ECHA
EUROPEAN CHEMICALS AGENCY

Work Programme 2015

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Work Programme 2015

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European Chemicals Agency

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List of acronyms

BPC	Biocidal Products Committee
BPR	Biocidal Products Regulation
C&L	Classification and labelling
CA	Contract Agent
CCH	Compliance check
Chesar	Chemical Safety Assessment and Reporting tool
CLH	Harmonised classification and labelling
CLP	Classification, labelling and packaging
CMR	Carcinogenic, mutagenic and reprotoxic
CoRAP	Community rolling action plan
CSA	Chemical safety assessment
CSR	Chemical safety report
DNA	Designated national authority
eChemPortal	OECD Global portal to information on chemical substances
ECHA	European Chemicals Agency
EU	European Union
Forum	Forum for Exchange of Information on Enforcement
HelpNet	REACH and CLP Helpdesk Network
HRMS	Human Resources Management System
IAS	Internal Audit Service of the Commission
IATA	Integrated Approach on Testing and Assessment
IPA	Instrument for Pre-Accession Assistance
ISO	International Organisation for Standardisation
ICT	Information Communications Technology
IR	Information requirements
IT	Information Technology
IUCLID	International Uniform Chemical Information Database
MAWP	Multi-Annual Work Programme
MB	Management Board
MS	Member State
MSC	Member State Committee
MSCA	Member State competent authority
NGO	Non-governmental organisation
OECD	Organisation for Economic Cooperation and Development
Odyssey	ECHA's tool to support evaluation tasks
PBT	Persistent, bioaccumulative and toxic
PIC	Prior Informed Consent
PPORD	Product and Process Oriented Research and Development
PSIS	Pre-Submission Information Sessions
(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	REACH-IT is the central IT system providing support for REACH
RIPE	REACH Information Portal for Enforcement
RMO	Risk management option
RMOA	Risk management option analysis
SEAC	Socio-Economic Analysis Committee
SIEF	Substance information exchange forum
SME	Small and medium-sized enterprises
SVHC	Substance of very high concern
TA	Temporary Agent
UN GHS	United Nations Globally Harmonised System of Classification and Labelling of Chemicals
UVCB	Substance of unknown or variable composition, complex reaction products or biological materials
WP	Work Programme

ECHA's legal mandate

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

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

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

The recast Prior Informed Consent (PIC) Regulation (Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals) also entered into force in 2012. Certain tasks related to PIC were transferred from the Joint Research Centre of the European Commission to ECHA in 2014.

These legislative acts are applicable in all EU Member States (MSs) without the need for transposition into national law.

ECHA's Mission, Vision and Values

<table>
<tr><th>Mission</th><th>Values</th></tr>
<tr><td>ECHA is the driving force among regulatory authorities in implementing the EU's groundbreaking chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness.

ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern.</td><td rowspan="3">Transparent
We actively involve our regulatory partners and stakeholders in our activities and are transparent in our decision-making. We are easy to understand and to approach.
Independent
We are independent from all external interests and impartial in our decision making. We consult members of the public openly before taking many of our decisions.
Trustworthy
Our decisions are science based and consistent. Accountability and the security of confidential information are cornerstones of all our actions.
Efficient
We are goal-oriented, committed and we always seek to use resources wisely. We apply high quality standards and respect deadlines.
Committed to well-being
We stimulate the safe and sustainable use of chemicals to improve the quality of human life in Europe and to protect and improve the quality of the environment.</td></tr>
<tr><td>Vision</td></tr>
<tr><td>ECHA aspires to become the world's leading regulatory authority on the safety of chemicals.</td></tr>
</table>

Introduction

The purpose of the EU's chemicals legislation is to ensure a high level of protection of human health and the environment, and to facilitate the free circulation of chemicals within the internal market. In addition, the aim is to enhance competitiveness and innovation, and to promote alternative methods to animal testing for assessing the hazards of chemicals. The EU regulatory system is based upon the principle that manufacturers, importers and downstream users should make sure that they manufacture, place on the market or use substances that do not adversely affect human health or the environment. The provisions are underpinned by the precautionary principle.

ECHA's mandate covers tasks under four regulations: REACH, CLP, Biocidal Products and PIC. The successful implementation of these regulations requires a well-functioning Agency, capable of delivering independent and high-quality science-based opinions within strict legal deadlines, as well as providing the necessary support to the concerned interested parties, including industry, in implementation to make sure that the operational aspects of the legislation function appropriately.

However, the efficient operation of the regulations also depends upon ECHA's institutional partners, in particular the Member States of the EU and the European Commission (hereafter referred to as 'the Commission') on the one hand, and on industry to implement the regulations properly, on the other. In addition, contributions by distributors, retailers and consumers, as well as workers and their representatives, are needed. Through the implementation of the above legislation, ECHA also contributes towards achieving the targets of the EU's Seventh Environment Action Programme.

The final ECHA budget and the establishment plan for human resources will be adopted in December 2014 by its Management Board (MB), following the final adoption of the general budget of the European Union by the Budgetary Authority (European Council and Parliament). Should the total revenue or authorised staff figures differ significantly from the current estimates, the Work Programme will be adjusted accordingly.

The planning in this Work Programme is founded upon the baseline figures presented in Annex 2, which are an update of the Commission estimates made at the time the REACH Regulation was prepared. Having passed three important deadlines for REACH registrations and CLP notifications respectively, in 2010, 2011 and 2013, ECHA can now base some of its predictions on real data. Some parts of the baseline numbers nevertheless remain subject to a significant degree of uncertainty, in particular with regard to authorisation applications for REACH and the Biocidal Products Regulation.

ECHA's strategic objectives 2014-2018

ECHA's strategic objectives have been defined in the Multi-Annual Work Programme 2014–2018 adopted by the Management Board on 27 September 2013. This Work Programme 2015 is based on the four strategic objectives, the achievements of which will be monitored through annual measurements and the results of which will be reported in the annual General Report:

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

Strategic objective 1 is divided into three main action areas: 1) improving the quality of dossiers; 2) maximising the impact of the communication of risk management advice in the supply chain, and 3) improving the dissemination of (high quality) information.

The monitoring system will cover the first action area: improving the quality of dossiers. For the second action area, ECHA will rely on the next five-year baseline study conducted by the Commission. Regarding the third action area, progress can be measured through stakeholders' surveys to be developed when the new dissemination pages are released in 2015 (the reference for comparison being the results of the extensive survey conducted in 2012-2013 as the basis for preparing for the future website).

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

Strategic objective 2 is focused on mobilising authorities to use data intelligently to identify and address chemicals of concern. In developing indicators for measuring ECHA's accomplishments in achieving strategic objective 2, the focus has been on four areas. The first is substance screening, where the emphasis should be on identifying chemicals of concern using ECHA's internal and external databases. The second and third areas are the processes of substance evaluation and regulatory risk management where the focus is on mobilising Member States and the desired outcomes of regulatory actions. The fourth area is the quality of the dossiers and opinions developed by the Member States and ECHA Committees.

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

In the overall context of the strategic objectives, strategic objective 3 and measuring/assessing its implementation is of qualitative nature. It can be considered both as an enabler for strategic objectives 1 and 2, and as an element to monitor ECHA's corporate performance as experienced by others. As an enabler, the main aim of strategic objective 3 is to pave the way for ECHA to successfully implement the other strategic objectives, whereas as an additional monitoring element it seeks to provide informed reflections by others on ECHA's general regulatory-scientific capacity. So, ECHA will measure whether it is successfully implementing actions that are intended to move the Agency from the current situation towards achieving the ultimate goals of strategic objective 3, whereas any quantifiable impacts of activities performed under strategic objective 3 will primarily be measurable through the implementation of strategic objectives 1 and 2.

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

ECHA strives to achieve its MAWP within the constraints set by the resource cuts applicable to all EU Agencies. To monitor the achievement of strategic objective 4, a relatively simple indicator to measure the ratio of human resources and delivery of final decisions and opinions, has been developed. The calculation is based on a number of selected final outputs of the Agency compared to the total number of staff.

Highlights of 2015

The second year of implementing ECHA's five-year strategy, described in the Multi-Annual Work Programme (MAWP) 2014-2018, involves further pursuit of the four strategic objectives and stabilising the newer authorisation and biocidal substances and products processes. However, regarding the activities related to biocides there is considerable uncertainty regarding the volume of applications and related fee income which makes the planning very challenging.

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

The year 2015 is crucial for ECHA's preparation for the last registration deadline of phase-in substances in 2018. ECHA will do its utmost to facilitate the optimal situation, where registrants are able to provide high quality data at the first submission. To this end, the Agency aims to have the revised IT tools for dossier preparation and submission, and support material ready for roll-out in 2016 to allow efficient formation of substance information exchange forums (SIEFs), fair and transparent SIEF operation and coordinated registration efforts in the coming years. The data generation efforts result in the safer use of chemicals and can also be used to promote innovation.

In providing advice and assistance to duty holders, the Agency will focus on further enhancing its support to small and medium-sized enterprises, giving more audience-adapted orientation in the form of updated guidance documents, web page texts and other means of communication, and by using various multiplier platforms to reach companies still unaware of their obligations under the EU chemicals legislation. ECHA also intends to support specific sectors developing targeted advice for their members.

At the same time, ECHA conducts compliance checks on the highest priority substances, focusing on higher tier human health and environment endpoints in lead and individual dossiers.

In 2015, ECHA will release a new dissemination platform with more user-friendly access to information. Moreover, to facilitate European citizens' right to get information on chemicals they may be exposed to, ECHA plans to start publishing information on substances in a new format containing all essential information on substances' intrinsic properties, hazards, uses and regulatory status in an easily accessible layout.

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

In 2015, the first results of the screening and data generation activities foreseen under the substances of very high concern (SVHC) roadmap to 2020 are expected to start to bear fruit, eventually leading to an increased number of Risk Management Option Analyses and subsequent proposals for regulatory risk management. Thereby, the number of substances put forward for the Candidate List would increase. It is also expected that a larger number of Member States will participate in these efforts.

After three years of substance evaluation, ECHA will assess the process, its outcomes and how substance evaluation supports and contributes to the regulatory risk management processes and improvement of data quality. A common screening approach, initiated in 2014, is expected to support Member States in selecting substances to be evaluated in view of more effective risk management at EU level.

The expected high number of authorisation applications will be challenging for the Secretariat as well as the Risk Assessment and Socio-economic Analysis Committees

from scientific and workload perspectives. The lessons learnt from the first applications for authorisation will be used to further enhance the efficiency of the opinion making system. In addition, the Commission is expected to establish simplified rules for special cases in an Implementing Regulation.

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

ECHA will continue building up a systematic approach for further developing the scientific capacity in accordance with its science strategy defined in 2014, which will outline the areas that ECHA considers most important from the regulatory decision-making perspective.

In the event that the European Commission will adapt the REACH information requirements (IR) to better take into account the specific aspects of nanomaterials; ECHA will increase its activities to improve the quality of registration data for nanomaterials. ECHA will also continue its contributions for the development of new testing and assessment methods, including alternatives to animal testing.

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

To achieve the ambitious targets of the Work Programme with decreasing staff resources, ECHA will have to further improve its efficiency. In 2015, the Agency will still have to invest in developing the IT systems to both serve the industry and Member States better but also to reduce manual work in its internal processes.

Regarding implementation of the Biocidal Products Regulation (BPR), ECHA will prioritise the preparation of decisions and the support to the review programme of active substances with reduced estimates for applications and fee income, while striving to maintain flexibility to react to unforeseen increases in the workload during the year.

The expected higher workload of the Secretariat and the Committees will increase the pressure to a level that requires continuous efficiency improvements. Therefore, ECHA plans to analyse different options for the Committees to deal with their workload.

Based on the measurements developed in 2014, ECHA will report on the progress made in achieving the strategic objectives for the first time in 2015.

ECHA will undertake several actions to support SMEs to meet their obligations:

- Implementation of the 2018 REACH Registration Roadmap will be geared towards providing support particularly to SME registrants.
- Equally, the deliverables provided by ECHA and its partners in 2015 under the CSR/ES Roadmap will support SMEs.
- The new dissemination pages will be beneficial to SMEs and allow them to find information on the properties and state of regulatory oversight over chemical substances for which they may have obligations.
- The Agency's improved communication to facilitate the preparation of "fit for purpose" applications for authorisation will foster predictability for SMEs' commercial decisions.
    - ECHA's communication of first experiences with the full cycle of authorisation applications and related decision making will do the same.
- ECHA's communications' activities on BPR and CLP obligations will particularly have SMEs in mind.
- ECHA will continue its efforts to provide translations of guidance in official EU languages, where appropriate.

1. Implementation of the Regulatory Processes

1.1. Registration, Data-sharing and Dissemination (Activity 1)

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

Due to the registration process, ECHA holds a unique database on chemicals, which can be efficiently used in further regulatory processes, especially in identifying whether certain chemicals deserve EU-wide risk management measures and informing the general public. The registration information is also the starting point for companies to develop their safety data sheets where they communicate the conditions of safe use further down the supply chain and make the safe use of chemicals a reality to tens of thousands of downstream users and their customers. It is, therefore, crucial that the registration information is of adequate quality to make sure that the key objectives of REACH are achieved. In practice, this means that the information is compliant with the regulations, fit for purpose and easily accessible to all parties.

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

1. Highlights of the year

Registration and dossier submissions

Registration

The majority of ECHA's resources devoted to registration and dossier processing will be consumed in managing the incoming dossiers, whether new submissions or updates. This is an area where ECHA will continue to seek improvements as efficient processing of these dossiers is key to ensuring a level playing field for companies and swift access to the market as well as enhancing ECHA's database on chemical substances.

Besides this core activity, the major development work in 2015 is targeted to tasks related to the preparation of the last registration deadline of 2018 which will be very different from the two previous ones due to the registrants' profile (many small and medium-sized enterprises (SMEs) acting in small SIEFs or joining existing larger SIEFs) and the volume of registrations expected (more than double the 2010 figures). This is also the opportunity to make sure that the knowledge and information gained with the two first deadlines help the new registrants to provide high quality data at the first submission, for the benefit of industry and ECHA's resources.

In 2015, ECHA will implement the first elements of the 'Roadmap for the 2018 deadline', established in 2014 in cooperation with industry stakeholders and the Commission. In

line with the chronological order of challenges that the registrants face, the first actions are likely to tackle aspects related to SIEF formation and management such as best practice and recommendations on data and cost sharing as well as establishing substance sameness (see detail below).

ECHA will also need to make sure that all identified improvement needs for the dossier creation and submission-related tools and support are efficiently gathered and channelled into the respective development work (see more in Activity 6 for IUCLID and REACH-IT and in Activity 5 for support). This is to make sure that the registrants of the last registration deadline can, already in 2016, benefit from these improvements which aim at meeting the needs of smaller companies and also at increasing the quality of the registrations. For the latter, the foreseen improvements include implementing the identified actions in the completeness check procedure such as upgrading the completeness check tool and introducing other potential measures based on the 2014 review to support the registrants to submit dossiers that are as complete and internally consistent as possible. This will be accompanied by communication activities to inform the existing and future registrants, update of relevant manuals and organisation of webinars. Cooperation with individual sectors developing support for their members will be considered. This type of work has already started for essential oils and dyes. The knowledge gained on dossier quality will also be put to good use for providing practical advice to the 2018 registrants on how best to build a compliant dossier.

ECHA will also reinforce the development of its data-screening and analysis methodologies for supporting its strategic objectives to improve data quality in the dossiers and for using this information in an intelligent way. In 2015, the focus is in ensuring that the methods developed in the previous years are being used to their maximum capacity for selecting substances that need further investigation or regulatory action on one side, and for stimulating updates from the registrants on the other side. In line with the strategy established in 2014, the screening activities will be common to all REACH and CLP processes, so that the most appropriate regulatory instrument can be proposed based on the screening findings and they will be directed towards those substances where most impact in terms of the safe use of chemicals can be achieved.

As in previous years, both regulatory and non-regulatory measures will be used with the aim of improving dossier quality. The non-regulatory measures include targeted campaigns addressing frequent deficiencies in dossiers, improved tools and general communication for the registrants. For example, in its actions on substances registered as intermediates only, ECHA will continue the verification of the uses and request further information when appropriate but will prioritise (potential) SVHCs. This will also support the proper implementation of the ‘SVHC roadmap to 2020’ and the authorisation process (see Activity 3). Furthermore, more novel measures, such as promotion of positive examples of companies proactively improving their dossiers are being considered. Resources of the screening activities will also be used to detect registrants that seem to be misusing the information gathered together by other companies without proper compensation.

Other types of dossiers submission, including biocides dossiers and PIC notifications

With a view to stimulating European innovation, companies can request temporary exemption of registration obligations for substances used in product and process oriented research and development ('PPORD notifications'). In 2015, ECHA has an effective system in place for assessing the PPORD notifications including requests for prolongation, i.e. verifying that the process is not abused but truly used for research and development and for setting conditions where it matters for safe use, after consultation with the Member State competent authorities.

Regarding biocides dossiers, 2015 will see further streamlining of the submission processes as well as implementing automation in the Register for Biocidal Products (R4BP), which will have been developed during 2014 for the majority of these processes. This is expected to reduce manual intervention, thus increasing the overall efficiency (See more in Activity 16).

Finally, the volume of export notifications under PIC is likely to be in the same order of magnitude as in 2014, with a peak of submissions towards the end of the year (See more in Activity 17).

Chemical safety assessment (CSA) programme

The communication of adequate risk management advice through exposure scenarios as part of the chemical safety report (CSR) and communicated through the supply chain in safety data sheets (SDSs) is vital to the successful implementation of the safe use concept under REACH. The need to promote extended safety data sheets as a central risk management tool, as well as address the problems with regard to their content and format hampering their workability was outlined in the REACH review performed by the Commission. Therefore, ECHA support to registrants and downstream users in this field is part of its strategic objectives and, within the Agency, the activities are grouped under the 'Chemical safety assessment (CSA) programme'. Collaboration with ECHA's stakeholders is realised through the Exchange Network on Exposure Scenarios (ENES) which operates through technical working groups and convenes at plenary meetings to share results and identify emerging issues twice a year.

ECHA's CSA programme will continue to channel the Agency's contribution to the implementation of the Chemical Safety Report (CSR) / Exposure Scenario (ES) Roadmap, along the lines established in the Roadmap's Coordination Group. In 2015, results include publication of illustrative examples on use description, as well as of related guidance, publication of harmonised layout for exposure scenario for communication in the supply chain, and release of the revised phrase library for preparing exposure scenarios. Finally, 2015 marks the two-year anniversary of the CSR/ES Roadmap, and review of the progress and potential revision of the document are foreseen.

The other activities under the CSA programme include further exemplification and methodology development in support of the chemical safety assessment of complex substances, such as substances of unknown or variable composition, complex reaction products or biological materials (UVCBs). This will lead to additional advice being given to registrants as well as completing the specifications which will be used for the development of the Chemical Safety Assessment and Reporting tool (Chesar 3, see Activity 6).

In addition, ECHA will also continue to help downstream users understand and comply with their obligations under REACH. The activities will focus on measures to promote

information in the supply chain that is realistic, relevant, efficiently generated and easily understood.

One element is to improve how downstream users provide relevant information on uses to registrants, by developing the current use maps. Another is to support formulators in developing methodologies to incorporate exposure scenario information in the generation of safe use information for mixtures, and to promote the outcome of these developments on ECHA's website. Projects relating to harmonisation of exposure scenarios are continuing and it is proposed to provide additional support related to generation of safety data sheets. User-friendly video tutorials on key downstream user issues will be developed, aimed at SME's and companies with limited knowledge of REACH.

Downstream users also have compliance obligations relating to chemicals from other legislation. ECHA, together with stakeholders, intends to exemplify how information and activities associated with EU-wide chemicals legislation and national obligations can be coordinated most effectively.

Substance identification and data sharing

Substance identity activities are part of all REACH, CLP and biocides processes. In 2015, the workload is expected to remain at least at the same level as previous years, i.e. more than 2 500 substance identification assessments, mainly related to inquiry and evaluation processes. The specific focus of 2015 will likely be on dossiers submitted in 2013 that require evaluation activities, especially for potential substances of concern. In addition, the regular processing of inquiries under REACH and Biocides, to put companies in contact and facilitate data sharing, is expected to remain at a high level, and will tie in a major part of the resources related to substance identification.

On the dossier quality side, in 2015 ECHA aims to conclude the work on a methodology for establishing substance sameness. The focus is on complex substances (UVCBs and some complex multi-constituent substances, which represent more than 30% of the substances on the market) for which registrants are facing difficulties in providing adequate information for unambiguously identifying their substance, and justifying certain data provisions in their dossiers, e.g. those based on read-across. The Commission contract on characterisation of UVCB substances will also be closely followed to implement its results in ECHA's processes and support material. ECHA's intention through this work is to prepare guidance for registrants to help their work in the SIEFs, and to identify elements that could be introduced to implementing legislation by the Commission, if appropriate.

ECHA will also continue to verify the substance identity information of registration dossiers, based on IT screening complemented with manual checks when needed, and will follow up on the first batch of verifications carried out in 2014. This is to make sure that registrants address the identified shortcomings or take further action if this is not been the case.

Finally, in the area of data sharing, the activities are expected to increase in 2015, especially for biocides where ECHA will process the technical equivalence requests and data sharing requests and provide the chemical similarity service on request. In 2015, a high volume of requests is expected in relation to the deadline of 1 September 2015 for suppliers that are not part of the review programme (see more in Activity 16). Under REACH, the data-sharing workload is expected to increase, following the trend already observed in 2014. This is due to the growing number of disputes submitted to ECHA, as more SMEs get involved in data sharing negotiations and rely increasingly on ECHA's support.

Dissemination – electronic public access to information

ECHA's dissemination portal serves as a showcase for both civil society and companies, where companies' efforts in collecting information to advance the safe use of chemicals are subject to scrutiny. At the same time, for European citizens the dissemination website is the place to get information on the chemicals they may be exposed to. In 2015, ECHA plans to launch the new dissemination web pages based on the 2013 stakeholders' study and subsequent workshops and consultations. The new pages will contain brief profiles (summaries) of substances to allow their properties and main uses to be understood at a glance.

In addition, the new pages will offer a more integrated view of the regulatory information for each substance as well as better access to key registration data through information being more easily downloaded. ECHA will continue to publish the evaluation decisions, but they will be made more visible in the substance pages as described above. It is ECHA's intention to make increased use of its website in its strategy for stimulating dossier updates in order to improve the information quality.

Other dissemination-related activities of 2015 include the conclusion of the remaining confidentiality requests received in May 2013, and the first level of assessment of the requests received in the 2014 registration dossiers so that the information that is deemed non-confidential can be made publicly available as soon as possible. These assessments will be completed, leading to either acceptance, rejection or requests for further justification.

Finally, the publication process for information submitted on active substances and biocidal products as well as on export notifications under PIC will be further integrated within the existing REACH processes and IT systems to ensure consistency of approach and to gain efficiency.

2. Objectives and indicators

Objectives

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

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

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

4. Industry is given high quality scientific and technical support to enable successful development of the chemical safety reports (CSRs) and adequate risk management advice through the supply chain in the exposure scenarios.

Performance indicators and targets

Indicator	Target in 2015	Means and frequency of verification
Percentage of registrations and PPORD notifications processed within the legal timeframe.	100%	Time recorded in REACH-IT. Monthly reporting.
Percentage of inquiries concluded within the internal timeframe (20 working days).	80%	Time recorded in REACH-IT. Monthly reporting.
Percentage of data sharing disputes concluded within the legal/internal timeframe.	100%	Assessment time recorded. Monthly monitoring.
Extent of publication of registration dossiers successfully submitted by the registration deadline of 31 May 2013.	100%	Rate of publication recorded. Monthly monitoring.
Level of satisfaction of interested parties with dossier submission and dissemination activities of ECHA, as well as with ECHA's activities on improving the quality of CSRs and exposure scenarios for communication.	High	Annual survey.

3. Main outputs

Registration and dossiers submissions

- Approximately 5 700 registration dossiers (mainly updates) and 400 Product and Process Oriented Research and Development (PPORD) notifications (including requests for extension) undergo the completeness check and are assigned a registration number or a PPORD notification number, where relevant.
- Up to 50 decisions on PPORDs.
- Up to 3 000 biocides applications (applications for national authorisation, applications for new active substances, renewals or review, Union authorisations of products) are processed and the applications for national authorisation transmitted to the Member States.

2018 Registration roadmap and dossier quality

- Strategy and methods for supporting 2018 registrants in relation to REACH Annex III
- Development of the completeness check tool and implementation of the revised process, if needed, for a release to registrants in 2016.
- Support packages made available to the registrants to stimulate spontaneous updates.

CSA Programme

- Illustrative examples on use description are published.
- Agreement on and publication of harmonised layout for exposure scenarios for communication in the supply chain.
- Review of the CSR/ES Roadmap is carried out.

Substance identification and data sharing

- Approximately 1 050 new inquiry numbers will be provided.
- Approximately 5 to 10 decisions on data-sharing disputes under REACH and equivalent number under the biocides legislations.
- Methodology established for substance sameness

Dissemination

- Information published on the Dissemination pages linked to the OECD Global portal to information on chemical substances (eChemPortal).
- Launch of the new Dissemination pages integrating information submitted to ECHA as part of the REACH, CLP and biocides legislations and arising from different regulatory processes.
- Publication of statistics and reports arising from the PIC Regulation.
- Up to 250 confidentiality requests under REACH from 2014 undergo initial assessment.

1.2. Evaluation (Activity 2)

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

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

1. Highlights of the year

Dossier evaluation

As an important part of the activities under strategic objective 1, ECHA continues to fully implement the multi-annual compliance check strategy consolidated in 2014[1]. On the other hand, 2015 is a peak year for issuing draft decisions on testing proposals from 2013 registrations and processing them through the decision-making process. Hence, the capacity for opening new compliance checks remains limited. Follow-up evaluation is reaching its peak workload as updated dossiers will be received from previous testing proposal decisions as well as compliance checks. Due to the high volume and complexity of the dossier evaluation process, it is regarded essential that efforts to improve the efficiency and effectiveness of the process are continued in 2015.

ECHA's focus of compliance check is on all received standard registrations from 2010 and 2013 in the two highest tonnage bands. Received registration dossiers go through the screening common to all REACH and CLP processes and priorities for compliance check are set accordingly. These priorities aim to ensure an efficient interface with and serve the needs of substance evaluation as well as regulatory risk management measures in general and SVHC Roadmap implementation in particular. Moreover, compliance check is more tightly integrated with other measures improving dossier quality and used for cases where it is the most effective measure to bring the dossier into compliance.

The highest priority substances are addressed under compliance check with the focus on the higher tier human health (i.e. genotoxicity, repeated-dose toxicity, pre-natal developmental toxicity, reproduction toxicity and carcinogenicity) and environment endpoints (i.e. long-term aquatic toxicity, biodegradation and bioaccumulation) of the lead and individual dossiers. Besides this, the substance identity, to the extent relevant, is always assessed once a dossier is opened for a compliance check. The scope of the check will be matched with the identified concerns, based on IT, manual screening and expert judgement. A small proportion of compliance checks will continue to be based on a random selection to make sure that no registrant can be certain that their dossier will not be examined.

Furthermore, ECHA will continue addressing the compliance of dossiers covering different forms, including nano-forms, of a substance. The Agency will implement the approach

[1] See document "Safer chemicals - focusing on what matters most" 26.9.2014.

developed in 2014 for addressing the chemical safety report-related issues and consolidate the approach for addressing dossiers that rely on inadequate read-across or category approaches.

Concerning the examination of testing proposals, ECHA will continue to conclude on the proposals in a systematic manner. The aim is to conclude (issue draft decisions) for at least 75% of all valid testing proposals submitted by the 1 June 2013 registration deadline.

In 2015, an important part of the resources will continue to be allocated to the decision-making process on the draft decisions issued in 2013 and 2014. The high number of cases puts high pressure on the MSCAs and also on the Member State Committee, if a high proportion of the draft decisions trigger proposals for amendments by MSCAs. ECHA will continue aiming to optimise involvement of the MSCAs and the Committee and to this end, i.e. organise webinars and other information sessions on technical and scientific issues to facilitate subsequent decision making on individual cases.

ECHA will continue to increase resources allocated to the follow-up examination of the information provided as a response to ECHA's dossier evaluation decisions and to indicate the case for regulatory follow-up where needed and to ensure provision of a solid basis for the national enforcement authorities to take action on incompliant dossiers. ECHA will review, and if necessary, revise its practice of requesting study audits from GLP (Good Laboratory Practice) monitoring authorities to promote GLP compliance.

ECHA will also continue to contribute to general dossier quality improvements through effective feedback to (where relevant specific) industry sectors using experience generated from dossier evaluation decisions; in particular, ECHA will extract and communicate key messages relevant for registrants of lower tonnages and SMEs in general. It will also consolidate reporting on the outcome of the dossier evaluation process with the aim of providing more transparency and a more comprehensive picture of the compliance of dossiers and availability of reliable information related to the higher tier endpoints relevant for the safe use and SVHC identification in particular.

Substance evaluation

In view of strategic objectives 1 and 2, ECHA will review the substance evaluation process from the period 2012-2014, in particular the complementary role with dossier evaluation and the functional role for regulatory risk management. This review will feed into ECHA's report on REACH implementation due in 2016 and requires the contribution of the Member State competent authorities (MSCAs).

ECHA continues to ensure that the process contributes fully to the improvement of dossier quality and efficiently feeds into risk management processes. Therefore, the emphasis should be on selecting further candidate Community rolling action plan (CoRAP) substances that require clarification of relevant risks for human health or the environment in order to decide on regulatory follow up, and in most cases, lead to requests for further information that cannot be requested under dossier evaluation as the issues require assessment at EU and substance level. The prerequisites for this are successful implementation of a common cross-process screening that serves both substance evaluation and regulatory risk management processes, and effective interplay with dossier evaluation, with the full involvement of MSCAs. Optimisation of the development of CoRAP updates will also consider substance similarities, regulatory relevance and efficient use of MSCA evaluation capacity, while maintaining the target of about 50 substances per year to be evaluated.

In 2015, the substance evaluation process will continue with the processing of the 2014

batch of draft decisions and managing an increasing number of reports, draft and final decisions and follow-ups generated under substance evaluation. ECHA will also continue to publish non-confidential versions of substance evaluation decisions and other relevant outcome documents.

ECHA will continue to support and interact with MSCAs working on substance evaluation by organising a workshop and technical meetings, issuing practical guides, and by performing consistency screening on draft decisions. Efficient administrative practices are a prerequisite to maintain and support the substance evaluation process.

2. Objectives and indicators

Objectives

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

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

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

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

Performance indicators and targets

Indicator	Target in 2015	Means and frequency of verification
Percentage of dossier evaluations treated within the legal timeframe.	100 %	Monthly internal report
Percentage of testing proposal examinations concluded for dossiers received by the 2013 deadline in order to reach the legal requirement to prepare draft decisions by the 1 June 2016 deadline.	75 %	Monthly internal report
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%	Quarterly internal report
Percentage of substance evaluations treated within the legal timeframe.	100 %	Monthly internal report

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

3. Main outputs

Dossier evaluation

- 200 compliance checks concluded (of which at least 50 % is planned to address the higher tier human health and environment endpoints), leading to ca. 150 new draft decisions
- At least 220 testing proposal examinations concluded with a draft decision
- Over 300 final dossier evaluation decisions, originating from draft decisions prepared in 2012-2015
- 400 dossier evaluation follow-up examinations
- ECHA's annual Evaluation Report[2] and related communications. Key messages relevant for registrants of lower tonnages and SMEs in general
- One workshop or technical meeting on dossier evaluation
- Annual evaluation report (Article 54)
- Non-confidential versions of dossier evaluation decisions published

Substance evaluation

- Third update of the CoRAP adopted by the end of March 2015 with at least 50 substances scheduled for evaluation in 2015
- Fourth draft update submitted to the Member State Committee for opinion by the end of October 2015
- About 40 substance evaluation draft decisions originating from the 2014 evaluations requesting further information
- At least 40 final decisions adopted, requesting further information or conclusions under substance evaluation; Non-confidential versions of all substance evaluation decisions published
- Conclusion documents published for all substance evaluations that have been completed
- Scientific, administrative and legal support to Member State competent authorities for their tasks on evaluation
- One workshop on substance evaluation
- Report on the substance evaluation process review 2012-2014

[2] REACH Art. 54.

1.3. Risk Management (Activity 3)

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

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

1. Highlights of the year

Identifying needs for regulatory risk management

Implementation of the SVHC Roadmap to 2020, which is a key element of ECHA's strategic objective 2, is at full speed. As the full name indicates ("The roadmap for SVHC identification and implementation of REACH risk management measures from now to 2020"), this roadmap covers a range of actions wider than SVHC identification and aims for a holistic and integrated implementation of the REACH and CLP risk management processes, making full use of the registration and other REACH/CLP databases as well as initiating dossier and substance evaluation where further information is needed.

Common screening serving REACH and CLP processes

The common screening will be used to help Member States and the Commission/ECHA to concentrate on substances and uses with highest concern and biggest impact first. This requires consolidation and increased common understanding on the priorities, i.e. which substances and uses matter most taking into account the priority objectives of the Seventh Environment Action Programme. ECHA will continue the discussion on these priorities and how they will impact the practical implementation of the common screening approach, which will be facilitated by a workshop. The experience gained during 2014 in implementing the common screening approach will be used to widen the scope to also support concern-based selection of substances for compliance check. All experience on the compliance check and substance evaluation will help to direct the use of these instruments to serve regulatory risk management needs.

The efforts during the previous legislation and the first years of the implementation of REACH have addressed many of the known and easily identifiable substances and uses causing risks. Further screening efforts need to concentrate on substances and uses which have so far received less attention, for instance due to a lack of information on properties, uncertainty on the criteria to be used (e.g. endocrine disruptors) or due to more complex exposure situations (e.g. substances in articles).

Assessment of hazard properties

Assessment of the persistent, bioaccumulative and toxic (PBT)/very persistent and very bioaccumulative (vPvB) and endocrine disrupting (ED) properties is supported by the respective expert groups. The PBT expert group will be working more and more on substances that are identified through REACH registration data as the substances inherited from the previous legislation have already been processed. ECHA will pay particular attention to supporting the efficient use of all available information and that further information is generated (e.g. through substance evaluation) only when it is necessary for decision making on whether a substance fulfils the criteria.

The ED expert group which in its set-up has benefited from the experience gained by the PBT expert group and is foreseen in 2015 to be actively supporting the substance specific work on endocrine disruptors.

Identification of most appropriate regulatory actions

The common screening and the PBT/ED assessment should lead to the identification of multiple candidates for further information gathering (e.g. through substance evaluation) or directly to the assessment of the most appropriate risk management options (RMOA).

It is foreseen that the RMO approach will be more streamlined and effective as the common screening approach and the SVHC Roadmap will give a better commonly agreed starting point for the identification of substances and actions. Further alignment of documentation and approaches used in substance evaluation and RMOA work is expected to result in efficiency gains, in terms of less resources needed and shorter throughput times. The outcome of the first substance evaluations followed by RMOAs might already result in the initiation of regulatory actions in 2015.

Cooperation and communication

The efforts needed for cooperation and coordination of the roadmap implementation work will remain high since achieving the roadmap objectives requires continuous involvement of and interaction with all authorities. ECHA will continue to support those Member States which so far have not actively contributed to the roadmap implementation work. In addition to the PBT and ED expert groups, the CMR (carcinogenic, mutagenic and reprotoxic) and sensitiser coordination groups will continue their work. The development and implementation of an approach to address non-fuel uses of petroleum and coal stream substances will be supported by an ad hoc group. Risk Management Expert meetings will continue to be organised together with Member States and will cover the SVHC Roadmap implementation aspects as well as linking the screening, assessment and RMOA work to the implementation of the regulatory processes.

The first progress report on activities to implement the SVHC Roadmap in 2014 will be published in quarter one. Communication on substance specific activities - initiation of hazard assessment and RMOA as well as RMOA conclusions - will reach a ‘business as usual’ stage in 2015. This will provide increased transparency and predictability for interested parties.

Authorisation

Identification of SVHCs and Annex XIV recommendations

The work on screening and assessment, including harmonisation of classification, as well as on RMOA should lead to SVHC identification proposals for substances for which there is a wide common understanding among authorities that inclusion in the Candidate List is

an effective and necessary regulatory action. In other words, 'right' substances are fed into the Candidate List. The actual number of substances will depend on how many Member States participate in the screening, assessment and RMOA work and how much resources are invested by them. The overall workload related to the SVHC identification process is foreseen to increase since an increased number of dossiers are expected to be on PBTs or substances of equivalent concern and hence will require specific effort during the identification process.

The development of the seventh Annex XIV recommendation will benefit from the experience gained in 2014 on the use of the revised Annex XIV prioritisation approach. How well the recommendation work will be able to serve the final decision making on inclusion of substances in Annex XIV depends on the level of agreement between the Commission and the Member States on which substances authorisation is the best RMO. In the longer term, the systematic RMOA work before the inclusion of substances in the Candidate List should make the recommendation phase more efficient and predictable.

Authorisation applications

It is anticipated that some 70 applications relating to the use of chromium compounds will be submitted in 2015 and some 30 in early 2016. However, there is much uncertainty associated with this number which essentially relates to the way the applicants will ultimately group themselves in the applications. At the time of writing (August 2014), ECHA has already received over 100 requests for information sessions.

ECHA could receive a higher number of applications (possibly up to 150). In any event, in 2015, ECHA will need to deal with an increased number of applications efficiently, openly and in a trustworthy manner and will develop contingency plans in case a higher amount of applications arrive. In addition to the above, the processing of the approximately 15 applications expected in 2014 will continue in 2015.

The ECHA Secretariat will continue to support RAC and SEAC, and in particular their rapporteurs, to develop high quality opinions in a transparent and efficient manner that can effectively support the Commission's decision making on granting or refusing an authorisation. ECHA plans to continue to actively promote the participation of third parties in the consultation process for each application to make sure that appropriate information on alternative substances or techniques, if available, will be fed into the opinion-making process.

ECHA will carefully monitor the working time needed for its own staff and the Committee members in managing this process, and will continue streamlining and providing further clarification to focus the opinion forming process in the Committees. This will help to adapt ECHA's own and its committees' operations in time before the increased number of applications arrive in 2015. The new version of REACH-IT that was taken into use in 2014 will enable more efficient communication with the applicants in 2015. A new tool to communicate effectively with the Committees, the *'Dynamic Case'*, was taken into use in 2014 in ECHA and it is projected to increase the efficiency and accuracy of the application process.

The lessons learnt from the first applications will be analysed together with the Commission, Member States and the stakeholders in early 2015 in a feedback seminar and will be used to further enhance the efficiency of the opinion-making system. Based on this feedback seminar, ECHA will assess if it will continue to hold "*Pre-Submission Information Sessions" (PSISs)* with future applicants. These sessions had proven to be appropriate to clarify any remaining technical issues relating to the preparation and submission of applications. Nevertheless, it is expected that clarity of communication to the applicants and collaboration with ECHA's stakeholders will continue to be needed.

Therefore, ECHA plans to continue to hold seminars and PSISs for potential applicants.

ECHA's goal is to have 'fit-for-purpose' applications that do not cause unnecessary cost or administrative burden to industry due to the application activities. Therefore, it clarified in 2014 that if the applicant uses the *"reference"* derived no-effect level (DNEL) or dose-response relationship established by RAC, the application does not need to include the hazard data. This simplifies and reduces the costs of applications considerably. Furthermore, in 2014 ECHA set up a *"Partners' service"* to help all potential applicants to know about each other in the supply chain. These two novelties, as well as the experience that ECHA has gained on the specific challenges relating to the applications made by downstream users, will be the basis for making the application process as lean and meaningful as possible. To that end, ECHA will work closely together with the Commission and the Member States to implement the recommendations that are under development in the taskforce for improving the workability of the authorisation process.

Restrictions

Each restriction dossier is unique in terms of the scope and scientific and technical aspects that need to be evaluated. Given this heterogeneity, it remains challenging for ECHA and in particular its committees to formulate their opinions and to make sure that these are processed with a high degree of scientific, technical and regulatory quality.

The ECHA Secretariat supports the Committees, and in particular the rapporteurs, in preparing opinions on restriction dossiers. The number of opinions worked upon in 2015 will depend on the number of Annex XV restriction dossiers received in 2014 and early 2015.

In 2015, ECHA expects to provide support to the RAC and SEAC rapporteurs on about 10 restriction dossiers, about the same amount as in 2014. The ECHA Secretariat will continue to provide high quality and timely support to RAC, SEAC and the Forum as they develop these opinions.

In 2014, the Members States, ECHA and the Commission set up a taskforce to give a coherent set of recommendations to improve the efficiency of the dossier preparation and opinion-making processes. In 2015, ECHA will implement those recommendations that are relevant for the secretariat, RAC, SEAC, or the Forum. Concurring with the recommendation of the taskforce, ECHA will provide assistance to Member States when preparing Annex XV restriction dossiers through workshops, *"Preparatory Information Meetings" (PRIM)* and through specific feedback, as required.

ECHA will also continue supporting Member State enforcement authorities and helpdesks, and improve the accessibility and readability of Annex XVII on its website. ECHA will continue answering questions relating to interpretation and enforcement of the restrictions.

ECHA will support the Commission in identifying the best possible substances for which ECHA will prepare restriction dossiers. Upon the Commission's request, ECHA will prepare up to three Annex XV restriction dossiers (covering either new proposals or reviews of existing restrictions).

To the extent possible, ECHA will continue giving expert advice and services on specific requests from the Commission, for example, in the context of the review of existing restrictions in Annex XVII. If requested, ECHA will provide technical support for the Commission in the adoption of regulations on the restriction dossiers, for which the opinions of RAC and SEAC were forwarded to the Commission in 2014-15. ECHA will also provide support to the Commission during the development of restriction proposals for CMRs in consumer articles under Article 68(2).

Article 69(2) requires ECHA to prepare restriction dossiers for articles including substances that are on the Authorisation List and pose a risk that is not adequately controlled. Based on an approach developed during 2014 and depending on the outcome of the analysis, ECHA will record the outcome and prepare and submit – if relevant – its proposals for such restriction types in 2015. ECHA will also assess in 2015 whether a restriction based on Article 69(2) would be necessary for the four phthalates for which the sunset date is February 2015 and, if so, prepare an Annex XV restriction dossier.

Other activities related to risk management

Socio-economic analysis

ECHA will continue its efforts to increase the knowledge on the practical application of Socio-economic analysis (SEA). The results of the health valuation study to avoid negative health effects became available in 2014. Hence, the reference values for the willingness-to-pay for the first set of human health endpoints are available for Member State competent authorities (for restrictions) and companies (for applications for authorisation). Methodologies will be further developed to better quantify the human health impacts through willingness-to-pay or Quality/Disability Adjusted Life Year approaches.

Building on the work published in 2014 on the costs of enforcing restrictions, ECHA will continue to develop methodologies to estimate the costs of implementing regulatory risk management. ECHA will continue to support SEA-related workshops through the "Network of REACH Socio-economic Analysis and Analysis of Alternatives Practitioners" (NeRSAP) with interested parties on applications for authorisation and with the MSCAs on restrictions.

Substances in articles

Awareness raising efforts on obligations related to the presence of Candidate List substances in articles will continue. ECHA will explore possibilities on how to cooperate with authorities and industry organisations in third countries to raise awareness of producers of articles that are meant for export to EU markets. This is to find means to support the article importers' communication in their upstream supply chains. The awareness raising efforts will also cover the requirements for treated articles stemming from the Biocidal Products Regulation.

ECHA will continue the work started in 2014 to identify and develop further means to support the duty holders, in particular importers of articles but also article distributers, and consumers in identifying which Candidate List substances could potentially occur in articles.

Links to other EU legislation

To enhance a better understanding on how chemicals are regulated and how different regulations complement each other, the possibilities for collecting and disseminating information on which substances are covered by different pieces of EU legislation will be further explored in 2015. In addition, ECHA will further explore options on how to support the effective use of REACH data by industrial end users to comply with their obligations under other legislation, such as the Industrial Emissions Directive, workers', environmental and product legislation and vice versa.

2. Objectives and indicators

Objectives

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

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

Performance indicators and targets

Indicator	Target in 2015	Means and frequency of verification
Percentage of SVHCs, restriction dossiers and applications for authorisation treated within the legal timeframe.	100 %	Monthly internal report
Level of satisfaction of the Commission, MSCAs, ECHA Committees, industry, NGOs and other interested parties with the quality of the scientific, technical and administrative support provided.	High	Annual survey

3. Main Outputs

- SVHC Roadmap progress report published.
- A workshop to promote coherent and effective implementation of REACH and CLP processes and on common priorities organised.
- Based on the common screening approach of the registration database, lists of substances of potential concern for further scrutiny provided to Member States.
- Upon request by the Commission, support provided for the development of up to five RMO analyses.
- Upon request by the Commission, up to five SVHCs proposed for the Candidate List.
- One to two updates of the Candidate List published.
- The Sixth Annex XIV recommendation submitted to the Commission. Development of a new draft recommendation for inclusion of Candidate List substances in the Authorisation List (Annex XIV).
- Scientific, administrative and legal support to both submitters of proposals for restrictions and to RAC and SEAC and its rapporteurs for their development of opinions on restrictions and applications for authorisation.

- Feedback seminar on the lessons learnt from the first authorisation applications together with the Commission and the stakeholders.
- Up to three Annex XV restriction dossiers prepared (including, where relevant, dossiers or reports related to reviews of existing restrictions).
- Further improved and adapted communication through the web and elsewhere for potential applicants, including SMEs, to facilitate the preparation of “fit for purpose” applications for authorisation.
- Instructions, guidance and clarifications to further improve the efficiency of ECHA’s scientific committees to manage the opinions on applications for authorisation and restrictions.
- Monetary reference values on second set of health endpoints.
- Up to two training events, workshops and advice delivered to Member States to help them to fulfil their tasks in preparing Annex XV restriction dossiers, including SEA.
- At least one seminar or workshop organised on applications for authorisation, including SEA, with industry and other interested parties.
- Possibilities to improve the flow and use of information between REACH and other legislations related to chemicals explored.

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

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

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

1. Highlights of the year

Handling proposals for harmonised classification and labelling (CLH)

ECHA will continue to provide, and where appropriate further intensify, support to the Member States and RAC rapporteurs during the preparation of proposals for harmonisation of classification and labelling and the development of opinions by RAC.

For active substances for both PPPs and BPs, the consequence of a classification in category 1A or 1B for carcinogenic, mutagenic and toxic for reproduction (CMR) is that use of the substance will in general not be approved. To streamline regulatory decision making, with a view to providing clarity to industry stakeholders and efficiency for all parties involved, ECHA makes a considerable effort towards alignment of the CLH process and the approval processes in the context of the PPP and BP regulations. The parallel processing of active substances in PPPs poses challenges in avoiding the risk of diverging opinions and adjusting the processes to the respective legal timeframes for decision making, whilst further enhancing the efficiency and predictability of the process.

While the total number of proposals for harmonised classification and labelling is expected to be at the same level as in previous years, the amount of active substances for pesticides and biocides is likely to increase, partly due to the biocides review programme. The timing of the CLH process, resource needs, exchange of relevant information as well as proactive solutions for contentious issues are closely and actively coordinated with Member States, EFSA and the European Commission.

To meet the high level of demand, continuous efforts will be made to enhance predictability of the timelines and further streamline working practices and procedures (for instance through expert meetings, awareness raising activities, criteria for dealing with new information received throughout the process) to reduce administrative burden. The ECHA Secretariat is committed to continuing its support to Member States preparing proposals and to RAC rapporteurs, to make sure that the RAC opinion forming has an adequate basis and that the resulting opinions support the final decision by the Commission.

Harmonised classification and labelling (CLH) is powerful as a regulatory risk management measure (RRMM) in itself and it also supports other RRMMs. With a view to the limitation in resources available in Member States for preparing proposals for CLH, support in selecting substances for which harmonisation is a priority is important. ECHA plans to keep its screening activities to identify priority substances at a high level. The screening of substances is combined with identifying priorities for other processes such

as SVHC and substance evaluation (see activity 3).

Classification and Labelling Inventory (C&L Inventory)

The C&L Inventory is a unique database of the classification and labelling of almost all substances on the EU market. In 2014, the database had 6.1 million notifications, covering the classification of 125 000 substances of which 115 000 are available in the public C&L Inventory. On average, more than 10 000 notifications are updated monthly. Such knowledge is not available anywhere else in the world. Though the inventory has been available since 2012, its maintenance and updating will continue in 2015, with the inclusion of SEVESO III[3] data as the main new feature.

For about 25 % of the substances in the C&L Inventory, the notified classification differs. More convergence in the self-classifications and clarity on the reasons for diverging classifications increases the usefulness of the inventory, in particular for SMEs. Adequate self-classifications are the responsibility of industry and in order for industry to be able to fulfil their legal obligation to come to an agreement on the entries, ECHA established an IT-platform which enables notifiers of the same substance to discuss their entries in the inventory without revealing their identity. As the use of this C&L Platform is far below expectations, ECHA will continue discussions with industry organisations and encourage industry to take their responsibility and make optimum use of the tools provided. ECHA plans to monitor the level of convergence on a regular basis.

The notification data in the inventory, in combination with other databases available, will increasingly be used to support Member States to target substances that would need priority for further risk management.

Alternative chemical names

In certain cases, manufacturers, importers and downstream users can request the use of an alternative chemical name to keep the precise name of certain ingredients in their mixtures confidential. Until June 2015, industry may request an alternative chemical name from either the Member States or ECHA. After this date, only ECHA will handle these applications. ECHA expects the number of requests to grow to about 150 yearly. The process for requesting alternative chemical names was launched in 2011. The process was designed to be efficient and flexible in order to handle a large number of requests within the short legal timeframe and to cope with peaks in the amount of requests.

Classification of mixtures

The obligation to apply CLP for mixtures after 1 June 2015 requires that the awareness raising with industry to apply CLP to their mixtures is continued. A key element of the awareness raising strategy is to support organisations that are in close contact with SMEs. Special attention will be given to the new elements in the mixture classification according to CLP. In addition, planning for activities to help the general public become more familiar with the new pictograms will need to be initiated.

[3] Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC.

2. Objectives and indicators

Objectives

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

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

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

Performance indicators and targets

Indicator	Target in 2015	Means and frequency of verification
Percentage of proposals for harmonised C&L and requests for use of alternative chemical name processed within legal timeframe.	100 %	Internal quarterly report
Level of satisfaction of the Commission, MSCAs, RAC and industry with the quality of the scientific, technical and administrative support provided.	High	Annual survey

3. Main outputs

- Scientific, administrative and legal support to both submitters of proposals for harmonised C&L, to RAC and its rapporteurs for their development of opinions and background documents and to the Commission to support further processing at their request.
- Alignment of development of CLH opinions for active substances in pesticides and biocides with the respective regulatory processes and timeframes.
- Continued analysis of databases with the aim of providing information to Member States and industry to identify priority substances for harmonised classification.
- Updated and well maintained C&L Inventory; updated and improved communication platform for notifiers and registrants of a same substance.
- Awareness raising activities together with industry and Commission to achieve more convergence in self-classifications and increased use of the C&L Platform.
- Monitoring data reflecting the degree of convergence in self-classifications.
- Continued awareness raising activities on the obligation to apply CLP for mixtures after 1 June 2015.
- Up to 150 legally sound decisions on the use of alternative chemical names.

1.5. Biocides (Activity 16)

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

1. Highlights of the year

2015 will be the second full year of operation under the Biocidal Products Regulation and as such will be a good point in time to refine the processes in the light of experience gained to maximise their effectiveness and efficiency. ECHA will continue liaising closely with the Member State competent authorities with a view to ensuring the respect of deadlines and the good progress of the Review Programme of active substances. This includes the best possible use of the IT tools (R4BP 3, Summary of Product Characteristics (SPC) editor and IUCLID) provided by the Agency. This will translate into providing an effective coordination function for the Review Programme and adequate support for the Member States, Biocidal Products Committee (BPC) opinion forming and decision making of the Commission.

An important event is the deadline that will be reached on 1 September 2015, two years exactly after the entry into operation of the regulation. Only the following biocidal products will be able to remain on the market: those containing active substances where either the substance supplier or the product supplier is included in the list described in Article 95. Accordingly, ECHA expects a peak of applications for the inclusion in this list for the first semester and their assessment will generate an increased workload.

At the same time, ECHA will be faced with the specific and critically important challenge to meet the ambitious annual target for 2015 to deliver an opinion on the assessment of the evaluating Member State of 50 active substances – product type combinations under the Review Programme. To achieve this target, two conditions will have to be met: the MSCAs have to be able to deliver the expected quantity of good quality assessment reports in time and the peer review process has to perform efficiently. ECHA will contribute with a strict management of the process, an effective management of meetings, its scientific contribution to issue solving and its upstream interaction with the evaluating competent authorities to ensure quality and consistency of the evaluations. However, due to resource constraints, ECHA may not be able to provide the planned level of support for this process, especially if the peak of applications referred to in the previous paragraph is higher than expected.

It is expected that the number of applications for Union authorisation of biocidal products will start to increase. This also requires well-coordinated and efficient support for the process including support and advice for the applicants, and similar coordination of the process as for active substances.

As a significant number of application types will only be made available in the IT systems at the end of 2014 with a major release of R4BP 3, the revised processes will have to be refined in light of the experience gained to maximise their effectiveness and efficiency as foreseen in the multi-annual work programme 2014 - 2018.

ECHA will also need to participate and contribute to the on-going European cooperation between assessment bodies to ensure consistency and coordination between the

assessments of the same chemical under different legislative scopes (e.g. plant protection products, feed additives, cosmetics).

2. Objectives and indicators

Objectives

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

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

Performance indicators and targets

Indicators	Target in 2015	Means and frequency of verification
Percentage of dossiers processed within the legal timeframe.	100 %	Quarterly monitoring
Level of satisfaction with the quality of scientific, technical, and administrative support provided to the members of the BPC, Coordination Group, the Commission, MSCA's and industry.	High	Annual survey

3. Main outputs

- Scientific, technical, legal and administrative support to the evaluation of applications for Union authorisation and active substance evaluation carried out by the MSCAs.
- Assessment of applications to be included in the Article 95 list and maintenance of this list: up to 200 decisions.
- Decisions on technical equivalence applications: up to 20 decisions.
- Decisions on chemical similarity of active substances: up to 10 cases.
- Workflows and processes for dealing with incoming dossiers fine-tuned where necessary.
- Participation and contribution to scientific events and workshops to further improve the understanding of the assessment of biocides (active substances and biocidal products).

1.6. PIC (Activity 17)

The Prior Informed Consent Regulation (PIC, Regulation (EU) 649/2012) administers the export and import of certain hazardous chemicals and places obligations on companies who wish to export these chemicals to non-EU countries. It aims to promote shared responsibility and cooperation in the international trade of hazardous chemicals, and to protect human health and the environment by providing developing countries with information on how to store, transport, use and dispose of hazardous chemicals safely. This regulation implements, within the European Union, the Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade.

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

1. Highlights of the year

In 2015, the Agency will be at cruising speed for processing and sending export notifications to the importing countries outside the EU, and keeping the database of the notifications and the explicit consents given by the importing countries using the new IT system (ePIC).

The main challenge will be faced in the beginning of the year to complete the processing of the expected peak in notifications received towards the end of 2014, the first handled entirely by ECHA and by using ePIC. As the procedure may consist of several steps before receiving the formal acknowledgment of receipt from the importing country, this will have repercussions on the workload of the first quarter. ECHA is committed to respecting the legal deadlines by ensuring that all notifications are processed in Q1/2015. 2015 will also be the first year when ECHA is responsible for compiling information and publishing a summary report on realised exports and imports at the Union level in 2014 for the substances listed in Annex I of the PIC Regulation. This will be done in a timely manner.

ECHA will continue to provide scientific and technical support to the Commission in their responsibilities under PIC, for example, drafting PIC notifications and related tasks. In addition, ECHA will continue supporting all relevant stakeholders and ensuring good collaboration with the EU and non-EU designated national authorities (DNAs).

2. Objectives and indicators

Objectives

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

Performance indicators and targets

Indicators	Target in 2015	Means and frequency of verification
Percentage of PIC notifications processed within the legal timeframe	100%	Time recorded in ePIC. Monthly reporting.

Level of satisfaction with the quality of scientific, technical, and administrative support provided to the Commission, Member State DNAs and industry.	High	Annual survey

3. Main outputs

- Approximately 4 000 PIC notifications are processed.
- Scientific and technical support provided to the Commission and, with the agreement of the Commission, to the DNAs.

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

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

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

1. Highlights of the year

Guidance

As was already the case in 2014, the main focus of ECHA's guidance activities for REACH will be on the needs of potential registrants for the 2018 deadline, taking into account an increased proportion of SMEs as potential registrants. As stable guidance on critical issues must be available well in advance of this deadline, ideally by 1 June 2016, emphasis will be placed on respective documents. For this purpose, for instance, following the outcome of a workshop on substance sameness that ECHA held in autumn 2014, the Agency will be considering whether to update its *Guidance for identification and naming of substances under REACH and CLP*. This should be developed during 2015 under the 2015 milestone for strategic action area 1.1 "Improving quality of information in dossiers" to allow the 2016 milestone of "review of the guidance on substance identification and naming" to be achieved in good time.

With SMEs and less experienced companies in mind, ECHA will focus on means to make its multifaceted assistance (which takes many forms, from Guidance documents to webinars, from fact sheets to user manuals and practical guides or explanatory webpages) more easily accessible. This recognises that "simplification" of guidance needs to be achieved by providing easier and more understandable access to all information of assistance to duty holders. This work on the content as well as the "accessibility" of documentation and its relationship to other sources of information will be based on the review that is part of the 2018 Registration Roadmap with the aim to make sure that users can find the correct level of complexity of document appropriate for their needs and competence. ECHA will also continue to provide simplified guidance in "Guidance in a Nutshell" documents (always provided in 23 official EU languages) as well as to translate other SME-relevant guidance documents.

If appropriate input from activities at the Organisation for Economic Cooperation and Development (OECD) level becomes available in time it may also be possible to start update work on IR&CSA Chapter R.6: Quantitative Structure-Activity Relationships (QSARs) and grouping of chemicals. Similarly, where a sufficient level of consensus has been reached on the revision of information requirements on nano-materials the corresponding updates to guidance can be started during 2015.

ECHA will further focus on implementing updates of prioritised parts of the Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA) as defined in the current CSA Roadmap originally initiated in 2013 – again especially on documents expected to be available a full two years ahead of the 2018 registration deadline – i.e. by 1 June 2016.

During 2015, the full incorporation of new guidance and new updates of guidance on the BPR into the "normal" ECHA procedures as defined in the updated guidance consultation procedure MB/63/2013 (final) will be completed. This will extend the already

implemented consultation of the Biocidal Products Committee whenever appropriate for REACH or CLP guidance (e.g. as already done during 2014 for the update to the *Guidance on the preparation of dossiers for harmonised classification and* labelling (CLH Guidance)). These fuller consultations and cross-consultations will contribute to the MAWP milestone for 2015 of "*improved coordination mechanism in place for implementation of legislations related to chemicals".*

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

During 2015, the ECHA Helpdesk will continue to provide advice and assistance to industry duty holders in response to their enquiries. In this regard, for regulatory matters, the ECHA Helpdesk generally only acts as the first port of call for non-EU/EEA enquirers as companies are expected to first address their queries to their respective national helpdesk which cannot only answer on most questions but also in their national language(s). With regard to providing support when using ECHA's scientific IT tools, the ECHA Helpdesk is the first port of call.

ECHA will emphasise activities particularly to make SMEs and "newcomer" duty holders aware of their BPR, CLP, PIC and REACH obligations, and for them to be supported by national helpdesks and ECHA in understanding them. As part of this effort, the HelpNet Secretariat will continue to promote cooperation between national helpdesks and their national EEN (European Enterprise Network) counterparts.

Furthermore, industry's preparations for the 2018 REACH registration deadline will provide a significant driver for ECHA's support in 2015, with a particular emphasis on adapting the support services and tools to the needs of less experienced companies. Developing and delivering support activities of the ECHA Helpdesk and of the HelpNet is included in ECHA's 2018 Registration Roadmap and will also specifically involve national REACH helpdesks in support and communication activities.

The CLP 2015 deadline for mixture classification will also determine the work of the ECHA Helpdesk: industry will benefit from an easier orientation towards available information and guidance; efforts of the ECHA Helpdesk will be targeted towards promoting successful implementation by concerned downstream users; the HelpNet Secretariat will strive towards increasing awareness and preparedness of industry by means of joint efforts of national CLP helpdesks.

Building on support initiated in 2014, MSCA users can expect support from the ECHA Helpdesk with regard to their access to ECHA's IT systems and their use. MSCA user administrators will be kept duly updated about any development of ECHA's scientific IT tools by means of an information exchange platform and during various events organised for them.

Overall, these activities for the benefit of industry and MSCAs are part of ECHA's efforts towards its strategic objectives 1 and 2 – to improve the quality of submitted dossiers and to help public administrations make best use of such submitted data.

2. Objectives and indicators

Objectives

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

2. Industry receives support through high quality guidance documents to fulfil its

obligations under REACH, CLP, the BPR and PIC.

Performance indicators and targets

Indicator	Target in 2015	Means and frequency of verification
Percentage of ECHA Helpdesk questions answered within the established timeframe (15 working days).	90% (REACH/CLP); 75% (BPR); 75% (MSCA IT support)	Business object report / monthly
Level of satisfaction of users with quality of ECHA Helpdesk services.	High	Customer surveys
Level of satisfaction of MSCA user administrators with ECHA MSCA IT Support services	High	Customer surveys
Level of satisfaction of HelpNet members with the HelpNet Secretariat	High	Customer surveys
Level of satisfaction expressed in feedback from guidance users.	High	Annual customer survey

3. Main outputs

Guidance

- Finalisation of guidance activities initiated in 2014 to be completed in 2015 (all **updates** unless indicated as "**new**"):
    - Update of Chemical Safety Assessment (CSA) -related elements of the Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA) – priorities to be identified early 2014 under the CSA programme – likely to include Chapter R12 (Use descriptor system) and other documents related to format and content of Chemical Safety Reports (CSRs).
    - Guidance on IR&CSA, Chapter R.7.a: Section R.7.6 - Update of guidance documents dealing with extended one generation reproductive toxicity studies (EOGRTS).
    - Guidance on IR&CSA, Chapter R7a, Sections R.7.2 (Skin and Eye).
    - Guidance on the Biocidal Products Regulation (BPR): Vol. I Identity/Phys-Chem/Analytical: Part B Effect/Hazard Assessment (**new**).
    - Guidance on the BPR: Guidance on Microorganisms (**new**).
- Guidance projects to be initiated and which are to produce draft consultation documents during 2015 (all **updates**, unless indicated as "**new**"):

- Guidance on labelling and packaging in accordance with Regulation (EC) 1272/2008 (CLP).
- Guidance for identification and naming of substances under REACH and CLP.
- Guidance on IR&CSA Chapter R.6: Quantitative Structure-Activity Relationships (QSARs) and grouping of chemicals – to be initiated only if suitable input for such an update becomes available from OECD guidance updates that may be published in the second half of 2014 and/or the ECHA workshop foreseen for Autumn 2014.
- Further updates of chemical safety assessment (CSA) - related elements of the Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA) – related to exposure assessment and risk characterisation.
- Update to guidance documents with regard to nanomaterials, if outcome of review of the REACH annexes with respect to nanomaterials is already available in early 2015.
- Guidance on IR&CSA, Chapter R7a, Sections R.7.3 (Sensitisation).
- Guidance on the BPR: Vol. II Efficacy: Part B Exposure, Effect/Hazard and Risk Assessment (**new**).
- Guidance on the BPR: Vol. III Human Health: Part B Exposure, Effect/Hazard and Risk Assessment review/revision of complete document and in particular section on Exposure Assessment (i.e. update of text published in December 2013).
- Guidance on the BPR: Volumes I, II III & IV: Part C Evaluation (**new**).

ECHA Helpdesk

Support to companies

- Questions from industry on REACH, CLP, the BPR and PIC regulations and ECHA's scientific IT tools replied to.
- One-to-one sessions provided at stakeholder events.
- Webinars on the use of ECHA's scientific IT tools delivered.

Support to MSCAs

- MSCA users are supported at the start-up of remote access establishment and during the deployment phases of ECHA's IT tools.
- The building of basic capacity for using ECHA's IT tools in the MSCAs is supported.
- As single point of contact for MSCAs, questions on issues related to ECHA’s scientific IT tools-related issues replied to.
- Training to user administrators and end-users in the MSCAs on the technical issues and user functionalities of ECHA's IT tools provided.

Support to national helpdesks

- Organisational and administrative support to the HelpNet Steering Group, such as the organisation of the HelpNet Steering Group meetings (at least one per year) and workshops, provided.
- Draft frequently asked questions (FAQs) prepared, discussed by the HelpNet Steering Group and published on the ECHA website as agreed by HelpNet.
- Questions from national helpdesks replied to.
- Capacity-building, sharing of best practice and information exchange of national BPR, CLP and REACH helpdesks for customer support enabled.
- Training of national helpdesks on ECHA processes and industry functionalities of scientific IT tools provided.

1.8. Scientific IT tools (Activity 6)

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. Highlights of the year

Delivering IT support for the regulatory processes is one of the strategic action areas of ECHA (MAWP 4.2.1).

In 2015, ECHA will release a new Dissemination Platform based on a restructured IT system addressing the shortcomings, limitations and constraints of the current dissemination systems, which represent the data processing engine of the web pages on information on chemicals published on the ECHA web site.

The Dissemination Platform will implement the new vision for the fulfilment of the dissemination tasks of ECHA, much more focused on integration of related information across processes and regulations – ultimately converging into the "chemical substance brief profile" model - and ease of use for the stakeholders.

To fulfil the objective of offering enhanced integration of the public information on substances, the new platform will leverage the investment made by ECHA on data integration and on internal case management systems to bring together data submitted by industry as well as data created by the regulatory processes in a substance centric view.

Significant progress is made in the implementation of the new generation of REACH-IT, IUCLID and Chesar to ensure launch of new versions in 2016.

The use of IUCLID formats is mandatory in REACH, CLP and the BPR. The tool is largely used, ECHA accounts for 30 000 registered users; ECHA has measured on average 3 000 - 4 000 downloads for each release version. Its current version, IUCLID 5, was designed in 2004 and requires a new phase of redesign. The use of IUCLID formats is mandatory in REACH, CLP and the BPR. In 2015, the IUCLID 6 project will complete restructuring the technical foundations of the application and ECHA will start using it internally. At the pace of changes of the IT environment, it is normal in the life cycle of a product to undergo a new phase of redesign. REACH-IT 3 will in its turn undergo a technology upgrade and will be restructured to adapt to IUCLID 6 and achieve much better maintainability. Development of the changes is needed as the preparations for the 2018 registration deadline will start.

The data integration project is closed and transitioned into a data management service in 2014. After a multi-annual programme of revision of ECHA's IT systems, in 2015 the Data Integration Platform (DIP) is finally the back-end for ECHA's output systems notably: Dissemination and Portal Dashboard for authorities. The sourcing of data from IUCLID and the submission systems into the DIP is updated to match the new generation of such systems.

The functionalities of the REACH Information Portal for Enforcement (RIPE) are consolidated into the Portal Dashboard, to finally implement the concept of a single-point-of-access for authorities.

The submission systems for the Biocidal Product Regulation – R4BP – and for the Prior Informed Consent regulation – ePIC – will be in maintenance mode during 2015. In 2015, the enforcement authorities in the Biocidal Products Regulation will be supported by the IT systems of ECHA.

ECHA will provide a dedicated collaboration solution hosted by the Commission and based on CIRCA-BC. The aim of the project is to ensure continuation of the use of CIRCA-BC – a platform well known to ECHA's external users – whilst at the same time upgrading security by introducing strong authentication. Thus, the solution will provide Committee members, MSCAs, the Commission and working groups with a familiar web collaboration platform, which will also be more secure. ECHA will facilitate the transition with its external users by providing a support service in the context of the already existing MSCAs IT support service.

The Enterprise Content Management (ECM) programme – which was started in 2011 to deliver IT support to the regulatory processes of the Agency through "case management" IT systems – will complete the roll-out to all REACH and CLP regulatory processes and, after the experience gained, will implement enhancements to increase process efficiency.

These "case management" IT systems – notably "ECM-DEP" for supporting the evaluation processes and "Dynamic Case" for supporting all other REACH and CLP processes – are used for the processing of business cases (e.g. compliance check of a registered dossier) and as a repository for the documents generated as well as the tracing of the process steps. Already in 2014, 2 931 compliance checks, 880 testing proposals were processed in ECM-DEP; in 2015, it is estimated that approximately 5 000 regulatory cases will be processed in ECM-DEP and Dynamic Case.

In 2015, the "case management" IT systems will be integrated with the new Dissemination Platform and will support the implementation of ECHA's policies on the control of documents and records on the retention of documents and records, as set in the IQMS. As an outcome, the management of records will be applied consistently and in an automated way across all regulatory processes.

2. Objectives and indicators

Objectives

1. ECHA provides specialised tools and related services, which efficiently support the MSCAs and industrial stakeholders in preparing and submitting dossiers to ECHA.
2. Well-functioning IT systems enable ECHA to receive and successfully process submissions, perform evaluations and risk assessment activities as well as to disseminate the public information, in the REACH, CLP, Biocides and PIC legislations.

Performance indicators and targets

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

3. Main Outputs

- New dissemination platform first release.
- IUCLID 6 technical foundations completed.
- REACH-IT 3 technical foundations completed.
- Security reinforced CIRCA-BC accessible to external users and user support service operational.
- The case management IT systems are used by all REACH and CLP processes, efficiency enhancements are delivered and provide better support to the regulatory processes under REACH.
- Records management is applied consistently by REACH and CLP processes.
- Consolidation of RIPE and the Portal dashboard in a single-point-of-access for Authorities.
- Enforcement in the Biocidal Products Regulation supported by the IT systems of ECHA.

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

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

1. Highlights of 2015

ECHA continues to implement its third strategic objective, i.e. addressing scientific challenges by serving as a hub for building the scientific and regulatory capacity of member states, European institutions and other actors. This will be steered by the Science Strategy established in 2014. In this context, ECHA in particular will continue implementing the competence management framework as an integral part of the Agency's planning and operational cycle, and will analyse the feasibility of extending that to further priority areas as well as to ECHA Committee members in addition to its own scientific staff after the pilot phase in 2014.

ECHA carries on actively contributing to the further development of test methods, including alternative test methods and Integrated Approach on Testing and Assessment (IATA), with a special focus on IATAs for skin sensitisation. This work is carried out with a view of supporting the registrants using most up to date methods and approaches when preparing for the 2018 registration deadline. ECHA will also promote regulatory science dialogue between authorities and researchers in the efforts of promoting alternatives to animal testing.

ECHA continues to implement its work plan on nanomaterials and will deal effectively with substances in nanoform under REACH, CLP, and the Biocidal Products Regulation. ECHA will particularly focus on the implementation of the expected revision of REACH annexes to adapt them specifically to nanomaterials for the purposes of registration, and subject to the adoption of this revision intends to increase its activities on nanomaterials in the following fields:

- Increased activities and discussions at the Nanomaterial Working Group;
- Updates and changes in the REACH guidance and other advisory documents;
- Support to MSCAs and the Commission with scientific and technical advice;
- Increased activities at international level, mainly through the OECD, in relation to testing and assessment of nanomaterials.

ECHA maintains efforts to efficiently identify PBT-like substances and endocrine disruptors under REACH, CLP, and the BPR, with the help of the PBT expert group and endocrine disruptor expert advisory group. Attention will be paid to the consistency of assessments between these regulations and to taking heed of the future criteria to be developed by the Commission for the identification of endocrine disruptors.

ECHA will start the preparation of the second report under Article 117(2) on the operation of REACH.

ECHA will review and further strengthen its scientific cooperation with the Commission's Joint Research Centre (JRC), and develops the scientific cooperation with other EU Agencies further both bilaterally (in particular EFSA and EMA), and through the EU Agencies' network for scientific advice.

Based on the foreseen Commission proposal for a future Fertiliser Regulation, ECHA will start preparing the implementation of the future EU register for plant biostimulants and agronomic fertiliser additives outlined in the proposal for a revised Fertiliser Regulation. This implies the preparation of the budgetary needs to develop the tools enabling the registration procedures to be up and running as soon as the future revised Fertiliser Regulation enters into force: this budget shall cover the preparatory works for the IT-tool, and other future tasks of ECHA. Furthermore, ECHA will support the Commission services in the legislative procedure regarding the Fertiliser Regulation, as far as the registration procedures for fertiliser additives are concerned.

2. Objectives and indicators

Objectives

1. ECHA delivers on request high quality scientific and technical advice on the safety of chemicals, including nanomaterials and endocrine disruptors, PBT-like substances, testing methods and the use of alternative methods.
2. ECHA is able to encompass scientific developments and emerging needs for regulatory science.

Performance indicators and targets

Indicator	Target in 2015	Means and frequency of verification
Level of satisfaction with the quality of the scientific, technical and administrative support provided to the Commission and MSCAs.	High	Annual survey

3. Main outputs

- Analysis of feasibility to extend competence mapping and capacity building activities to Committee members and to additional scientific topics/areas.
- One topical scientific workshops organised e.g. in the field of soil risk assessment.
- Cooperation with scientific societies (SETAC[4], EUROTOX[5]); hosting special sessions in the annual meetings.

[4] Society of Environmental Toxicology and Chemistry.

[5] Federation of European Toxicologists & European Societies of Toxicology.

- ECHA's work plan on test methods, including alternative methods, updated.
- Updates to ECHAs web pages on new and updated EU/OECD test guidelines, with information to the registrants.
- Practical guides/examples published on the use of alternative methods.
- Read-across assessment framework (RAAF) refined and extended to environmental effects.
- Contribution to development of OECD Test Guidelines and on Adverse Outcome Pathways/Modes of Action, as well as to the OECD and ECHA IATA development of alternatives for different toxicological endpoints, and in particular regarding IATA for skin sensitisation with a view of its finalisation in 2016.
- Contribution to further development of hazard and risk assessment methodologies, including e.g. uncertainty analysis, epigenetic effects, and approaches for complicated endpoints such as reproductive toxicity.
- Contribution to FP7 research projects in the field of characterisation, hazard, exposure and risk assessment, and risk management of nanomaterials.
- Contributions to the follow-up of Commission review of the recommendation on the definition of nanomaterials.
- Support to the Commission in preparing for the implementation of the revised Fertiliser legislation.

2. ECHA's Bodies and Cross-cutting Activities

2.1 Committees and Forum (Activity 8)

The Committees – Member State Committee (MSC), Committee for Risk Assessment (RAC), Committee for Socio-economic Analysis (SEAC) and the Biocidal Products Committee (BPC) – form an integral part of ECHA. They play a crucial role by providing scientific and technical advice (i.e. agreements and opinions) as a basis for ECHA and Commission decision making. The Forum for Exchange of Information on Enforcement provides a network of Member State authorities responsible for the enforcement of the REACH, CLP, and PIC regulations, with the aim of harmonising their approach to enforcement.

1. Highlights of the year

In 2015, the REACH Committees are running at full capacity in providing high quality scientific and technical advice within tight timelines. Their main challenge is to manage an even higher workload than in previous years while ensuring their advice focuses on the relevant elements in the regulatory context, i.e. it is fit for purpose. The Biocidal Products Committee is also facing an increased workload and will need to reach cruising speed in its opinion forming. This requires the Committee members to maintain a high level of contribution to the work of the Committee by regularly taking on the role of rapporteur in addition to peer-review tasks and attendance at Committee meetings. In addition, the Member States need to provide adequate support for the Committee members to carry out their work.

Additional challenges will be to continue providing a high level of transparency while, at the same time, respecting confidentiality requirements and effectively managing potential conflicts of interests in the Committees.

The Committees Secretariat will have to efficiently and effectively manage such a high workload to fulfil the tight legal timelines while maintaining the high quality of the work. In particular, the increasing need for rapporteurships and active membership will require continuing good communication with MSCAs and the Management Board. As part of the preparation for the second ECHA report under Art 117(2) of REACH, the Agency will analyse different options for the future to allow the Committees to deal with their ever increasing workload.

Member State Committee (MSC)

In 2015, all Committee processes (i.e. SVHC identification, opinion on ECHA's draft recommendation for Annex XIV, dossier evaluation, opinions on CoRAP and substance evaluation) are running at maximum volume for the second consecutive year. In particular, dossier evaluation will focus on compliance checks while continuing to address draft decisions on testing proposals, and substance evaluation will process the decisions requesting further information for substances from the third CoRAP list. The MSC will continue to focus on the efficiency of its procedures and working practices, and revise them where necessary.

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

Both Committees will handle a high number of authorisation applications in parallel with other processes – i.e. CLH in the case of RAC and restriction dossiers in both

Committees. The high workload will test their maximum capacity and the efficiency of their procedures. The recommendations for improving the restriction process will be implemented to increase the efficiency where possible. A first review of lessons learnt from the authorisation application process will be carried out.

SEAC will continue addressing complex issues of socio-economic analysis and assessment of health and environmental impacts.

Good interaction and cooperation between RAC and SEAC will continue to be essential for communicating the risks and uncertainties in order to facilitate the socio-economic analysis. Similarly, good cooperation between RAC and the BPC is needed to effectively coordinate the CLH opinion forming for biocidal active substances. Cooperation with other EU scientific committees and bodies (in particular the Scientific Committee on Occupational Exposure Limits (SCOEL)) will continue in order to avoid and swiftly solve potential divergences of opinions.

Biocidal Products Committee (BPC)

In 2015, the Committee will reach its cruising speed in opinion forming for active substances and will also need to process the first opinions for applications for Union authorisation and amendment of Annex I to the BPR (active substances eligible for the simplified authorisation procedure). In addition, opinions related to the mutual recognition process may need to be concluded. The high workload will test the maximum capacity and the efficiency of the Committee's procedures.

Forum

In 2015, many of the activities of the Forum for Exchange of Information on Enforcement will focus on enforcement projects. The final report of the third Forum-coordinated enforcement project (REF-3) on registration obligations and establishing cooperation with the customs authorities will be finalised and published. The fourth major Forum coordinated project (REF-4) (UPDATE: subject to be selected in Q4 of 2014) as well as a second pilot project on authorisation will enter into their preparatory phase, which means that the Forum will be preparing the respective project manuals.

In 2015, inspections will also start under the Forum's first pilot project on authorisation thus putting into practice one of the milestones of ECHA's MAWP 2014-2018. This pilot project is intended to gather first experiences and to build processes for controlling authorisation-related obligations. Delivery of the final report of that pilot project is planned for by the end of 2015.

In the course of 2015, the Forum is also expected to select the subject of its fifth major enforcement project (REF-5) and to decide on further practical activities related to authorisation obligations.

Furthermore, the Forum will also continue to support the enforcement by the national enforcement authorities by assisting ECHA and the European Commission in on-going improvement and modernisation of the IT-tools available to inspectors such as RIPE (REACH Information Portal for Enforcement) or ICSMS (Internet-supported information and communication system for the pan-European market surveillance). In that regard, ECHA intends to release a second major version of RIPE integrated with the Portal Dashboard tool for the MSCAs in the first half of 2015.

Having expanded the range of ECHA decisions followed up by inspectors in 2014, the Forum will continue to mobilise authorities to use ECHA's information intelligently to identify and address chemicals of concern (ECHA's second strategic objective of its MAWP 2014-2018). This will be facilitated through further development and streamlining

of the institutional interlinks between ECHA and national enforcement authorities and achieved by a progressively detailed description of the follow up processes for different types of decisions and, potentially, through practical testing in small scale pilot projects.

As in previous years, the Forum will also further support the development of capabilities of inspectors by developing and delivering an annual training for trainers who will in turn train inspectors on the national level.

The timely delivery of quality advice on enforceability of restriction proposals will also be a key deliverable of the Forum's business as usual. Additionally, the Forum will work on the further expansion of its compendium of analytical methods recommended for checking compliance with the restrictions as listed in Annex XVII of REACH.

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.
   - To deliver high quality scientific and technical advice, opinions and agreements that support the regulatory decision making in a transparent manner while ensuring the necessary confidentiality.

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

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

Performance indicators and targets

Indicator	Target in 2015	Means and frequency of verification
Percentage of opinions/agreements delivered within the legal timeframe.	100 %	Annual internal report
Percentage of unanimous MSC agreements.	80 %	Annual internal report
Percentage of Committee opinions adopted by consensus.	80 %	Annual internal report

Degree of Committee opinions taken on board in the final decision of the Commission.	High	Annual internal report
Level of satisfaction of the members and other participants with the functioning of the Committees and the Forum.	High	Survey, every second year[6]
Occurrence of conflicts of opinions with scientific committees of other EU bodies.	Only in well justified cases	Annual internal evaluation report

3. Main outputs

Member State Committee

- Over 90[7] unanimous MSC agreements on draft decisions on testing proposals and compliance checks, originating from draft decisions prepared in 2012-2015.
- Preparation of at least 35 unanimous agreements on draft substance evaluation decisions.
- Opinion on the third draft update of CoRAP.
- Unanimous MSC agreements (or opinions) on Annex XV proposals for identification of substances of very high concern (SVHC) prepared by MSCAs or ECHA.
- Opinion on ECHA's sixth draft recommendation for Annex XIV.
- Six plenary meetings and additional working group meetings.

Committee for Risk Assessment

- 50 RAC opinions on CLH dossiers.
- Nine RAC opinions on restriction proposals.
- Adoption of 40 RAC opinions on applications for authorisation.
- Adoption of RAC opinions on requests from the Executive Director (Article 77.3.c of REACH).
- Up to six plenary meetings and working groups as well as regular use of adoption by written procedure, as appropriate.

[6] Members and other participants of the Committees: evaluation of the indicator will be done in 2015.

[7] This number is based on the assumption that about 40 % of the cases go to the MSC and about 20 % of these will be referred to the Commission thus not included in this number.

Committee for Socio-Economic Analysis

- Nine SEAC opinions on restriction proposals.
- Adoption of 40 SEAC opinions on applications for authorisation.
- Adoption of SEAC opinions on requests from the Executive Director (Article 77.3.c of REACH).
- Up to five plenary meetings and working groups as well as use of adoption by written procedure, as appropriate.

Biocidal Products Committee

- 50 opinions on active substances.
- Five opinions on technical and scientific matters related to the mutual recognition process.
- One opinion on amendment of Annex I.
- Five BPC plenary meetings and five meetings of each standing working group.

Forum

- Final report of the third coordinated enforcement project (REF-3) on registration obligations and cooperation with the customs authorities.
- Manual of the fourth Forum coordinated REACH enforcement project (REF-4).
- Selected topic of the fifth Forum coordinated REACH enforcement project (REF-5).
- Results of the Forum pilot project on authorisation-related obligations.
- Decision on further activities related to authorisation obligations.
- Training for Enforcement Trainers for 2015.

2.2. Board of Appeal (Activity 9)

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 and Article 77 of the BPR).

1. Highlights of the year

During 2015, the Board of Appeal (BoA) will be called upon to process appeals which differ significantly from those on which it has already decided during previous years.

In particular, the BoA will decide on the first appeals against substance evaluation decisions which were lodged during the second half of 2014. It is expected that these appeals will present a number of novel issues which are scientifically, legally and administratively complex. For example, for the first time, the BoA has to handle cases where several registrants jointly lodged appeals against the same ECHA decision.

In addition, the first appeals against ECHA decisions taken under the BPR were lodged towards the end of 2014. The BoA will therefore process those appeals during the course of 2015. At the same time, the BoA will further improve its capacity in the area of the BPR to ensure that high quality decisions are taken in a timely manner. The BoA will also continue to raise awareness among interested parties on the scope of appeals and the appeals process under the BPR.

Decisions on appeals will help to clarify certain aspects of the REACH Regulation and the BPR that may be subject to different interpretations. These clarifications will in turn help to improve the quality of data submitted by industry and increase the efficiency of the processes set out in the REACH Regulation and the BPR.

The BoA will continue to publish its final decisions, announcements of appeals, and decisions on confidentiality claims and applications to intervene. Furthermore, it will continue its engagement with stakeholders to explain the appeals process and the work of the BoA. Through these measures, the BoA will endeavour to make sure that all stakeholders consider it to be both independent and impartial.

Whilst the workload of the BoA is outside its control, in terms of the number of appeals it receives, it must remain flexible and creative enough to ensure that it can react to the demands placed on it whilst continuing to deliver high quality decisions without undue delay. The BoA will therefore continue the process of reviewing its working methods to ensure that they reflect the changing demands placed on it and enable it to manage efficiently the increasing number of procedural measures and correspondence.

2. Objectives and indicators

Objectives

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

Performance indicators and targets

Indicator	Target in 2015	Means and frequency of verification
Percentage of final decisions made within 90 working days of the closure of the written or oral procedure.	90 %	Annual report of the BoA

3. Main outputs

- Up to 15 final decisions adopted.
- Procedural decisions, as needed, adopted.
- A robust body of high-quality decisions published online.
- Effective (i.e. clear, accurate and timely) communication with the (potential) parties in relation to appeal proceedings.

2.3. Communications (Activity 10)

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

1. Highlights of the year

As ECHA progresses into the seventh year of the operation of REACH, the number of companies having to comply with its requirements becomes larger and more of those companies will be small and inexperienced with the legislation. That brings increased demands on the communications function, to reach out to companies that are unaware of their responsibilities under REACH and the other legislation implemented by the Agency: to register, notify, communicate up and down the supply chain and follow the safety information provided by suppliers. Smaller companies with fewer resources will also require more support and, where possible, simplified and shorter information to guide them. The communications activities to help companies in the run up to the final REACH registration deadline in 2018 will therefore begin in 2015.

An additional challenge for 2015 is the deadline on 1 June for all mixtures containing classified substances above certain thresholds to be labelled and packaged according to the Globally Harmonised System of Classification and Labelling of Chemicals, enacted by the CLP Regulation. Significant activities in the first half of the year will therefore build on work begun in 2014 to make sure that companies are aware of their obligation. Awareness raising will also continue related to the Biocidal Products Regulation, for example in relation to the deadline of 1 September regarding Article 95 of the BPR and the duties of SMEs.

Building on ECHA's first efforts to reach out to the general citizen in 2014 (through the website, videos and social media), there will be further awareness raising activities for general audiences (particularly consumers) on their "right to ask" and on the CLP pictograms which, as of June, will be visible on consumer products.

ECHA's Stakeholders' Days will again be regular features of 2015.

Working with its accredited stakeholder organisations, ECHA will also be enacting a new transparency policy which was drafted in 2014. The policy will further develop the Agency's openness and ability to satisfy the interest of citizens to follow and monitor its work and to hold it accountable for its actions.

ECHA will continue to work closely with communications experts within the Commission, fellow EU Agencies and its accredited stakeholder organisations.

The Agency's internal communications will remain a priority, playing a key role in enabling staff to play their roles with commitment, motivation and efficiency. These communication activities will contribute directly to the achievement of the Agency's strategic objectives 1, 2 and 4 in particular.

2. Objectives and indicators

Objectives

1. ECHA's external audiences are communicated with effectively, in 23[8] official EU languages where necessary and particularly with a view to the needs of SMEs, and ECHA benefits from an accurate and proportionate media presence.

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

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

Performance indicators and targets

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

3. Main outputs

- Up to 100 pieces of communication published in 23 official EU languages – documents, web pages, publications of guidance, particularly with a view to the needs of SMEs, etc.
- Coordinate communication activities for specific target groups (e.g. SMEs, retailers, downstream users, consumers, etc.).
- Up to two Stakeholders' Days, one workshop for accredited stakeholder organisations and ad hoc stakeholder events held.
- Up to a dozen press releases, 50 news alerts, 50 weekly e-News bulletins and a bimonthly newsletter produced.

[8] Irish Gaelic not included.

- Up to six webinars and four short videos produced.
- A bimonthly Stakeholder Update published for accredited stakeholder organisations.
- Internal information provided daily for staff on the intranet and internal information screens.

2.4. International Cooperation (Activity 11)

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

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

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

1. Highlights of the year

Regarding the OECD activities, in 2015, the development of formats and tools will remain a steady activity.

On the IUCLID side, the finalisation of the updates and the validation of the IUCLID 6 application will mean close collaboration with the OECD IUCLID Expert group. As this new IUCLID version will also support easier customisation to meet the needs of other legislations, promotion will be needed to ensure that this feature is well known from regulatory authorities worldwide. The activity in support of the OECD harmonised templates, which constitute the core of IUCLID, will also continue with the further improvement and development of new formats in line with latest internationally agreed test guidelines.

For the OECD QSAR Toolbox, the focus will be on the development of version 4, with the main objective of increasing usability for less experienced users and usefulness for justifying read-across cases as well as for implementing additional Adverse Outcome Pathways, upon the decision of the OECD Management Group.

Regarding the OECD eChemPortal, the Agency will continue its further development and hosting, as well as its promotion to the public, in close collaboration with the OECD Steering group. ECHA will also contribute to the revised Cooperative Chemicals Assessment Programme of the OECD, and in particular to promote common understanding on the use of alternative methods of assessing chemical hazards. ECHA will carry on supporting the OECD work on nanomaterials, in particular related to developing the approaches for their testing and assessment.

ECHA's scientific and technical support to the European Commission will focus on two core areas: capacity building in candidate countries and potential candidates in line with the European Union's external policies and contributions to the EU's work on international chemicals management. In 2015, ECHA's third capacity building project under the Instrument for Pre-Accession Assistance (IPA II)[9] will aim to maintain and

[9] A project plan is foreseen to be submitted and approved in late 2014; the final text of the WP 2015 may need to be adapted accordingly.

further enhance its beneficiaries' knowledge of the EU chemicals *acquis* and of ECHA's work. Other key areas of support will be the United Nations sub-committee on the Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS) and if requested, the Commission's participation in the fourth International Conference on Chemicals Management (ICCM-4) as well as Stockholm and Rotterdam Convention meetings. ECHA will contribute to the pilot exercise, carried out under the lead of the OECD, on the classification of substances for the development of a global list of substances classified in accordance with the UN GHS.

The Agency will continue cooperating with peer agencies in Australia, Canada, Japan and the USA. Joint activities will include mutually beneficial work such as the prioritisation of chemicals for assessment and assessment methodologies, sharing best practice and addressing emerging issues.

As a significant part of registrations is linked to imported substances, presentations to audiences in non-EU/EEA countries will be delivered to support third country manufacturers in making their products comply with EU legislation. In this regard, ECHA's international activities contribute to the Agency's strategic objective of improving the quality of dossiers. In addition, ECHA will interact, in liaison with the Commission, with authorities in countries that are reviewing or establishing their chemical safety legislation. The Agency will, as in previous years, contribute to the 2015 Helsinki Chemicals Forum (HCF).

2. Objectives and indicators

Objectives

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

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

Performance indicators and targets

Indicator	Target in 2015	Means and frequency of verification
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	Surveys

3. Main Outputs

- OECD Projects: Upgrade of eChemPortal to ensure that data prepared in the new or updated harmonised formats, including IUCLID 6 can be published. First release of the next version of the OECD QSAR Toolbox delivered to ECHA and OECD.
- Training on the OECD QSAR Toolbox and/or other tools including the new tool development.
- Contribution to the OECD cooperation under Hazard Assessment Taskforce, and Working Party on Manufactured Nanomaterials, in particular by chairing one of its steering groups.
- Provision of scientific and technical support to the Commission, including on UN GHS, e.g. potential participation and input at UN GHS meetings, Conventions and ICCM-4.
- Continued cooperation with the regulatory agencies in Australia, Canada, Japan and the USA in line with agreed Rolling Work Plans.
- Capacity building activities targeted at EU candidate countries and potential candidates as outlined in ECHA's third IPA project plan.[10]
- Presentations at seminars/workshops/conferences in key third countries (either in person or by video conference) and hosting visits by representatives of such countries.

[10] A project plan is foreseen to be submitted and approved in late 2014.

3. Management, Organisation and Resources

3.1. Management (Activity 12)

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

1. Highlights of the year

The ECHA Secretariat will continue to efficiently support the work of the Management Board in its role as governing body of the Agency. Supported by its working groups, the Management Board plays a key role in the implementation of the four strategic objectives, in particular by facilitating the implementation of the Multi-Annual Work Programme 2014-2018 through the adoption of annual work programmes.

Other core functions of the Management Board include the adoption of the budget and annual report, as well as the adoption and review of internal Agency rules. In addition, the Management Board closely monitors the performance of the Agency and the implementation of its strategic aims. To this end, the Board receives regular reports on the progress with work programme implementation, and specific topic-related reports from the Secretariat.

ECHA will continue to strengthen relations with the Member State competent authorities and mandated national institutions, and improve communication and coordination through information exchange, visits and an annual competent authorities directors' planning meeting. When doing this, ECHA will also promote common understanding on priorities while taking into account resource constraints of both Member States and of ECHA. ECHA will foster the dialogue with key institutional partners including the European Commission, Parliament and the Council of Ministers and continue contributing to the work of the Network of EU Agencies.

In 2015, developing effectiveness and efficiency of the Agency through different means will continue to be a priority in line with strategic objective 4. The Agency will focus on the continual improvement of its Integrated Quality Management System, certified by an independent accredited Certification Body according to the International Organisation for Standardisation (ISO) 9001:2008 standard. ECHA will emphasise a risk-based approach to avoid unnecessary controls. The Agency will start integration of a relevant environmental management system in its Integrated Quality Management System (IQMS). Audits will be performed in order to detect improvement opportunities and correct inefficiencies. The annual planning cycle will encompass recommendations deriving from evaluations and audits. It will also take into account stakeholder feedback. Planning of the Agencies activities and resources will be strengthened through a dedicated tool. Improving the management of the information in the Agency will facilitate the performance of the activities and allow traceability.

The Agency will ensure compliance with relevant regulations and internal policies, procedures and instructions by application of internal management standards and a regular management review. Management responsibilities also include

performing assurance audits, protecting personal data, efficiently managing the declarations of interest of staff, Management Board and Committee members as well as protecting the security of confidential personal and industry information with a high standard security system. ECHA will also ensure the continuous performance of the Agency tasks with a comprehensive business continuity system. Moreover, the legal expertise needs to be continuously maintained to guarantee the legal quality of ECHA decisions.

2. Objectives and indicators

Objectives

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

Performance indicators and targets

Indicator	Target in 2015	Means and frequency of verification
Percentage of very important audit recommendations implemented within the deadline (IAS).	100 %	Internal auditor's annual report

3. Main outputs

- Four Management Board meetings and corresponding working groups organised to allow the Board to take all necessary decisions.
- One meeting for Member States/MSCA Directors organised.
- ISO 9001 certification on selected processes.
- Start implementation of EMAS[11] or equivalent environmental standard.
- Strong legal support provided for the drafting of ECHA decisions and for their effective defence.
- Annual report of the Data Protection Officer provided to the European Data Protection Supervisor.
- At least one meeting of the Security Officers' Network organised.
- 120 access to documents decisions covering approximately 700 documents.
- Regulatory multi-annual and annual plans and annual reports produced.

[11] European Eco-Management and Audit Scheme

3.2. Finance, Procurement and Accounting (Activity 13)

1. Highlights of 2015

The rules governing ECHA's financial management are adopted by the Agency's Management Board after consultation with the European Commission, and must be compliant with the regulation on the financial rules applicable to the general budget of the Union (Financial Regulation)[12]. The funding and expenditure of the REACH, Biocidal Products and PIC regulations have to be separated.

The overall focus of ECHA's financial management will be on assuring the best use of available financial resources in line with the principles of economy, efficiency and effectiveness.

Own income for REACH/CLP activities in 2015 will include fees stemming from registrations, authorisation applications, appeals, additional fee income following SME status verification, administrative charges, and interest revenue. By the end of the year, the reserve is expected to be exhausted and the Agency will return to a mixed funding regime for REACH/CLP where part of the expenditure will be covered by fee income and the rest balanced by an EU subsidy.

Whereas the financing of the PIC activities will continue to be fully based on an EU subsidy, the biocides activities will increasingly rely on fee financing. Given the high uncertainty on the level of industry driven fee income both for REACH/CLP and Biocides activities, ECHA will invest significantly on forecasting and modelling and constantly monitor its revenue and expenditure forecast to be able to signal any shortfall to the Commission for the appropriate action to balance the budget.

Efficient financial management will continue to be assured through prudent management of income, tight control of expenditure, increased emphasis on business case evaluation and specific work processes identified for streamlining. With regard to procurement and contracting, ECHA will again outsource part of its activities to support the implementation of its Work Programme. The establishment of appropriate contractual arrangements will continue imposing demands for efficient procurement. Particular attention will be paid to make the most effective and economic use of the large number of framework contracts that the Agency and the Commission have in place.

Efforts will be continued to make sure that the REACH, CLP and biocides fee regulations are correctly implemented. To this end, the systematic control function that has been put in place to check the correctness of SME reductions granted for REACH fees, and hence the fees paid to ECHA, will be continued. Regarding the Biocidal Products Regulation, ECHA will, in advance, verify the companies requesting a fee reduction based on SME status and, depending on the number of requests, part of the human resources will be allocated to the Biocides-related SME verifications.

The Agency will continue to segregate funds and split human resources between the REACH, Biocidal Products and PIC regulations in its budgeting and reporting. ECHA will also monitor that the carryover to the following year of committed funds will be within the limits set by European Court of Auditors (ECA) with the exception of operational expenditure linked to multi-annual projects. ECHA will also work with the Commission to ensure its functioning on the basis of mixed financing (balancing subsidy and fee

[12] REACH Article 99.

revenues). In this context, the Agency will put in place a forecasting and reporting mechanism in cooperation with the Commission.

2. Objectives and indicators

Objectives

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

Performance indicators and targets

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

3. Main outputs

- Rigorous budget and liquidity management with evaluation of large programmes.
- Follow-up and execution of the budget to reach the targeted commitment and payment rate.
- Close monitoring and management of Agency's cash reserves.
- Considerable number of new procurement initiatives carried out and new contracts

established to serve efficient budget implementation.

- Reporting on the use of funds under different legislations.
- Activity-based expense reporting throughout the year.
- Annual accounts 2014 prepared in time.

3.3. Human Resources and Corporate Services (Activity 14)

1. Highlights of 2015

Human Resources

As a decentralised Agency of the EU, ECHA has to conduct its activities in compliance with the EU Staff Regulations of officials and the conditions of employment of other servants of the European Communities (Staff Regulation) and all ECHA staff are obliged to act in conformity with ECHA's code of good administrative behaviour and with consideration of the public service principles for the EU civil service issued by the European Ombudsman.

ECHA's operating environment will continue to be impacted by the prevailing economic situation in Europe and the associated resource impact on national and EU public administrations. In 2015, ECHA is faced with a reduction of its core staff for REACH and CLP and, due to budget constraints, ECHA will need to continue to keep, as a short-term measure, a proportion of its posts allocated for biocides activities vacant.

The strategic HR management pendulum has now swung from recruitment to engagement and retention in that, for the foreseeable future, ECHA has in place the main cadre of staff to fulfil its objectives and does not have the possibility of recruiting to the extent of previous years. Consequently, ECHA's human resource strategy will continue to evolve from its initial focus on growth towards enabling an organisation that is effective, efficient and that maintains the flexibility and agility to adapt to the needs of its stakeholders and the capacity to respond effectively to future legislative and/or policy challenges. A new category of Contract Agent staff (short-term) will be introduced to ensure increased organisational capacity and flexibility in periods of peak workloads.

While ECHA, as a knowledge organisation, requires a certain degree of turnover (for example, to update its competences), it also needs to constantly consider retention initiatives to ensure that turnover of key staff remains at an acceptable level. A key area of focus will be to ensure that the key performers with the required profiles and skills are motivated to work at ECHA. ECHA's MAWP 2014-2018 (strategic objective 3) outlines the requirement for enhanced capacity building of scientific and regulatory competences within ECHA in identified priority areas. The competency mapping exercise will guide ECHA's actions required to strengthen its competence in such priority areas. The new HRMS will create efficiencies within the organisation through, for example, streamlining separately generated data flows into one central module, and enable a considerable improvement in manpower planning.

Corporate Services

The main focus will be on the feasibility study aimed at investigating the options for ECHA's future premises in light of the expiry of the current building contract in the end of 2019. The feasibility study is intended to provide ECHA with a basis for an objective evaluation and decision on the longer term premises needs and location for ECHA.

While planning for the future premises will be of major concern in 2015 and the year to follow, the preventive and corrective maintenance works performed by the landlord of the current premises will continue to be monitored to keep the building facilities at an acceptable standard. Cooperation with the landlord and its contracted building maintenance providers will be more strictly monitored. In 2015, a common maintenance monitoring tool between the landlord and ECHA will be put in place to provide more transparency of the maintenance works done specifically in relation to contractual

obligations of the landlord. Strict monitoring of the maintenance works is also intended to ensure that the building adheres to environmental and health standards.

Considering that some maintenance projects may pose considerable impact on the general working environment, each project will be carefully evaluated vis-à-vis the impact.

Improving safety and security measures through trainings will be given attention through general evacuation drills, training of fire wardens and First Aid training, and awareness campaigns of security rules in place. Based on the audit report of the current access control system completed in 2014, a follow-up work will continue in 2015 to ensure that the Agency has a reliable access control system which is crucial part of the ECHA's physical security.

With the increase utilisation of the meeting facilities, it is vital that the meeting facilities are reliable and well-functioning and a key to this is to keep a regular maintenance of the meeting facilities. This will be reinforced in 2015 together with updating of some equipment. As meetings are often essential components to achieving operational objectives, providing reliable meeting facilities will remain a vital task of ECHA.

Recognising that the efficiency of a travel agency has a significant impact on the planning and execution of ECHA meetings, the services offered by the new travel agency will be closely monitored through regular satisfaction surveys.

By mid-2015, the work of the physical archives will be completed.

2. Objectives and indicators

Objectives

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

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

Performance indicators and targets

Indicators	Target in 2015	Means and frequency of verification
Percentage of REACH and PIC establishment plan posts filled at the end of the year.	95 %	Annual internal report
Percentage of biocides establishment plan posts filled at the end of the year.	88 %	Annual internal report
Turnover of Temporary Agents	< 7.5 %	Annual internal report
Turnover of Contract Agents (excluding	< 12.5 %	Annual internal report

short-term CAs).		
Level of satisfaction of the Committee, Forum, and MB members with the functioning of the conference centre.	High	Annual survey
Level of satisfaction of staff with the corporate services.	High	Annual survey

3. Main outputs

Human resources

- Payroll for statutory staff and other payments to staff, SNEs and trainees (numbering approximately 550 persons overall).
- An estimated 10 selection procedures to be launched.
- An estimated 25 recruitments to be completed.
- Performance appraisal and reclassification exercise for around 500 statutory staff.
- Advice and assistance delivered to staff and management on Human Resources (HR) matters, in particular on individual rights and wellbeing.
- Staff survey conducted.
- Active management of the people and performance management processes and methods.

Corporate services

- Feasibility assessment on ECHA needs on premises.
- Timely purchase of equipment, materials and services through appropriate procurement procedures.
- Monitoring tool for the preventive and corrective maintenance works performed by the landlord accessible also to ECHA.
- Safety and security trainings.
- Good support for meetings and conferences.
- Well-functioning audio-visual equipment with good technical support.
- Effective and efficient service of the Travel Agency.
- Timely calculations and reimbursements of missions and travel reimbursements to meeting participants.
- Efficient mail services.
- Well-organised and correctly managed library and archives.
- Up-to-date and correct inventory of non-IT assets.

3.4. Information and Communication Technology (Activity 15)

1. Highlights of 2015

Delivering IT support for administrative processes as well as ensuring adequacy of ICT infrastructure are both strategic action areas under strategic objective 4.

After the establishment of a centralised access management service in 2014, the Identity Management (IDM) model is progressively adopted by ECHA core applications, achieving improved control of and efficiency in access management to IT systems and services.

ECHA will further pursue the revision of the Information Communications Technology (ICT) infrastructure initiated in 2014, to optimise costs, sustain growth and withstand the impact of the 2018 deadline. During 2014, different options were assessed, among which the main ones are: continuing the current outsourcing model based on owned infrastructure or a gradual transition to outsourcing on external computing infrastructure, owned and fully managed by an outsourcer (so called Infrastructure as a Service model). Both options were assessed against the same requirements of performance, security, adequacy of the support offered to business continuity. The implementation plan, stemming from the decision, will cover the definition of the future contractual and operational model for outsourced hosting services and its execution will start in 2015.

To achieve an increase in the flexibility of IT services and enhanced means of communication and collaboration, whilst at the same time enforcing security, ECHA will pursue a further extension of the coverage of the WiFi network.

Update of ECHA's IT security related policies to take into account the new infrastructure and new IT solutions mentioned above is planned.

In 2014, the Agency analysed a solution for enhanced planning and reporting, based on the identified scope for IT support an implementation project will be started in 2015.

After the complete overhaul of the internal information management platform in 2014, the applications are upgraded to support the new functionalities and the Agency's information management policies.

Human Resources management system (HRMS) Phase II covering: selection and recruitment, performance and career management, learning and development will be released thus bringing efficiencies to HR processes.

2. Objectives and indicators

Objectives

1. Supporting ECHA administrative processes and management reporting with the assistance of well-functioning IT systems. ECHA makes effective use of its information; documents and records received, generated and used by its staff are properly controlled.

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

3. The IT Business Continuity Plan adequately covers ECHA's mission-critical systems and is adapted to the evolution of the ICT infrastructure.

Performance indicators and targets

Indicators	Target in 2015	Means and frequency of verification
Availability of mission-critical systems for external customers (i.e. uptime during service hours).	On average 98 %	Data centre statistics
Level of internal and Member States' user satisfaction with IT services, relative to staff/ support ratio.	High	Annual customer survey and *ad hoc* feedback

3. Main outputs

- The plan for the revision of the ICT infrastructure of ECHA is pursued and the IT Business Continuity and Disaster Recovery plans are adapted.
- Extended coverage of the WiFi network.
- High level design of the IT solution for enhanced planning and reporting defined and implementation started.
- The migration to the new platform for internal information management and to the new information management standards, in accordance with the filing plan and the policy on classification and handling of information, is completed.
- Access control to IT systems and services is progressively adapted to a unified and centralised access management model.
- IT Asset management is performed at an adequate level of accuracy and timeliness; potential retirement of ICT assets is adequately prepared and handled in compliance with the internal policies and procedures.

4. Agency Risks

ECHA conducts an annual risk management exercise to identify, assess and manage the potential events that could put the achievement of the objectives defined in the Work Programme at risk. As a result of this exercise, a number of risks were identified, assessed and considered in the preparation of Work Programme 2015. ECHA's management ranked the following main risks as most important with regard to their likelihood of occurrence and impact on the implementation of Work Programme 2015, and defined risk mitigation measures whose effectiveness will be closely monitored during the year.

Under the current Financial Regulation, ECHA may not be able to balance its volatile income and expenditure without some form of balancing mechanism. ECHA considers that improved income forecasts with a number of scenarios and fall-back plans will allow for actions if there is a change in the circumstances, while a balancing mechanism could ensure control over this risk.

The Biocidal Products and PIC regulations bring new obligations and tasks to ECHA. Due to lower fee income than expected, and to ensure a balanced budget, ECHA will need to continue not to fill part of the establishment plan posts in the short term. This is generally a risk regarding the ability to achieve the work programme objectives, and in particular regarding the ability to cope with workload peaks in any area of biocides activity. Considering the tight deadlines and the resource issues both in ECHA and in some Member States, together with the uncertainty of the income forecast, ECHA and/or the MSCAs may not be able to process all applications under the BPR and deliver all reports in good quality and due time, which may negatively impact the targets in the Review Programme. ECHA considers that close cooperation with the MSCAs, including support with guidelines, templates and capacity building is very important to mitigate this risk. With regard to human resources, ECHA will need to be flexible in internal reallocation, should the fee income in the BPR not suffice for the resources recruited or if there is an unexpected peak of work in applications. If there is a significantly lower income than expected, work which is not directly related to applications may be de-prioritised to enable resources to be downsized without compromising the capacity to deliver the work related to applications.

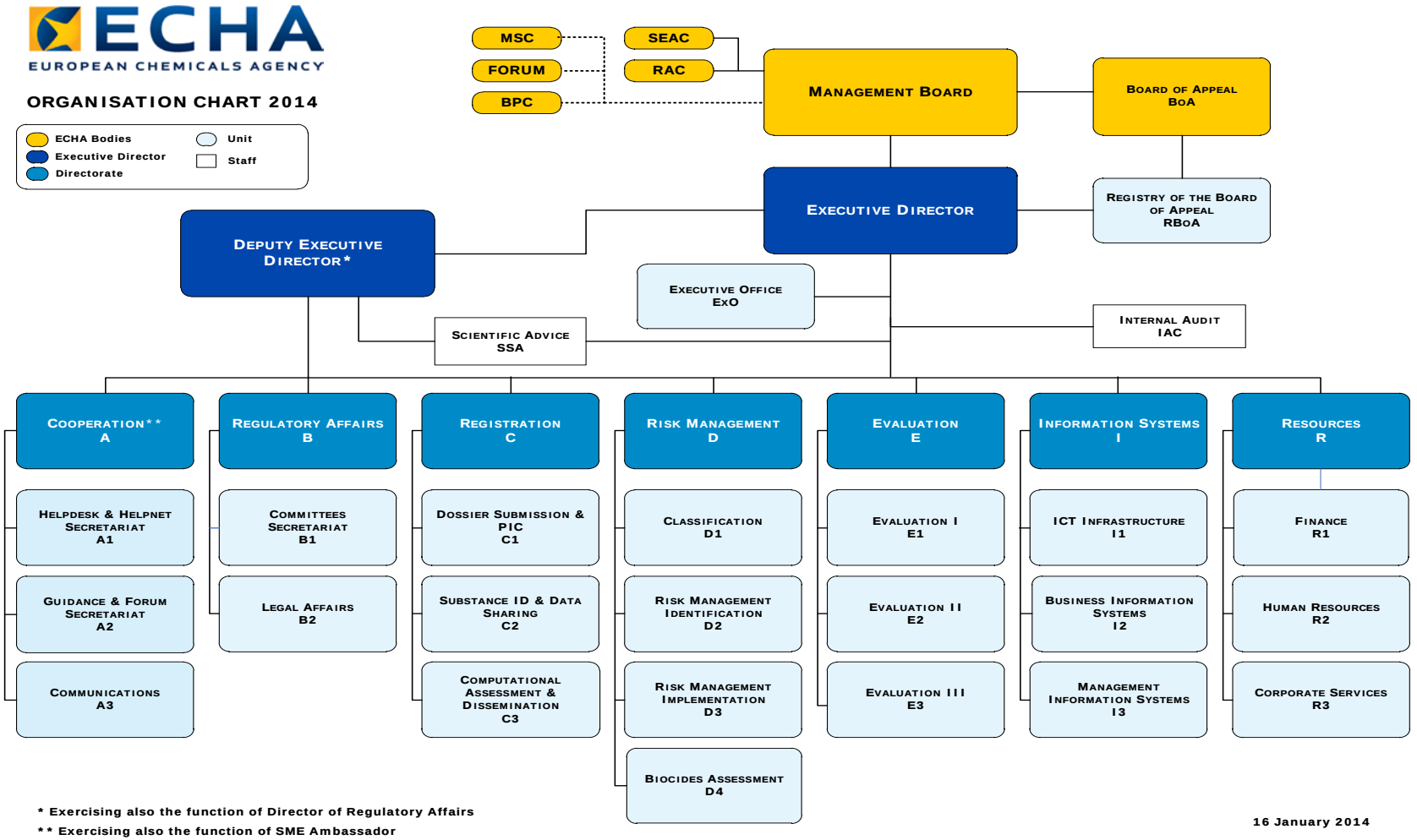
A risk with regard to the authorisation applications under REACH was identified in relation to two potential scenarios. If there is a peak in the authorisation applications, which may impact both the staff ability to manage the volume and the opinion-making process of the Committees, the Agency has foreseen a flexible internal reallocation and a potential involvement of all Committees members as rapporteurs. The risk of a significantly lower income than forecasted is tackled as part of the general financial risk the Agency is facing with regard to the income uncertainty for the coming years.

A major risk in the implementation of the dossier evaluation work plan is the impact of the foreseen review of the information requirements in relation to the endpoint on reproductive toxicity. It is expected that the REACH Annexes will be revised (by the end of 2014) by including the extended one generation reproductive toxicity studies (EOGRTS) under information requirements for reproductive toxicity. As part of this exercise, the Commission will have to deal with the backlog of testing proposal and compliance check cases referred to the Commission for decision making, due to the lack of unanimity in the MSC concerning this endpoint (currently nearly 200 cases). While the mechanism of dealing with these cases is still under discussion, it is expected that ECHA will be asked to considerably contribute to solving them. Depending on the solution this may lead to serious disruption of the other dossier evaluation work. To mitigate this risk, ECHA is negotiating a phased approach to implement the strategy with special regard to timelines.

A number of work programme objectives are highly dependent on the IT governance system and the IT infrastructure. In 2015, along with a number of other ambitious IT projects, a new dissemination website is to be launched. A risk stemming from the potential change of the existing contractor due to consumption of all resources up to the ceiling of the current framework contract may result in delays or reduction of the scope of this project. A number of measures including management intervention to control the performance of the project have been foreseen.

General maintenance problems of the Agency building as well as unplanned serious renovations work may seriously disrupt the normal working process. The Agency has already taken a number of measures to mitigate this risk, such as agreement on a refurbishment plan with the landlord for the remaining years of lease, which will take into consideration the need to temporarily relocate teams within and outside the building.

ANNEX 1: ECHA Organisation



ANNEX 2: Baseline assumptions

	Main drivers of REACH and CLP activities	Estimate for 2015
Activity	**Dossiers arriving**	
1	Registration dossiers (including updates)	5 700
1	Confidentiality requests	240
1	PPORD notifications (including requests for extension)	400
1	Inquiries	1 400
1	Data sharing disputes	7
2	Substances on the CoRAP to be evaluated in 2015 by Member States	55
2	Testing proposals	60
3	Restriction proposals (Annex XV) Out of which restriction proposals developed by ECHA	9 3
3	Proposals for identification as SVHC (Annex XV)[13] Out of which developed by ECHA	50 5
3	Authorisation applications	70
4	Alternative name requests	150
4	Proposals for harmonised classification and labelling (Annex VI of CLP Regulation)	60
Any	Access to data older than 12 years	350

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

	Main drivers of REACH and CLP activities	Estimate for 2015
Activity	**ECHA decisions**	
1	Decisions on data sharing	7
1	Decisions on completeness check (negative, i.e. rejections)	60
1	Decisions on confidentiality requests (negative)	30
1	Decisions on PPORD	50
1	Revocations of registration numbers	20
2	Final decisions on dossier and substance evaluation	
2	- Testing proposals	180
2	- Compliance checks	120
2	- Substance evaluations	40
12	Decisions on access to documents requests	120
13	Decisions on SME status (negative)	200

	Main drivers of REACH and CLP activities	Estimate for 2015
Activity	**Others**	
2	Draft CoRAP for substances subject to evaluation	1
2	Dossier evaluation follow-up examinations	400
3	Recommendations to the Commission for the Authorisation List	1
5	Questions to be answered (REACH, CLP, as well as respective IT tools)	4 800
8	MSC meetings	6
8	RAC meetings	6
8	SEAC meetings	5
8	Forum meetings	3
9	Appeals submitted	20
9	Appeal decisions	15
10	General enquiries by phone or email	600

10	Press enquiries	500
10	Press releases and news alerts	60
12	Management Board meetings	4
13	SME status checks	400
14	Recruitment due to turnover	25

Activity	Main drivers of biocides and PIC activities	Estimate for 2015
16	Number of active substances to be assessed under the Review Programme	50
16	Biocides Inquiries	50
16	Biocides Data sharing disputes	5
16	Applications for new active substance approval	2
16	Applications for renewal or review of active substances	3
16	Applications for Union authorisation for biocidal products	12
16	Applications for active substance suppliers (Article 95)	150
16	Applications for technical equivalence	20
16	Applications for chemical similarity	10
16	Submissions to Member States	3 000
16	SME status checks	30
16	Appeals	3
16	BPC meetings	5
16	BPC WG meetings	20
17	PIC notifications	4000
16, 17	Questions to be answered (BPR, PIC Regulation as well as respective IT tools)	1 200
16, 17	Recruitment due to turnover for Biocides and PIC	3

ANNEX 3: Estimated resources for 2015

Annex 3: 2015																				
	REACH Staff Resources 2015				Budget 2015	BIOCIDES Staff Resources 2015				Budget 2015	PIC Staff Resources 2015				Budget 2015	ECHA (Total) Staff Resources 2015				Budget 2015
The numbering below refers to the WP 2015, not to the numbering in the budget	AD	AST	CA	Total	Total	AD	AST	CA	Total	Total	AD	AST	CA	Total	Total	AD	AST	CA	Total	Total
Implementation of the Regulatory Processes (Operational Budget)																				
Activity 1: Registration, Data-sharing and Dissemination	37	8	13	58	8 941 860	4	1	4	9	1 263 694				0	0	41	9	17	67	10 205 553
Activity 2: Evaluation	74	12	5	91	15 607 832				0	0				0	0	74	12	5	91	15 607 832
Activity 3: Risk Management	36	5	5	46	7 469 234				0	0				0	0	36	5	5	46	7 469 234
Activity 4: Classification and Labelling	14	2	2	18	2 631 439				0	0				0	0	14	2	2	18	2 631 439
Activity 5: Advice and Assistance through Guidance and Helpdesk	19	7	5	31	4 829 701	1		1	2	360 710				0	20 000	20	7	6	33	5 210 411
Activity 6: IT Support to Operations	30	11	4	45	19 058 598		1	1	2	771 710		1		1	362 571	30	13	5	48	20 192 879
Activity 7: Scientific Activities and Technical Advice to EU Institutions and Bodies	9	0	1	10	1 906 355				0	20 000				0	0	9	0	1	10	1 926 355
ECHA's Bodies and Supporting Activities																				
Activity 8: Committees and Forum	22	7	5	34	6 996 607	3	2		5	1 330 274				0	66 000	25	9	5	39	8 392 882
Activity 9: Board of Appeal	6	3	3	12	1 837 626	1			1	157 855					0	7	3	3	13	1 995 481
Activity 10: Communications	9	8	7	24	6 955 252		1	1	2	625 710				0	10 000	9	9	8	26	7 590 962
Activity 11: International Cooperation	3	0	0	3	1 176 907				0	70 000				0	0	3	0	0	3	1 246 907
Management, Organisation and Resources																				
Activity 12: Management	26	16	6	48	8 625 505	1	0	0	1	378 855				0	10 000	27	16	6	49	9 014 360
Activities 13-15: Organisation and Resources (Title II: Infrastructure)	28	45	42	115	16 173 084	2	1	4	7	964 984		1		1	112 571	30	47	46	123	17 250 639
Activity 16: Biocides						27	3	3	33	4 549 210				0		27	3	3	33	4 549 210
Activity 17: PIC											1	3	1	5	640 857	1	3	1	5	640 857
Total	**313**	**124**	**98**	**535**	**102 210 000**	**39**	**9**	**14**	**62**	**10 493 000**	**1**	**5**	**1**	**7**	**1 222 000**	**353**	**138**	**113**	**604**	**113 925 000**
In Establishment Plan:	[437					58					6					501]				

ANNEX 4: Procurement Plan

[To be inserted in December 2014]

European Chemicals Agency

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