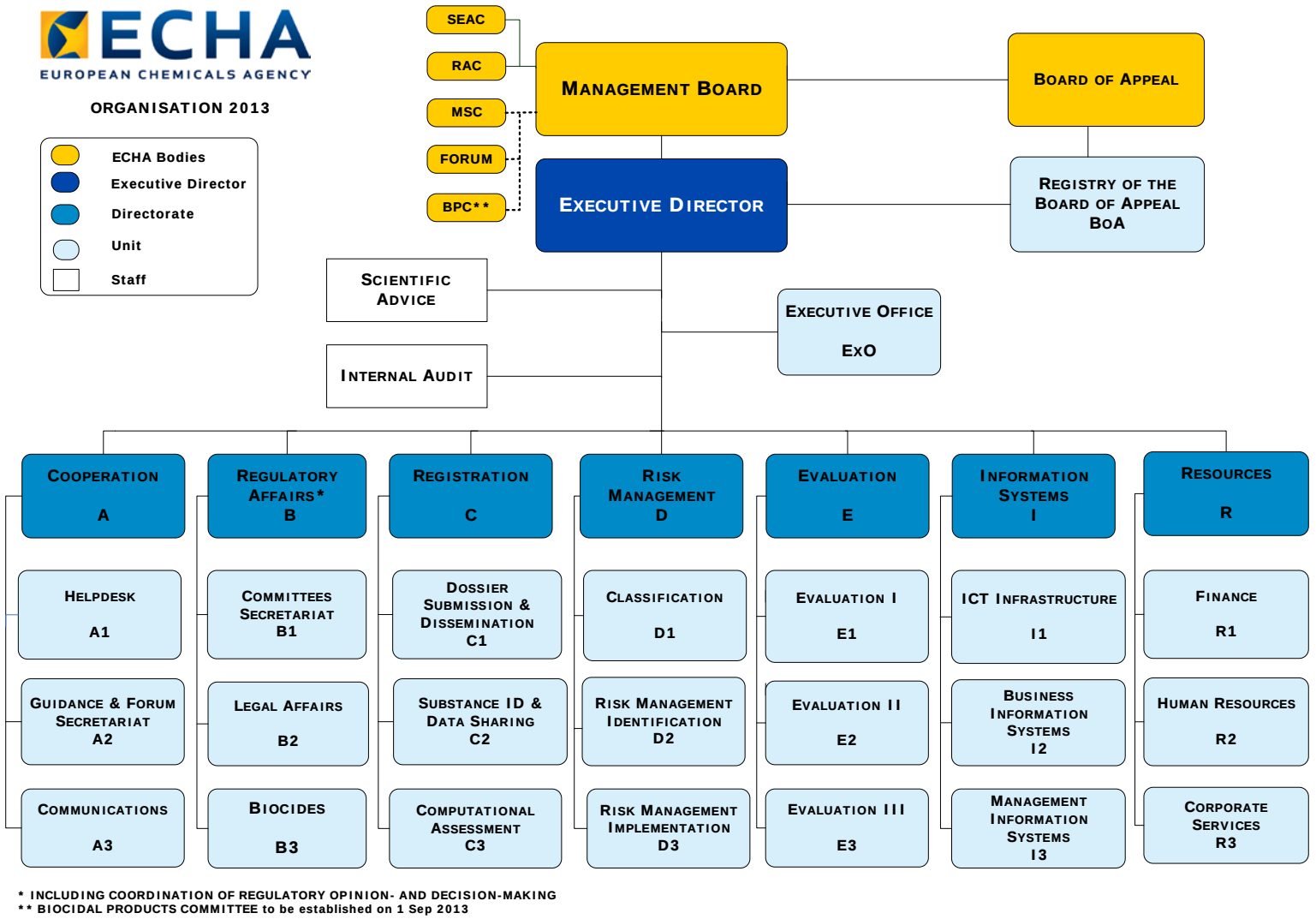
Indicator	Target in 2013	Result in 2013
Availability of mission-critical systems for external customers (i.e. uptime during service hours).	On average 98 % over 12 months	100 %
Level of internal user satisfaction with IT services, relative to staff/ support ratio.	High	High
Level of coverage of mission-critical systems in the business continuity solution involving external data centre(s).	REACH-IT, the ECHA website, the email system and internet connectivity are covered	100 %

3. Main Outputs

- Appropriate performance and availability of over 70 ICT-services constituting an ever-increasing ICT Service Catalogue and serving all functions in ECHA and, frequently, outside.
- Improved business continuity support through an increased portfolio of highly available mission-critical systems serving external stakeholders (e.g. biocides), leveraging outsourced hosting services.
- A first implementation of a Record Management System based on the records related to the Secretariat of the Management Board, the planning, monitoring and review process and the Director's coordination meetings.
- Award of the Framework contract and implementation started for a complete Human Resources management system based on a hosted software package.

- Identity Management System implemented providing increased user management efficiency among systems with automated provisioning and de-provisioning of users.
- Management of the platform for Document Management and for e-mail outsourced.
- External computing capacity procured and management outsourced.
- Around 700 laptop devices upgraded with minimal downtime to provide the new Office Automation environment.
- Over 50 CAs and over 500 MSCA users supported and supplied with access to ECHA's IT systems for the biocides go-live.

ANNEX 1: ECHA Organisation 2013



* INCLUDING COORDINATION OF REGULATORY OPINION- AND DECISION-MAKING
** BIOCIDAL PRODUCTS COMMITTEE to be established on 1 Sep 2013

Members of the Management Board on 31 December 2013

Chair: Nina Cromnier

Members	
Thomas JAKL	Austria
Jean-Roger DREZE	Belgium
Boyko MALINOV	Bulgaria
Bojan VIDOVIĆ[8]	Croatia
Leandros NICOLAIDES	Cyprus
Karel BLAHA	Czech Republic
Peter ØSTERGÅRD HAVE	Denmark
Aive TELLING	Estonia
Pirkko KIVELÄ	Finland
Catherine MIR	France
Alexander NIES	Germany
Kassandra DIMITRIOU	Greece
Krisztina BIRÓ	Hungary
Martin LYNCH	Ireland
Antonello LAPALORCIA	Italy
Armands PLATE	Latvia
Marija TERIOSINA	Lithuania
Paul RASQUÉ	Luxembourg
Francis E. FARRUGIA	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

[8] In observer status as official nomination pending.

Representatives appointed by the European Commission

Antti PELTOMÄKI	Directorate General for Enterprise and Industry
Björn HANSEN	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 MSC - Member State Committee on 31 December 2013

Chair: Anna-Liisa SUNDQUIST

Members	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
Arno BIWER	Luxembourg
Tristan CAMILLERI	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 2013

Chair: Tim BOWMER

Members	Nominating state
Annemarie LOSERT	Austria
Sonja KAPELARI	Austria
Safia KORATI	Belgium
Veda Marija VARNAI	Croatia
Marian RUCKI	Czech Republic
Frank JENSEN	Denmark
Peter Hammer SØRENSEN	Denmark
Urs SCHLÜTER	Estonia
Riitta LEINONEN	Finland
Elodie PASQUIER	France
Stéphanie VIVIER	France
Norbert RUPPRICH	Germany
Nikolaos SPETSERIS	Greece
Christina TSITSIMPIKOU	Greece
Anna BIRO	Hungary
Katalin GRUIZ	Hungary
Thomasina BARRON	Ireland
Yvonne MULLOOLY	Ireland
Paola DI PROSPERO FANGHELLA	Italy
Pietro PARIS	Italy
Normunds KADIKIS	Latvia
Jolanta STASKO	Latvia
Lina DUNAUSKIENE	Lithuania
Žilvinas UŽOMECKAS	Lithuania
Hans-Christian STOLZENBERG	Luxembourg
Betty HAKKERT	Netherlands
Marja PRONK	Netherlands
Christine BJØRGE	Norway
Marianne VAN DER HAGEN	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 2013

Chair: Tomas ÖBERG

Members	Nominating State
Simone FANKHAUSER	Austria
Georg KNOFLACH	Austria
Catheline DANTINNE	Belgium
Elina Velinova STOYANOVA-LAZAROVA	Bulgaria
Mirta POKRSCANSKI LANDEKA	Croatia
Georgios BOUSTRAS	Cyprus
Jiri BENDL	Czech Republic
Lars FOCK	Denmark
Johanna KIISKI	Finland
Jean-Marc BRIGNON	France
Karine FIORE-TARDIEU	France
Franz-Georg SIMON	Germany
Karen THIELE	Germany
Angela LADOPOULOU	Greece
Dimosthenis VOIVONTAS	Greece
Endre SCHUCHTÁR	Hungary
Zoltan PALOTAI	Hungary
Marie DALTON	Ireland
Flaviano D'AMICO	Italy
Silvia GRANDI	Italy
Ilona GOLOVACIOVA	Lithuania
Tomas SMILGIUS	Lithuania
Cees LUTTIKHUIZEN	Netherlands

Thea Marcelia SLETTEN	Norway
Zbigniew SLEZAK	Poland
João ALEXANDRE	Portugal
Robert CSERGO	Romania
Janez FURLAN	Slovenia
Karmen KRAJNC	Slovenia
Maria Jesús RODRIGUEZ DE SANCHO	Spain
Åsa THORS	Sweden
Stavros GEORGIOU	United Kingdom

Members of BPC – Biocidal Products Committee on 31 December 2013

Chair: Erik VAN DE PLASSCHE

Members	Nominating State
Edmund PLATTNER	Austria
Boris VAN BERLO	Belgium
Ivana Vrhovac FILIPOVIC	Croatia
Andreas HADJIGEORGIOU	Cyprus
Jørgen LARSEN	Denmark
Anu MERISTE	Estonia
Tiina TUUSA	Finland
Pierre-Loic BERTAGNA	France
Kerstin HEESCHE-WAGNER	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
Vesna TERNIFI	Slovenia

María Luisa GONZÁLEZ MÁRRQUEZ	Spain
Mary IAKOVIDOU	Sweden
Nicola GREGG	United Kingdom

Members of the Forum for Exchange of Information on Enforcement on 31 December 2013

Chair: Szilvia Deim

Members	
Eugen ANWANDER	Austria
Paul CUYPERS	Belgium
Parvoleta LULEVA	Bulgaria
Tasoula KYPRIANIDOU-LEONTIDOU	Cyprus
Oldřich JAROLÍM	Czech Republic
Birte Nielsen BØRGLUM	Denmark
	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
Jill WEBER	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 numbers

Main drivers of ECHA activities	Estimate for 2013	Total	Actual %
Dossiers arriving in 2013			
Registration dossiers (including updates)	15 200	14 839	**98%**
Testing proposals*****	410	410	**100%**
Confidentiality requests (new claims received)***	770	548	**71%**
Access to data older than 12 years*	240	106	**44%**
PPORD notifications	400	299	**75%**
Inquiries	1 200	1425	**119%**
Data Sharing disputes	33	19	**58%**
Number of notifications under Article 7(2)	70	98	**140%**
Number of reports and notifications under Article 38 of REACH	400	147	**37%**
Restriction proposals (Annex XV)	8	4	**50%**
Restriction proposals developed by ECHA	3	1	**33%**
Proposals for harmonised classification and labelling (Annex VI of CLP Regulation)	70	29	**41%**
Proposals for identification as SVHC (Annex XV)	30	17	**57%**
SVHC proposals developed by ECHA	5	0	**0%**
Authorisation applications	20	13	**65%**
Alternative name requests	150	38	**25%**
Substances on the CoRAP to be evaluated by MS	50	46	**92%**
ECHA decisions in 2013			
Concluded evaluations			
no. of draft decisions on TP	20	46	**230%**
no. of CCH concluded	560	928	**166%**
- out of which draft CCH decisions (30%)	350	566	**162%**
no. of draft substance evaluation decisions	30	32	**107%**
Decisions on data sharing	3	11	**367%**
Decisions on completeness check (negative, i.e. rejections)**	470	15	**3%**
Decisions on confidentiality requests (negative)	80	198	**248%**
Decisions on access to documents request			
initial requests	400	53	**13%**
confirmatory requests	8	3	**38%**
Appeals submitted in 2013			
Appeals submitted in 2013	36	22	**61%**
Others			
Draft CoRAP for substances subject to evaluation	1	1	**100%**
Recommendations to the Commission for the Authorisation List	1	1	**100%**
Questions to be answered/harmonised answers (REACH Advice, REACH-IT, IUCLID 5, others)	8 500	6698	**79%**
SME checks	300	516	**172%**
Management Board meetings	4	4	100%
MSC meetings	6	6	**100%**
RAC meetings	5	4	**80%**
SEAC meetings	4	4	**100%**
Forum meetings	3	3	**100%**
General enquiries by phone or email	3 300	763	**23%**
Press enquiries	1 000	478	**48%**
Press releases and News alerts	75	95	**127%**

New CA posts to be filled for REACH/CLP	11	11	**100%**
Recruitment due to turnover	25	21	**84%**
Biocides/PIC activities			
Applications for new active substance approval	1	1	**100%**
Applications for renewal or review of active substances	3	1	**33%**
Applications for Union authorisation	9	0	**0%**
Assessment of technical equivalence	25	1	**4%**
BPC meetings	3	3	**67%**
New TA/CA posts to be filled for Biocides****	28	24	**86%**
New TA/CA posts to be filled for PIC	3	3	**100%**

*Access to data older than 12 years: this information is now retrievable in the inquiry process. This is the number of inquiries containing such requests for information that the Data-Sharing team handles.

**It covers only rejections due to failure in TCC (=fee paid + TCC failed)

***Based on completion date of the dossiers

**** 10 posts to be filled in 2014

***** No. of new registrations completed within given quarter, including one or more TPs

ANNEX 3: Resources 2013

Resources 2013

	REACH Staff Resources 2013				Budget 2013		BIOCIDES Staff Resources 2013				Budget 2013		PIC Staff Resources 2013				Budget 2013		ECHA (Total) Staff Resources 2013				Budget 2013	
	AD	AST	CA	Total	Initial Budget	Total committed	AD	AST	CA	Total	Initial Budget	Total committed	AD	AST	CA	Total	Initial Budget	Total committed	AD	AST	CA	Total	Initial Budget	Total committed
Implementation of the Regulatory Processes (Operational Budget)																								
Activity 1: Registration, Data-sharing and Dissemination	36	9	10	55	9 114 246	9 507 778	2	1		3	503 263	325 849					100 000	0	38	10	10	58	9 717 509	9 833 627
Activity 2: Evaluation	75	12	3	90	18 350 360	15 834 466					29 109	0					0	0	75	12	3	90	18 379 468	15 834 466
Activity 3: Risk Management	31	5	4	40	7 612 764	6 641 766					0	0					0	0	31	4	4	40	7 612 764	6 641 766
Activity 4: Classification and Labelling	12	3	1	16	3 278 161	2 436 944					0	0					0	0	12	2	1	16	3 278 161	2 436 944
Activity 5: Advice and Assistance through Guidance and Helpdesk	21	7	6	34	6 109 346	5 410 510	1		1	2	153 543	332 440					20 000	0	22	7	7	36	6 282 889	5 742 950
Activity 6: IT Support to Operations	28	9	2	39	17 338 646	15 361 701	1	1	0	2	1 665 713	2 207 038	1	1		2	925 200	1 152 700	29	10	3	42	19 929 559	18 721 438
Activity 7: Scientific Activities and Technical Advice to EU Institutions and Bodies	10	1	1	12	1 895 841	1 967 546					17 900	15 062					0	0	11	1	1	12	1 913 741	1 982 609
ECHA's Bodies and Supporting Activities																								
Activity 8: Committees and Forum	22	7	4	33	7 190 661	6 483 500	3	2		5	224 500	636 600					57 100	59 107	24	9	4	38	7 472 261	7 179 207
Activity 9: Board of Appeal	6	3	1	10	1 813 591	1 597 398					114 615	3 403					0	0	6	3	1	10	1 928 206	1 600 802
Activity 10: Communications	10	8	7	25	7 725 594	6 778 980		1		1	504 815	320 061					70 400	3 517	10	9	7	26	8 300 809	7 102 558
Activity 11: International Cooperation	3	0	0	3	1 589 089	743 614					39 900	0					0	0	3	0	0	3	1 628 989	743 614
Management, Organisation and Resources																								
Activity 12: Management	26	16	4	46	8 075 967	8 835 586					165 506	49 374					0	0	25	16	4	46	8 241 473	8 884 960
Activities 13-15: Organisation and Resources (Title II: Infrastructure)	24	46	32	102	19 127 989	15 760 779	1	0	4	5	630 892	521 359		1		1	113 867	99 875	25	48	36	108	19 872 748	16 382 013
Activity 16: Biocides							19	1	4	24	3 170 743	2 769 512						0	20	1	4	25	3 170 743	2 769 512
Activity 17: PIC												0		2	1	3	274 933	225 746	0	2	1	3	274 933	225 746
Total	**304**	**126**	**75**	**505**	**109 222 254**	**97 360 568**	**27**	**6**	**9**	**42**	**7 220 500**	**7 180 698**	**1**	**4**	**1**	**6**	**1 561 500**	**1 540 945**	**332**	**136**	**85**	**553**	**118 004 254**	**106 082 211**
In the Establishment Plan 2013		451	94					47	10					5	1					503	105			

Total number of TA positions occupied at 31 December 2013: 468
Total number of CA positions occupied at 31 December 2013: 85
Other staff (Seconded National Experts, interims, trainees) at 31 December 2013: 74
Financial and human resources per Activity (excluding vacant posts and those being filled)

ANNEX 4: Candidate List of Substances of Very High Concern (SVHCs)

Substances added to the Candidate List in 2013

Substance Name	EC number	CAS number	Date inclusion Candidate List	SVHC scope	Candidate List Decision	Intended by
Cadmium sulphide	215-147-8	1306-23-6	16/12/2013	Carcinogenic (Article 57a);#Equivalent level of concern having probable serious effects to human health (Article 57 f)	ED/121/2013	Sweden
Dihexyl phthalate	201-559-5	84-75-3	16/12/2013	Toxic for reproduction (Article 57 c)	ED/121/2013	Germany
Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	209-358-4	573-58-0	16/12/2013	Carcinogenic (Article 57a)	ED/121/2013	Netherlands
Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo] -5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	217-710-3	1937-37-7	16/12/2013	Carcinogenic (Article 57a)	ED/121/2013	Netherlands
Ethylene thiourea; imidazolidine-2-thione; 2-imidazoline-2-thiol	202-506-9	96-45-7	16/12/2013	Toxic for reproduction (Article 57 c)	ED/121/2013	Sweden
Lead di(acetate)	206-104-4	301-04-2	16/12/2013	Toxic for reproduction (Article 57 c)	ED/121/2013	Netherlands
Trixylyl phosphate	246-677-8	25155-23-1	16/12/2013	Toxic for reproduction (Article 57 c)	ED/121/2013	Austria
4-Nonylphenol, branched and linear, ethoxylated	-	-	20/06/2013	Equivalent level of concern having probable serious effects to the environment (Article 57 f)	ED/69/2013	Germany
Ammonium pentadecafluorooctanoate (APFO)	223-320-4	3825-26-1	20/06/2013	Toxic for reproduction (Article 57 c);#PBT (Article 57 d)	ED/69/2013	Germany
Cadmium	231-152-8	7440-43-9	20/06/2013	Carcinogenic (Article 57a);#Equivalent level of concern having probable serious effects to human health (Article 57 f)	ED/69/2013	Sweden
Cadmium oxide	215-146-2	1306-19-0	20/06/2013	Carcinogenic (Article 57a);#Equivalent level of concern having probable serious effects to human health (Article 57 f)	ED/69/2013	Sweden
Dipentyl phthalate (DPP)	205-017-9	131-18-0	20/06/2013	Toxic for reproduction (Article 57 c)	ED/69/2013	Poland
Pentadecafluorooctanoic acid (PFOA)	206-397-9	335-67-1	20/06/2013	Toxic for reproduction (Article 57 c);#PBT (Article 57 d)	ED/69/2013	Germany

ANNEX 5: Analysis and assessment of the AAR of the Authorising Officer for 2013

MB/05/2014 final
20/03/2014

ANALYSIS AND ASSESSMENT OF THE ANNUAL ACTIVITY REPORT OF THE AUTHORISING OFFICER FOR THE YEAR 2013

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,

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

Having regard to the Financial Regulation of the European Chemicals Agency (MB/53/2008), and in particular Article 40 thereof,

Having regard to the Work Programme of the European Chemicals Agency for the year 2013 adopted by the Management Board at its meeting of 28 September 2012,

Having regard to the Annual Activity Report of the Authorising Officer of the European Chemicals Agency for the year 2013 as submitted to the Board on 07 March 2014.

WHEREAS,

The authorising officer shall report to the Management Board on the performance of his duties in the form of an annual activity report, together with financial and management information 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 15 June each year, the Management Board shall send the budgetary authority and the Court of Auditors an analysis and an assessment of the authorising officer's annual report on the previous financial year. This analysis and assessment shall be included in the annual report of the Agency, in accordance with the provisions of the Regulation (EC) No 1907/2006.

HAS ADOPTED THE FOLLOWING ANALYSIS AND ASSESSMENT,

1. Welcomes the results presented in the Annual Activity Report of the Authorising Officer as well as the high performance level achieved with regard to discharging the tasks under the REACH Regulation (EC) 1907/2006 and the CLP Regulation (EC) No 1272/2008. This is reflected in the fact that 53 out of the 56 performance

targets set in the Work Programme 2013 were met.

2. CONGRATULATES ECHA for the operational work performed in 2013 and, in particular, for the achievements in:

   a) The successful management of the 2013 REACH registration deadline, the smooth entry into operation of the Biocidal Products Regulation in September 2013 and the preparatory work for the entry into operation of the PIC Regulation in March 2014.

   b) Continuing to make the information on the chemicals registered or notified publicly available, in particular from all dossiers registered by the 2013 deadline. By the end of the year, information from about 40,000 registration dossiers covering more than 10,000 substances was freely available on the ECHA website.

   c) Concluding 928 compliance checks performed on dossiers registered during the first registration deadline of 2010, thereby exceeding the 5% target, adopted in 2013 as a self-commitment.

   d) Updating the Community rolling action plan for substance evaluation, including 36 substances for 2012-2014, supporting Member States in the evaluations of 55 substances and leading to the first decisions that received agreement in the Member States Committee.

   e) Adding 13 Substances of Very High Concern (SVHCs) to the Candidate List bringing the total number of substances on the Candidate List to 151 by the end of the year.

   f) Finalising the fourth recommendation for inclusion of priority substances in the authorisation list and preparing the fifth recommendation.

   g) Providing support to applicants for authorisation by organising 9 pre-submission sessions for companies applying for authorisation and successful handling of the first applications submitted.

   h) Finalising the SVHC 2020 Roadmap Implementation Plan and further developing screening tools to support the Risk Management Option Analysis Approach.

   i) Facilitating the sharing of information between Member States to enhance coordination and cooperation in risk management.

   j) Adopting 2 RAC and 2 SEAC opinions on restriction proposals and adopting 34 opinions of RAC on CLH proposals and 1 SEAC and RAC opinion each on the first authorisation application.

   k) Helping to considerably increase the output of the three committees (RAC, SEAC and MSC), while maintaining quality and respecting the legal deadlines. Establishing and making operational the new Biocidal Products Committee and the Coordination Group.

   l) Maintaining up-to-date the C&L inventory with a total number of processed notifications since 2010 of 6.1 million, covering 125,000 distinct substances, and having publicly disseminated C&L information for 116,000 substances.

   m) Supporting industry in building up capacity, particularly for registration and authorisation, via various communication tools in the form of webinars and targeted materials in 23 EU languages.

   n) Taking an important step in designating an “SMEs’ Ambassador” to take due account of SMEs efforts and challenges to comply with additional administrative and financial burdens and to provide SMEs with tailored additional support and guidance.

o) Providing direct support to registrants via the ECHA Helpdesk and in producing updated and new guidance documents for industry and making a substantial number of these available in 23 EU languages well ahead of the registration deadline; engaging national helpdesks via the Helpnet in this effort.

p) Putting in place the necessary tools and procedures by 1 September to allow companies to submit their applications under the new Biocidal Products Regulation; providing industry with the necessary guidance and manuals to start implementing their obligations under that Regulation, and extending both the ECHA Helpdesk and the Helpnet to provide advice also for biocides.

q) Designing the Efficiency Development programme 2014-2016 to be able to cope with staff reductions as required from all EU agencies while facing growing dossier numbers.

r) Achieving a high rate of budget execution of commitment appropriations – over 98% for all Regulations.

s) Achieving the recruitment target for all legislations and developing a Staff Retention Policy and an outplacement service.

3. Notes the 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, PBT substances and endocrine disruptors.

4. Welcomes, that the Agency continues to work transparently, that the committees involve stakeholders and case owners as appropriate and that a workshop with those organisations was held in Brussels to facilitate their input in ECHA's work programmes.

5. Welcomes that the Agency took an important step towards an improved dissemination website in response to a stakeholders' survey.

6. Welcomes the Agency's strengthened and continued efforts to improve dossier quality, including with regard to intermediates, through the revision of the completness and compliance check strategy and encouraging registrants to proactively update their dossiers.

7. Notes that the MSC continued to be unable to reach unanimous agreement on any of the proposals for testing reproductive toxicity and that over 82 dossiers have been referred to the EU Commission last year.

8. Welcomes the annual meeting with Directors of MSCAs, as of 20 November 2013, which considerably helps to deliver effective planning.

9. Welcomes the work of the Forum in harmonising the approach to enforcement and in particular in concluding the Interlinks project, which provides a basis for the enforcement of regulatory decisions.

10. Notes with concern that the final report on the second coordinated enforcement project of the Forum highlighted significant deficiencies with regard to Safety Data Sheets.

11. Appreciates the delivery of the first appeal decisions on dossier evaluation of the Board of Appeal.

12. Looks forward to being informed of further progress towards ISO 9001:2008 certification, as well as towards meeting the requirements of the Framework

Financial Regulation on efficiency and effectiveness of the internal control systems, and in particular the adoption of the Integrated Management Standards and the continuing analysis and management of risks.

13. Notes the success of the Agency and its continuing efforts in verifying the SME status of registrants.

14. Notes that the revenue from fees and charges under REACH and CLP activities in 2013 amounted to 85.8 million euro thus exceeding the forecasts, and from the Biocidal Products Regulation activities to 313,000 euro.

15. Notes with concern the difficulties of the Agency, in the absence of a financial reserve, to obtain additional subsidy in those years where the financial revenue will be lower than estimated.

16. Congratulates the Agency on reducing its carry-over rate of REACH and CLP funds to 10.4% and encourages the Agency to continue its efforts to reduce the carry over as far as possible.

17. Notes that the carry-over rates on Biocides and PIC funds were lower than the previous year, and encourages the Agency to further reduce it.

18. Notes the Agency's continuing work to support the access of Member State authorities to the R4BP, REACH-IT and IUCLID IT systems, as well as the secure use of the information in these systems.

19. Notes that in 2013 ECHA upgraded its ICT infrastructure and set up outsourced services for the management of REACH- IT to ensure 24/7 monitoring and support in line with its IT Business Continuity Plan for the IT systems necessary to support the 2013 REACH registration deadline.

20. Notes the further progress made in the area of conflicts of interest in developing and implementing the Agency's procedures to address the recommendations of the Court of Auditors.

21. Recommends that ECHA:

    a) Better aligns its planning and reporting processes, by pursuing further improvement of the links between the Multiannual and Annual Work Programmes and the preparation of the budget and informing the Management Board respectively.

    b) Continues improving the efficiency of its bodies, such as streamlining of RAC and SEAC opinion development processes.

    c) Continues finding synergies between the different activities and revises procedures in order to better manage the resource constraints of the coming years.

    d) Reinforces competitiveness and innovation by further articulating where its activities support and reflect such aspects in its work.

    e) Continues making efforts to improve the user-friendliness of its dissemination website.

    f) Uses multilingual communication in its contacts with companies, in particular SMEs.

    g) Continues efforts to streamline substance identity information requirements.

h) Reinforces support to SMEs in view of the next deadlines of 2015 (CLP mixture classification) and 2018 (REACH registration of lower volumes).

i) Continues using the experience gained in data-sharing to provide targeted advice to companies, in particular SMEs.

j) Builds on experience from authorisation applications to enable industry to put together their dossiers in the most effective and efficient manner.

signed
For the Management Board
Nina Cromnier