

Work Programme 2013



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The report includes recommendations to potential registrants in order to improve the quality of future registrations. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice and does not represent the position that the European Chemicals Agency may adopt in a particular case.

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Work Programme 2013

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List of Acronyms

AD	Administrator
AST	Assistant
ATP	Adaptation to Technical Progress
BPC	Biocidal Products Committee
BPR	Biocidal Products Regulation
C & L	Classification and Labelling
CA	Contract Agent
CCH	Compliance checks
CG	Coordination Group
Chesar	Chemical Safety Assessment and Reporting tool
CLH	Harmonised classification and labelling
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic or toxic to Reproduction
COM	European Commission
CoRAP	Community Rolling Action Plan
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DCG	Directors' Contact Group
DNA	Designated National Authorities
eChemPortal	OECD Global portal to information on chemical substances
EC	European Commission
ECA	European Court of Auditors
ECHA	European Chemicals Agency
ECB	European Chemicals Bureau
ECM	Enterprise Content Management
EDEXIM	European Database of Export and Import of Dangerous Chemicals
EEA	European Economic Area
EFSA	European Food Safety Authority
EIES	Electronic information exchange procedure system
ENES	ECHA-Stakeholder Exchange Network on Exposure Scenarios
ENP	European Neighbourhood Policy
ENPI	European Neighbourhood and Partnership Instrument
ES	Exposure scenario
EU	European Union
FAQ	Frequently Asked Questions
Forum	Forum for Exchange of Information on Enforcement
HelpNet	REACH and CLP Helpdesk Network
HR	Human Resources
IPA	Instrument for Pre-Accession Assistance
IQMS	Integrated Quality Management System
ISO	International Organization for Standardization
ICT	Information Communications Technology
IR	Information Requirements
IT	Information Technology
IUCLID	International Uniform Chemical Information Database
JRC	European Commission's Joint Research Centre
MB	Management Board
MS	Member State
MSC	Member State Committee
MSCA	Member State Competent Authority
NEA	National Enforcement Authority

OECD	Organisation for Economic Cooperation and Development
Odyssey	ECHA's tool to support evaluation tasks
PBT	Persistent, Bioaccumulative and Toxic
PIC	Rotterdam Convention on the Prior Informed Consent Procedure
PPORD	Product and Process Oriented Research and Development
PPP	Plant protection product
(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
SAICM	Strategic Approach to International Chemicals Management
SEAC	Socio-Economic Analysis Committee
SIEF	Substance Information Exchange Forum
SME	Small and Medium-sized Enterprises
SNE	Seconded National Expert
SVHC	Substance of Very High Concern
TA	Temporary Agent
TP	Testing Proposals
UN	United Nations
UN GHS	United Nations Global Harmonised System of classification and labelling of chemicals.
WP	Work Programme

Presentation of the European Chemicals Agency

Established on 1 June 2007, the European Chemicals Agency (ECHA) is at the centre of the new regulatory system for chemicals in the European Union (EU), set out in Regulation (EC) No 1907/2006 of the European Parliament and the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). At the beginning of 2009, REACH was complemented by the Regulation on Classification, Labelling and Packaging of substances and mixtures (CLP Regulation (EC) No 1272/2008 of the European Parliament and the Council). These legislative acts are applicable in all EU Member States without the need for transposition into national law.

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

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

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

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

ECHA's Mission

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.

ECHA's Vision

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

ECHA's Values

Transparent

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

Independent

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

Trustworthy

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

Efficient

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

Committed to well-being

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

Introduction

This Work Programme outlines the European Chemicals Agency's objectives for 2013, which will be its sixth year of activity. The Multi-Annual Work Programme 2013-2015, adopted in June 2012 by the ECHA Management Board after a public consultation, provides the basis for this annual Work Programme. The structure of the Work Programme follows ECHA's Activity Based Management approach and is divided into 17 Activities. Each Activity has a set of objectives and outputs, as well as performance indicators, through which achievements can be followed up.

A new strategic approach has been adopted by ECHA's Management Board in the Multi-Annual Work Programme 2013-2015 and will provide a steer to the Agency in prioritisation and resource allocation. The annual Work Programme objectives will derive from the strategic approach. There are four strategic aims:

1. Maximise the availability of high quality data to enable the safe manufacture and use of chemicals.
2. Mobilise authorities to use data intelligently to identify and address chemicals of concern.
3. Address the scientific challenges by serving as a hub for scientific and regulatory capacity building of Member States, European institutions and other actors.
4. Embrace current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints.

The new Biocidal Products Regulation will be applied from 1 September 2013. The regulation provides additional tasks and resources for ECHA – in particular, the review of applications for authorisation of certain biocidal products. ECHA will continue to prepare itself to be ready to implement the regulation in September 2013. The complete handover of the Biocides activity from the Commission's Joint Research Centre (JRC) will be done by the end of 2013.

A recast of the PIC Regulation¹, which concerns the export and import of dangerous chemicals, will also bring new tasks to ECHA. In 2013, ECHA will work towards ensuring good progress in the preparatory activities so that the Agency will become operational for the new PIC tasks by March 2014, after the handover of the activities from the Commission's JRC.

The final ECHA budget and the establishment plan for human resources will be adopted in December 2012 by its Management Board, 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.

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

ECHA's Challenges and Priorities for 2013

The four strategic aims will provide a steer on how to face the challenges of the different Activities described in this Work Programme. The year 2013 will be a peak year in several ways: the second registration deadline and its implications, a peak in compliance checks to reach the 5 % target, the steadily increasing number of substance evaluations, the first authorisation applications and the continuously high workload related to proposals for harmonised classification and labelling. In addition, the Biocidal Products Regulation will become operational on 1 September 2013 and the biocides activities will have to be integrated with other activities in order to maximise the synergies.

The second registration deadline¹ under the REACH Regulation will require industry to submit thousands of registration dossiers. In addition to merely processing the registrations, the number of inquiries, helpdesk enquiries, data sharing disputes, confidentiality requests and appeals will also increase. The high number of dossier submissions will also increase the need to publish information on the registered substances. Moreover, ECHA will provide support to lead and member registrants to assist them in preparing high quality technical dossiers and chemical safety reports that meet the legal requirements and contribute to achieving its strategic aims.

Compliance checks are the main vehicle for checking the compliance of dossiers with the REACH Regulation thus pursuing the strategic aim of maximising high quality data. Evaluation targets will remain high in 2013. Evaluation, together with industry's own responsibility, should instil confidence in the EU citizens that industries' registration dossiers are of a good quality and meet the requirements. ECHA will ensure intelligent use of the data submitted by industry for effective regulatory chemicals management by selecting and addressing dossiers for compliance check in a way that ensures efficient interface with the risk management processes. ECHA has committed itself to reaching the 5 % target of compliance checks on the highest tonnage band by the end of 2013. A high share of targeted compliance checks should help achieving the ambitious target. Furthermore, substance evaluation should reach a cruising speed. Achieving final decisions on all testing proposals for the 2010 deadline and the follow-up of previous decisions require the action of ECHA and the Member States.

In the area of Risk Management, the identification of substances and the most appropriate risk management by MSCAs and the Commission/ECHA will continue in pursuit of using the data intelligently and addressing chemicals of concern. This will gradually lead to more proposals for restrictions and more substances placed on the Authorisation List. Moreover, handling authorisation applications, as a new process, will be challenging as the number of applications will increase. For 2013, the challenge will be to develop sound opinions by RAC and SEAC on the first applications that are expected to arrive in late 2012.

A further challenge for ECHA will be ensuring its readiness for the entry into operation of the new Biocidal Products Regulation. ECHA will have to be ready for the submission and processing of different types of biocides dossiers; to make the Biocidal Products Committee operational; as well as recruiting and training scientific and other experts to process and assess the many dossier types. Moreover, ECHA's Helpdesk and those of Member States will have to be able to handle questions from industry on biocides; guidance, manuals and other tools to assist industry will need to be ready; and a communication campaign to alert industry, Member States competent authorities and other stakeholders on the obligations resulting from the new legislation will also be necessary.

¹ 31.5.2013 for substances manufactured or imported in quantities of 100 tonnes or more (REACH Art. 23).

Lastly, it will be a challenge to provide scientific expertise to the Commission in its further development of the chemicals management policy, in particular as a follow-up to the 2012 review of REACH. This derives from ECHA's aspiration to become a hub for scientific and regulatory knowledge building of the Member States, European institutions and other actors, and to use this new knowledge to improve the implementation of the chemicals legislation.

Although the level of activity and resource needs will be at its peak in 2013, the austerity measures with regard to the EU budget demand savings in both human and financial resources in all EU bodies. So, ECHA is likely to be in a situation where, in addition to maximising the synergies between different processes and legislations, it needs to find further efficiencies, cutting back or slowing down activities that are not mandatory or where legislation does not provide fixed deadlines.

1. Implementation of the Regulatory Processes

Activity 1: Registration, Data-sharing and Dissemination

1. Main Challenges in 2013

Registration and dossier submissions

Registration

REACH is based on the principle that the responsibility for the identification and management of risks from a substance lies with the company that manufactures, imports, markets, or uses the substance. Companies that manufacture or import substances in quantities of one tonne or more per year need to demonstrate that they have assumed that responsibility by means of a registration dossier, which is submitted to ECHA. After receiving the registration dossier, ECHA verifies the completeness of the information provided and the payment of the registration fee, before assigning a registration number.

The year 2013 is the year of the second registration deadline for phase-in substances² that benefit from a transitional regime under REACH. Companies that manufacture or import substances in quantities of more than 100 tonnes per year must submit their registration dossier to ECHA on 31 May 2013 at the latest. Based on surveys carried out in cooperation with industry in 2012, ECHA is prepared for three different scenarios, the planning baseline being approximately 8 000 dossiers due by the registration deadline and approximately 7 000 registration dossiers of other types, like new substances or updates. It is assumed that most of the registrations will arrive in two peaks, lead registrants submitting at the end of the first quarter to benefit from a shorter deadline for completeness checks by ECHA, and member registrants submitting closer to the deadline. Building on the experience gained in 2010 from the first registration deadline, ECHA has put in place a plan to handle the workload peaks, relying on existing and interim staff trained for the purposes of temporary redeployment. This is to ensure that the dossiers will undergo the completeness check in an efficient and timely manner. However, focusing resources on the registration process may have an impact on other tasks, such as dissemination, which are likely to be postponed to the last quarter when all registration numbers will have been assigned.

ECHA is committed to providing well-targeted submission support to the registrants in the final months preceding the second registration deadline in order for them to meet their legal obligations and submit high quality dossiers. In order to be up-to-date on the industry progress and to be able to react promptly to any potential issues that might endanger registration, ECHA will actively participate in the work of the Directors' Contact Group (DCG) which had played an important role in achieving a successful result in the 2010 registration deadline. For the 2013 deadline, the DCG is paying specific attention to outreach activities towards SMEs via European and national authorities and associations. It is expected that the DCG work will intensify in the run-up to the registration deadline of May 2013. In addition, to help downstream users monitor the progress of the registration process, ECHA will regularly publish the list of substances for which a dossier has been received on its website. Finally, ECHA will handle pre-registrations and

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

registrations from Croatia³, in accordance with the transitional arrangements foreseen in their Treaty of Accession to the EU.

Finally, with increased force the Agency will continue its activities on checking the validity of the registration dossiers received for substances used as intermediates to verify whether the uses specified are in line with the definition of intermediate use and that strictly controlled conditions are applied.

Computational tools and methods

Registration is only the first step in the chain of events leading to an increasingly safe use of chemicals as foreseen in REACH. Therefore, ECHA wants to encourage the registrants to continuously improve their registration dossiers as they gather new information on their substances. To this end, ECHA will continue developing screening methods and automated tools to identify shortcomings in the dossiers. The findings from screening, together with best practices, will be communicated to registrants with the aim of stimulating spontaneous updating.

The second registration deadline means that in 2013 there will be a significant stepwise increase in the content of ECHA's database on substances. The Agency will ensure intelligent use of this data for effective regulatory chemicals management by progressively increasing its data mining and data analysis capacity, subject to availability of resources, in order to accurately identify information to best serve the interest of other REACH and CLP processes, such as targeted evaluation and risk management.

Other types of dossier submissions

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 (so called 'PPORD notifications'). As the number of PPORD notifications is lower than expected, ECHA intends to make this possibility better known to companies. The first PPORD exemptions expire in 2013, at which time assessment of potential requests for their prolongation will begin. Informed decisions on the extension requests of PPORDs will be based on assessment of the original applications from 2008, which will be completed by early 2013.

In addition to handling registrations and PPORD notifications, ECHA receives information on substances in the form of downstream user reports (if downstream use is not covered by the supplier's exposure scenario) and notifications of substances in articles. Downstream users of 2013 registrants will be supported in their reporting obligations by providing practical support in the form of simple guides and examples as well as user-friendly tools.

The Biocidal Products Regulation will enter into force on 1 September 2013 and companies will start submitting their biocides dossiers to ECHA. In addition, the handover of the PIC-related activities from the Commission to ECHA is scheduled for March 2014. In the first half of the year, the preparatory activities for receiving and processing these new types of dossiers and notifications will run in parallel with the registration peak. This will be challenging and has to be carefully monitored to avoid any disruption in either. At the same time the biocides and PIC dossier submission will benefit from synergies with the REACH and CLP legislations, allowing, in the long-term, the most efficient use of resources. From 1 September 2013 onwards, the Agency will be prepared to receive the biocides dossiers and will handle them according to the legal deadlines.

³ Croatia is expected to join the EU on 1 July 2013.

CSA Development Programme

Substances manufactured or imported in quantities above 10 tonnes per year, including all phase-in substances due by the second registration deadline, require a detailed chemical safety assessment (CSA), documented in a chemical safety report (CSR). For most of the substances classified as hazardous, use-specific exposure scenarios documenting the conditions of safe use must be reported in a CSR and provided to the registrants' downstream users as attachments to a safety data sheet (SDS). A roadmap until 2020 to guide continuous improvement in the quality of CSRs, including exposure scenarios (ESs), will be finalised in cooperation with the MSCAs and industry.

In 2013, based on the analysis of the registrants' CSRs from the first registration deadline, ECHA will focus on the further development of methods and tools for exposure assessment in those areas where major gaps exist. ECHA will continue to publish examples of CSRs that demonstrate different aspects of good quality in various real-life situations. Furthermore, ECHA will continue to support registrants as well as downstream users in building capacity to develop good quality ESs to be included in their CSRs and SDS. Focus will be placed on practical solutions that can be implemented to ensure the safe use of chemicals. In particular, work will aim to support downstream users to comply with the requirements by improving methodology and providing examples for substances used in mixtures and in consumer products, as well as the service life stages. ECHA will develop and improve its evidence-base from which to target its support for industry by more systematically reviewing the available CSRs.

ECHA will also promote initiatives, such as seminars and trainings, to increase the awareness and capability of interested parties on ES-related issues, and to promote the communication and sharing of information between industry and authorities on the effective implementation of ES principles. In this respect, the "ECHA-stakeholder exchange network on exposure scenarios" (ENES) and the topic specific work between the network meetings will play a key role.

Data sharing and substance identification

Data sharing is a REACH process which precedes the joint submission of registration information by companies who manufacture or import the same substance. The aim of data sharing is to minimise registration costs for companies, to prevent duplication of animal and other tests, and to facilitate the common classification and labelling of substances. Data sharing is obligatory for studies in which vertebrate animals are used. ECHA facilitates data sharing between potential registrants and has an arbitration role in settling potential data sharing disputes. There are two separate routes foreseen for data sharing: the establishment of Substance Information Exchange Fora (SIEFs) for pre-registered phase-in substances, and the inquiry process for other substances.

The number of data sharing disputes has remained quite low since 2008. However, because 2013 is a year of registration, it is anticipated that there will be, in early 2013, an increase in requests for arbitration regarding disputes on phase-in substances between companies working together in SIEFs. ECHA is readying its capacity for solving these disputes in a timely manner before the registration deadline so that all registrants can submit their dossiers in time. For inquiries, there could be a peak similar to what happened in the months preceding the 2010 deadline, for the phase-in substances that were not pre-registered in 2008. This would have an impact on ECHA's ability to process them in the target timeframe and also on other substance identification activities, especially in compliance checks.

Correct substance identification underpins all REACH and CLP processes, as both regulations operate on the concept of substances. Successful joint registration, correct data-sharing and appropriate read-across (prediction of the properties and effects of the

substance from those of another substance within the same substance category) are only possible if all parties have a clear understanding of substance identification under REACH. Therefore, ECHA will continue its efforts to clarify the substance identification requirements and the substance sameness concept through discussions with interested parties, within or outside the regulatory processes, with a view to initiating an update of the guidance for identification and naming of substances well ahead of the last registration deadline. ECHA also intends, subject to availability of resources, to conduct a feasibility study on giving solid regulatory status to chemicals for which it has assigned list numbers (i.e. to substances for which there was no EC number available).

Dissemination – electronic public access to information

ECHA is required to make information on registered substances publicly available on its website. This activity is expected to have a positive impact on health and environmental protection both in Europe and worldwide, as everyone has the possibility to consult information on the chemicals they use. Further to the second wave of registrations in 2013, ECHA will have received and stored information from an estimated additional 8 000 registration dossiers for substances manufactured or imported in quantities of 100-1000 tonnes per year. ECHA will start publishing the information from these dossiers in September 2013, once they have received a registration number.

Activities for developing the website as a central point of access for all information contained in ECHA databases on a given substance will continue. ECHA will analyse the feedback from the stakeholders collected in a survey during 2012, with a view to prioritising the forthcoming improvements. Specifically, the needs of the general public, an audience that is not familiar with the technical format currently used for publication, will be taken into consideration. ECHA will also prepare for publishing information stemming from the Biocidal Products and PIC Regulations. Finally, the C&L inventory will be further improved as detailed in Activity 4.

Another activity related to dissemination is to assess whether requests for confidentiality introduced by the registrants in their dossiers are justified and valid. The process is done in two steps: i) a first assessment leading either to immediate acceptance of the claim or to a request for receiving additional information and ii) the final assessment in which the new argumentation provided for the claim is reviewed. The workload associated with confidentiality assessment is expected to be very high in 2013. First, ECHA will have to conclude on the cases opened in 2012 for which a request for information was issued (ca. 500 cases). In addition, ECHA will begin the first assessment for claims introduced in new registrations in 2012 (ca. 200 cases). Then, further to the implementation of the revised policy concerning the publication of information contained in the SDS (including the company name), there is uncertainty on how many existing registrations will be updated with new claims on this information (baseline planning: 500 cases). Finally, based on current practice, the new 2013 dossiers are expected to contain an estimated number of 770 confidentiality claims.

The volume of assessment work that will be carried out in 2013 will depend on whether temporary redeployment will be needed to handle the registration peaks. Therefore, priority will be given to concluding the 2012 cases and, as regards new claims, on those concerning IUPAC names, especially in dossiers that contain testing proposals involving vertebrate animals so that they are associated with a clear substance identity at the time of the public consultation. ECHA will also verify that the proposed public name reveals enough of the intrinsic properties of the substance even though it masks its full chemical identity.

2. Objectives and Indicators

Objectives

1. All dossiers, inquiries and data sharing disputes undergo the required checks and the respective decisions are given, and confidentiality claims assessed, according to the standard procedures, ensuring timely identification of problematic dossiers to stimulate their updates and have an impact on the data quality, and within the legal deadlines or internal targets set.
2. Decisions are well justified and of a high technical and scientific quality.
3. Stakeholders and the public have an easy access to information from all dossiers of registered substances and C&L notifications within a reasonable time after the registration/submission of notification.

Performance Indicators & Targets

Indicator	Target in 2013	Means and frequency of verification
Percentage of registrations, PPORD notifications processed within the legal timeframe.	100 %	Time recorded in REACH-IT. Monthly reporting.
Percentage of inquiries processed within the internal timeframe (20 working days).	80 %	Time recorded in REACH-IT. Monthly reporting.
Percentage of data sharing disputes processed 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.	90 %	Rate of publication recorded. Monthly monitoring.
Level of satisfaction of interested parties with dissemination, data sharing and dossier submission processes of ECHA.	High	Annual survey.

3. Main Outputs

- Approximately, 15 000 registration dossiers and 400 PPORD notifications (including updates and requests for extension) undergo the decision making process and assigned a registration or PPORD notification number, where relevant.
- Approximately, 1 200 new inquiries will be processed within the target timeframe and, when accepted, given an inquiry number. The inquirer has been put into contact with the previous registrant(s) where relevant.
- Up to 35 data sharing disputes resolved.
- Up to 65 decisions on PPORDs.
- 100 new confidentiality claims undergo initial assessment and 500 cases from 2012 undergo final assessment.
- Information from the registration dossiers published on the ECHA website and linked to the OECD eChemPortal.
- Practical information to registrants on how to submit registration dossiers to ECHA, accompanied by other support, available in a timely manner for both lead and member registrants.
- Procedures and systems put in place to receive and process biocides dossiers.
- CSA development programme outputs as established in the multi-annual CSA roadmap, including examples of exposure scenarios, other practical tools and events to support downstream users in complying with their obligations and organising two ENES events.

Activity 2: Evaluation

1. Main Challenges in 2013

Dossier Evaluation

Dossier evaluation comprises both compliance checks and the examination of testing proposals. The purpose of the compliance check is to examine whether registration dossiers are in compliance with the requirements of the REACH Regulation, and thereby instilling confidence in the general quality of the registrations. The examination of testing proposals aims to ensure that the generation of information on a given substance is tailored to real information needs and that unnecessary animal testing is avoided where possible. Dossier evaluation involves scientific decision-making using expert knowledge from a variety of scientific disciplines. It provides significant contributions to ECHA's strategic aims to "improve the quality of data submitted by industry" and the "intelligent use of data for better chemical management".

ECHA decisions will be under considerable scientific and legal scrutiny. This requires that the scientific judgements, resulting in legally sound decisions, are well founded and generally accepted by the Member States. This is also a major efficiency challenge for the ECHA Secretariat, especially in combination with the requirement for a high throughput of hundreds of dossier evaluations per year and a complex, multi-step decision making process involving all Member States.

Considering that by the end of 2013, ECHA aims to carry out compliance checks for at least 5 % of the dossiers that meet the 2010 registration criteria, a major part of resources allocated to the Evaluation Activity go to this process. Compliance checking has become more important given that ECHA has observed that there is a general need to improve the quality of the registration dossiers. As REACH places the burden of proof on industry to demonstrate safe use of their chemicals, it is clear that good quality data on the intrinsic properties and uses of substances are at the basis of appropriate classification and labelling and reliable chemicals safety assessment (CSA). In order to achieve (as a minimum) the 5 % threshold, 560 compliance checks should be concluded in 2013. Based on the current experience, it is estimated that more than 50 % of the checks (ca. 350) would lead to a draft decision. To reduce the number of final decisions, and thereby not to overburden the MSC, incentives to encourage proactive updating of dossiers will be necessary.

Based on its earlier observations in relation to the quality of registration dossiers, ECHA will continue to implement a concern-based selection strategy for the compliance checks in 2013. This strategy focuses the attention of the dossier evaluation to information requirements that are immediately relevant for the safe use of substances. In particular, these include the endpoints relevant for assessing persistence, bioaccumulation, repeated dose toxicity, carcinogenicity, mutagenicity, toxicity to reproduction and aquatic toxicity. IT-based screening will support the selection of dossiers from ECHA's registration database. This targeting process implies that compliance checking of dossiers will gradually assess selected information requirements rather than the full dossier content. As a result, this could mean that a single registration dossier may receive multiple draft decisions for different concern-based screening exercises.

In addition to the evaluation of dossiers driven by the concern-based strategy, a share of dossiers will still be selected on a random basis. These random-based compliance checks will serve to monitor the overall quality status of REACH registration dossiers and address the full dossier content where its quality allows a meaningful assessment.

Finally, flexible targeting of dossiers for compliance checks will help ECHA to ensure that

the available resources will be utilised most efficiently when it addresses those dossiers and substances of concern that are scheduled to be tackled through other relevant REACH processes (substance evaluation, authorisation, restriction or classification and labelling). It will allow ECHA to initiate regulatory action as early as possible on priority substances and their uses causing (potential) risks. More specifically, the focus will be predominantly on cases that have not yet been adequately regulated before. As such, ECHA's Evaluation strategy will allow intelligent use of data for effective regulatory chemicals management by selecting and addressing dossiers for compliance checking in a way that ensures efficient interface with and serves the needs of the risk management processes.

With regard to the other dossier evaluation process, i.e. the testing proposal evaluation, ECHA is obliged to examine all testing proposals submitted by registrants or downstream users and to prepare a draft decision within the deadlines provided for in the REACH Regulation. In the first half of 2013, a significant number of draft decisions on the 2010 testing proposals sent to the registrants for their comments before 30 November 2012 will still need to be put through the decision making process. ECHA will receive new testing proposals for those dossiers that will be due for the 31 May 2013 registration deadline. While the deadline for those draft decisions is 1 June 2016, ECHA will start to process the requests during the last quarter of 2013. In addition, for testing proposals for all registered non-phase-in substances, draft decisions must be prepared within 180 days. ECHA expects up to 30 testing proposals for non-phase-in substances in 2013.

The general results of both dossier evaluation processes (compliance checks and testing proposals) from 2012 will be contained in the annual progress report delivered by ECHA at the end of February 2013. This report will include recommendations to potential registrants in order to improve the quality of future registrations, including feedback to optimise the application of alternative animal testing methods and assessment approaches. ECHA will use several communication tools and channels, such as stakeholder events, workshops and fact sheets to ensure that industry has a proper understanding of, and feedback from, the dossier evaluation process. In the context of dossier evaluations, ECHA will also communicate its findings and recommendations for improvements of the quality of CSRs and exposure scenarios to industry at large, as appropriate. Continued further communication with other interested parties will also be needed, especially in relation to the ongoing testing proposal evaluations and potential decisions requesting *in vivo* animal testing. Dedicated strategies will be developed for both of types of interested parties.

During the second half of 2013, ECHA will start an extensive analysis and assessment of the expanded registration database in function of the second triannual Article 117(3) report on the implementation and use of animal testing alternatives under REACH. The next Article 117(3) report will be published in June 2014.

Further efficiency improvements of the dossier evaluation internal workflow will be pursued, and among others scaling and standardising of the scientific and legal multidisciplinary activities will be explored to deliver on such improvements. The necessary scientific and administrative capacity building of ECHA staff will be further continued. A focus area for this essential capacity building will be on alternative methods and strategies such as read-across and grouping which have been extensively used to fulfill the higher-tier information requirements. ECHA's past experience in evaluation has shown that assessing such alternative strategies involves more complex and scientifically challenging activities compared to the evaluation of test results from standardised test methodologies.

ECHA will need to monitor, develop positions on, and where appropriate manage, scientific and legal issues supplementary to the scientific and legal issues arising from the ongoing evaluation decision making (such as reproductive toxicity testing,

nanomaterials, endocrine disruption, etc.).

Follow-up to Dossier Evaluation

The formal outcome of dossier evaluation is a request for registrants to provide further information in an updated dossier and/or an updated CSR by a specific deadline. These deadlines range from two months to four years, depending on the information requested. After the deadline has passed, ECHA examines whether the dossier has been updated and whether the update corresponds to the information requested in the decision. The conclusion of this follow-up process may be that the registrant failed to meet the obligation to provide the requested information. This will have the consequence that ECHA will ask the relevant Member States to consider enforcement actions. In case of continued non-compliance with a decision, ECHA considers under which conditions withdrawal of the registration number will be appropriate to ensure the correct implementation of REACH. When the information requested by the decision has been submitted by the registrant, ECHA will inform the Member States and the Commission of the results. On this basis, further compliance checks may need to be performed or other appropriate REACH processes may be triggered (e.g. substance evaluation, authorisation).

During 2013, ECHA will need to reserve a significant amount of staff resources for the timely and adequate follow up of the incoming updates of registration dossiers as a result of a former (compliance check or testing proposal) final decision. However, when setting the annual target for follow-up, the backlog stemming from 2011 and 2012 dossier evaluation cases and other priorities have had to be taken into account. The workload involved will need to be managed in an efficient manner and may involve potential further actions with, for example, the relevant enforcement authorities.

Substance Evaluation

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

The information collected and received as a result of substance evaluation and the conclusions drawn are made available and are meant to feed into actions under other REACH and CLP processes or under other legislative frameworks. By ensuring the generation of all necessary information for the safe use of chemicals, also beyond the REACH standard information requirements, substance evaluation is complementary to dossier evaluation and bridges two of ECHA's strategic aims: "improve the quality of data submitted by industry" and "intelligent use of data for better chemicals management".

Community Rolling Action Plan

ECHA has a principal role in establishing and annually updating the Community Rolling Action Plan (CoRAP) for the substances to be evaluated. The first CoRAP was published on 29 February 2012 and covered the years 2012-2014. The first CoRAP update will be adopted by 31 March 2013 and will include the revision of substances for the years 2013 and 2014, as well as the addition of substances for the year 2015. The second CoRAP update is foreseen by 31 March 2014 and will cover the years 2014-2016.

The annual CoRAP update should ensure that the substance evaluation process adds value to other evaluation processes and efficiently feeds into risk management processes. For this purpose, the selection of candidate CoRAP substances will address the need for:

- the clarification of relevant risks for human health or the environment in order to decide on regulatory follow up actions;
- an assessment at EU and substance level, and in most of the cases the requirement of further information that cannot be requested under dossier evaluation.

It is expected that the preparation of the second CoRAP update can continue to be based on selection criteria established by ECHA in collaboration with MSCAs in 2011. The foreseen evaluation turnover would require the identification of at least 40 new CoRAP substances per year. Candidate substances will be identified either by ECHA or the MSCAs on the basis of information obtained under dossier evaluation or other ECHA processes.

ECHA will also coordinate the allocation of substances to MSCAs. The aim is to achieve an increasing and evenly distributed input of MSCAs in substance evaluation and to ensure an average number of ca. 40-50 substances evaluated per year.

Substance evaluation process

ECHA will act as a coordinator in the overall substance evaluation process. After the publication of the CoRAP update, MSCAs have 12 months to evaluate their substances and prepare draft decisions requesting further information to clarify the detected concern, where appropriate.

Based on the capacity indicated by MSCAs in 2012, it is estimated that 45 substances will be evaluated in 2013. At the same time, as a result of the evaluation of substances in 2012, ECHA will need to coordinate the decision making process of the first substance evaluation draft decisions and the conclusion of those evaluations that will not require a request for further information. Therefore, in 2013 ECHA will need to manage an increasing number of evaluations and final decisions generated under substance evaluation.

ECHA will continue providing support to the substance evaluation performed by MSCAs. At the end of 2012, ECHA will agree a programme of supporting activities with the MSCAs, such as workshops, training sessions, practical guides and consistency screening, to be accomplished in 2013. Based on prior experience with the substance evaluation process, ECHA will continue to revise procedures, templates and practical guides (e.g. Q&A documents) and identify the best practices and need for harmonised policies. For this purpose, the organisation of at least one workshop and specific working groups, and the optimisation of communication means between MSCAs and ECHA will be a priority in 2013.

Furthermore, ECHA will also provide advice to ensure harmonisation, consistency and legal soundness of decisions, evaluation reports and conclusions prepared by MSCAs. More in particular, ECHA will offer the possibility of a consistency screening of draft decisions before they are sent to registrants. It is estimated that for the approximated 45 substance evaluations this will result in up to 30 draft decisions, which may be screened by ECHA staff for legal and scientific consistency. Furthermore, ECHA will coordinate and provide administrative support to the decision making process.

As the interlink between the evaluating MSCAs and multiple registrants, ECHA's administrative role in substance evaluation is quite challenging. The first experiences with this role will allow a start of the business analysis for the integration of the substance evaluation process within ECHA's enterprise content management system.

ECHA will further need to handle the transfer of funds to MSCAs. This will involve establishing individual service contracts between ECHA and individual MSCAs (within the existing cooperation agreement) and processing of the invoices sent to ECHA.

Communicating the achievements of substance evaluation to registrants and the general public is also a task under ECHA's responsibility. It will include, *inter alia*, the publication of the draft and the adopted CoRAP updates, the refined criteria for selecting CoRAP substances, and the relevant outcome documents.

2. Objectives and Indicators

Objectives

1. Scientifically and legally sound draft and final decisions on dossier evaluation are prepared, in compliance with the legal requirements and in line with the multi-annual planning steered by ECHA's strategic approach.
2. The compliance with dossier evaluation decisions is followed up without undue delay after the deadline given in the decision has passed and Member State authorities are informed about the outcome and cases requiring their action.
3. All substance evaluations are planned in the CoRAP, prepared and processed with a high degree of scientific, technical and legal quality according to agreed standard approaches and procedures and within the legal deadlines.

Performance Indicators & Targets

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

3. Main Outputs

- 560 compliance checks concluded, leading to ca. 350 draft decisions.
- 30 non-phase-in testing proposal examinations concluded (draft decision stage).
- Approximately, 120 follow-up evaluations performed.
- The first annual update of the CoRAP by 31 March 2013. The second draft CoRAP update submitted to the Member State Committee by 31 October 2013. At least 40 candidate CoRAP substances identified.
- Supporting activities for MSCAs performing substance evaluation according to 2013 programme.
- All the service contracts with MSCAs in place by the publication of the first CoRAP update.
- 36 final decisions requesting further information or conclusions under substance evaluation.
- Annual evaluation report (Article 54) and related communications.

Activity 3: Risk Management

1. Main Challenges in 2013

Screening for Risk Management

While the primary responsibility for the safe use of chemicals lies with manufacturers, importers and downstream users of the substances, the authorities have a possibility and obligation to intervene where the registration and downstream user duties do not guarantee a high level of protection of human health and the environment. Information generated via different REACH processes, together with other available data, is to be used to identify potential needs for regulatory risk management.

The registrations submitted by the 31 May 2013 deadline will be available for the screening of substances for further risk management towards the end of the year. Furthermore, it is expected that a growing number of updates of previous registrations, as well as downstream user reports and substances in articles notifications will be submitted. Dossier evaluations will also generate an increasing amount of new data and the first results of substance evaluations can be expected. The main challenge of 2013 is to develop efficient ways to use these different data sources and new/updated information to complement and reassess the previous screening conclusions and to identify substances which may require further risk management. Special attention will be given to the identification of potential concerns due to the exposure of substances during the service life of articles.

MSCAs and the Commission with the support of ECHA will continue to identify substances for further information generation and further regulatory risk management. To be efficient, this work needs to be based on an enhanced common understanding on the optimal use of different REACH processes. ECHA will continue to support this by providing overviews and analyses on the different options and approaches. Furthermore, further development and continued maintenance of tools to support and coordinate the identification and initiation of the most appropriate regulatory action is foreseen.

Authorisation

Identification of SVHCs and Annex XIV recommendations

The focus of Substance of Very High Concern (SVHC) identification continues to shift from known CMRs and known PBT/vPvB substances to substances of equivalent level of concern. This is to ensure that sufficient attention is paid to substances which have not been addressed by the same level of regulatory requirements as substances with a harmonised classification as CMR category 1A or 1/B. To support this shift of focus, ECHA continues to provide a platform to discuss new PBT/vPvB identification in the PBT working group and to develop common approaches for identifying substances of equivalent level of concern (e.g. endocrine disruptors, respiratory sensitisers).

ECHA will continue to fulfil its commitment to support the Commission in identifying the most appropriate candidates and to prepare Annex XV dossiers for identification of SVHCs on their request.

Working closely together with the MSC, the experience obtained so far will be used to scrutinise the approach used for prioritisation of substances from the Candidate List to Annex XIV and where necessary adapted to meet the challenges of the growing Candidate List.

Authorisation applications

One of the main challenges for ECHA has been to identify how many and what kind of applications for authorisation will be submitted by industry. Indications thus far seem to indicate that industry is not preparing as many applications as originally predicted. Therefore, ECHA is expecting to receive up to 20 new applications for authorisation in 2013. While ECHA has prepared itself and its Committees to receive these applications and has developed substantial support and guidance for future applicants, it is clear that – as was the case for the first registration of substances – the applicants, ECHA, as well as the other interested parties will be “learning by doing”.

On the basis of the applicants’ notifications of intention to submit an application for authorisation, ECHA will provide applicants with the opportunity to request an information session in order to receive clarifications on any remaining technical issues relating to the preparation and submission of their applications. Overall, ECHA including its Committees, will build on the preparatory work carried out in 2012 to successfully manage the challenge of handling the first applications and developing high quality opinions on applications that can effectively support the Commission’s decision-making on granting or refusing an authorisation. A particular challenge will be to get ready to cope with an increasing, but not well known, number of applications in the years to come and to gradually build up the related IT (workflow) system.

Restrictions

REACH foresees a restriction process to regulate the manufacture, placing on the market or use of certain substances if they pose an unacceptable risk to human health or the environment. A restriction is designed as a “safety net” to manage risks that are not already adequately controlled by industry or addressed by the other REACH processes.

Each restriction dossier is rather unique in terms of 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 ensure that these are processed with a high degree of scientific, technical and legal quality.

If requested, ECHA will provide technical support for the Commission in the adoption of decisions on the restriction dossiers, for which opinions of the RAC and SEAC were forwarded to the Commission in 2012-13.

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 or review existing restrictions in 2013. Based on the work on screening CMR substances in consumer articles in 2012, it may be possible that an Annex XV dossier will be included as a new request. 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.

ECHA will also support RAC and SEAC rapporteurs in preparing opinions on restriction dossiers. The number of opinions worked upon in 2013 will depend on the number of Annex XV restriction dossiers received in 2012 and early 2013⁴. The ECHA Secretariat

⁴ At the time of writing, Sweden has informed about its intention to submit an Annex XV restriction report on Lead and lead compounds in articles intended for consumer use (in April 2013) and the Netherlands on 1-methyl-2-pyrrolidone (NMP) (in April 2013) and the Commission has indicated that it would be requesting ECHA to prepare Annex XV restriction reports on some substances.

will continue to provide high quality and timely support to RAC, SEAC and the Forum as they develop these opinions. It will also provide assistance to Member States when preparing Annex XV restriction reports, e.g. through workshops and specific feedback, if requested. ECHA will also maintain the questions and answers of the existing restrictions section on its website and be the focal point for answering any restriction related questions, as agreed with the Commission in 2012.

Other activities related to risk management

ECHA will continue to increase the knowledge on the practical application of Socio-economic analysis (SEA). The willingness-to-pay estimates to avoid negative health effects of some 10 to 15 health outcomes will become available in 2013. These will be used and shared with relevant interested parties. ECHA will focus on having improved methodology to estimate administrative costs (e.g. enforcement costs) related to regulatory risk management while further work on abatement costs will be carried out. ECHA will continue to hold SEA related workshops with interested parties on applications for authorisation and with MSCAs on restrictions.

Subject to the availability of staff resources, ECHA may also develop methodologies to better derive the human health and environmental impacts from the outcome of risk assessments.

Furthermore, ECHA will continue to develop practical tools and advice and raise the awareness of the importers and producers of articles on requirements related to SVHCs.

On the basis of experiences so far, the substances in articles notifications alone will not be a sufficient source of information to decide on the need for further action on substances in (imported) articles. ECHA will look for complementary information sources and efficient ways of compiling the information to support the decisions on whether to initiate the restriction process in advance of the first sunset dates (August 2014).

2. Objectives and Indicators

Objectives

1. All dossiers related to the authorisation and restriction processes are prepared and processed with a high degree of scientific, technical and legal quality according to the standard approaches and procedures adopted by ECHA and within the legal deadlines or targets set.
2. Industry, Member States and the Commission are provided with the best possible scientific and technical support and advice to identify substances that require further risk management and to define the best risk management approach, including further development of the use of exposure scenarios.

Performance Indicators & Targets

Indicator	Target in 2013	Means and frequency of verification
Percentage of registered substances preliminary screened for further regulatory risk management.	25 %	Annual internal report.
Percentage of SVHC dossiers treated within the legal timeframe.	100 %	Monthly internal report.
Percentage of restriction dossiers treated within the legal timeframe.	100 %	Monthly internal report.
Percentage of applications for authorisation treated within the legal timeframe.	100 %	Monthly internal report
Level of satisfaction of the Commission, MSCAs, ECHA Committees and other interested parties with the quality of the scientific, technical and administrative support provided.	High	Annual survey

3. Main Outputs

- On the basis of the screening of available information and in cooperation with MSCAs, substances identified for further risk management.
- Up to three meetings of PBT Expert Group.
- Up to three meetings of the Risk Management Expert Group in cooperation with volunteering MSCAs.
- At least five Annex XV SVHC dossiers prepared at the request of the Commission.
- One to two updates of the Candidate List published.
- Development of a new recommendation for inclusion of SVHCs in the Authorisation List (Annex XIV), potentially to be submitted to the Commission in early 2014.
- Scientific, administrative and legal support to both submitters of proposals for restrictions and to the RAC and SEAC and its rapporteurs for their development of opinions on restrictions and applications for authorisation.
- Up to three Annex XV restriction dossiers prepared (including, where relevant, dossiers or reports related to reviews of existing restrictions) and, where possible, submitted to the Committees for the formulation of the opinion.
- 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 organised on applications for authorisation, including SEA, with industry and other interested parties.
- At least one SEA related workshop organised to build capacity to estimate administrative and compliance costs.

Activity 4: Classification and Labelling (C&L)

1. Main Challenges in 2013

Handling proposals for harmonised Classification and Labelling (CLH)

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. In certain cases, Member States or industry can propose harmonisation of the classification of a substance in the EU. This is normally done for carcinogenic, mutagenic and reprotoxic substances, as well as for respiratory sensitisers, but other hazard classes may be harmonised if there is a need. A peak number of proposals for harmonised classification of plant protection products and biocides was submitted to the Agency in late 2010 and early 2011, and these proposals will be processed by the RAC during 2012 and 2013. The increased number of CLH dossiers has prompted the RAC to request an increase in the support from the ECHA Secretariat. The high number of dossiers in the process (119) in combination with the request for increased support per dossier, presents a real challenge to the Secretariat. The RAC opinions do not only have to be of high scientific quality, but the Secretariat should also ensure that the opinion and the background documentation reflect the proper conduct of the process. This, together with continuous efforts in streamlining working practices and procedures (for instance via expert meetings, awareness raising activities, criteria for dealing with new information received throughout the process etc.), will play an important role to meet the high level of demand.

The active substances in plant protection products are assessed by EFSA and ECHA in parallel. EFSA assesses the risk of these active substances, while ultimately ECHA is responsible for assessing the hazards that trigger their classification. However, as laid down in Regulation 1107/2009 on the placing on the market of plant protection products (PPPs) the consequence of a classification in category 1 (A or B) for carcinogenic, mutagenic and toxic for reproduction (CMR) is that the substance will in general not be approved for use as an active substance in PPPs. The parallel processing of active substances in PPPs conducted by ECHA and EFSA provides specific challenges in order to avoid the risk of diverging opinions. Different timelines for the two processes also pose a challenge. It is expected that in 2013 the first active substances will have undergone this parallel process.

Furthermore, active substances for use in biocidal products will in general not be approved in the case of CMR category 1A or 1B classification. The classification of biocides may also have consequences for the possibility of obtaining product authorisations for use by the general public. Similar challenges as mentioned above for parallel processing for PPPs are, therefore, also faced for biocides.

Classification & Labelling Inventory (C&L Inventory)

The C&L Inventory is a unique database that provides an overview of the classification and labelling of almost all substances on the EU market. Such detailed knowledge is not available anywhere else in the world. It enables authorities to identify and address chemicals of concern. Substances not placed on the market or placed on the market in very small quantities, e.g. by laboratory supply companies, can be deprioritised for e.g. the CLH process. On the other hand, new CMR substances can be identified and prioritised.

The first version of the C&L inventory was published in February 2012. The maintenance and updating of the inventory will remain an important task during 2013. It is foreseen

that development of new functionalities has to be performed to increase usability of the inventory, whilst ensuring that confidential information is not disclosed. Companies having notified different classification and labelling of the same substance to the inventory have a legal obligation to undertake all efforts to come to agreed entries. Publication of the identity of notifying companies is not foreseen in the public version of the inventory.. In order for industry to be able to fulfil this obligation, ECHA will develop and establish an IT-platform which should enable notifiers of the same substance to communicate without revealing their identity. It is envisaged to launch the platform (first version) in early 2013, but further development is likely to be necessary during the course of the year. The maintenance and development of the platform is being investigated, but it may potentially be labour intensive.

Evaluating requests for the use of 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. Under the previous Directive on the classification and labelling of mixtures (then called preparations), evaluation of the requests for the use of alternative chemical names was done by the Member States, but under the CLP Regulation ECHA will decide on this. Until 2015, industry may request an alternative chemical name from either the Member States or ECHA. 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 legal timeframe, in order to cope with peaks in the amount of requests. So far, only a few requests have been received but in 2013 the number is expected to rise.

2. Objectives and Indicators

Objectives

1. All dossiers related to the harmonised C&L process are processed with a high degree of scientific, technical and legal quality according to the standard approaches and procedures adopted by ECHA and within the legal deadlines or targets set.
2. Any request for the use of an alternative chemical name is processed within the legal timeframe.
3. The Classification and Labelling Inventory and C&L communication platform are kept up-to-date and their functionalities and user-friendliness are further improved.

Performance Indicators & Targets

Indicator	Target in 2013	Means and frequency of verification
Percentage of proposals for Harmonised C&L processed within legal timeframe.	100 %	Internal quarterly report.
Percentage of requests for use of alternative chemical name processed within legal timeframe.	100 %	Internal quarterly report.
Level of satisfaction of the Commission, MSCAs and RAC 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, and to the RAC and its rapporteurs for their development of opinions and background documents.
- Updated and improved C&L Inventory.
- Updated and improved communication platform for notifiers and registrants of a same substance.
- Up to 150 legally sound decisions on the use of alternative chemical names.

Activity 5: Advice and assistance through Guidance and Helpdesk

1. Main Challenges in 2013

ECHA Helpdesk and HelpNet

The ECHA Helpdesk gives advice to companies in order to prepare high quality dossiers; it clarifies obligations under the REACH and CLP Regulations and provides support to users of the ECHA IT tools (such as IUCLID, Chesar and REACH-IT) which includes assistance with the submission of dossiers. The network of national REACH and CLP helpdesks (HelpNet) aims to foster a common understanding of the REACH and CLP obligations among national helpdesks and thereby harmonise their responses to questions from industry. ECHA manages the HelpNet and chairs the Steering Group.

The common objective of the ECHA Helpdesk and the national helpdesks is to support registrants to successfully register and submit their registration dossier. The ECHA Helpdesk will face a peak in the workload ahead of the 31 May 2013 registration deadline and will, in cooperation with the national helpdesks, provide a special service to registrants in the immediate run-up to the deadline. Along with the members of the HelpNet, the ECHA Helpdesk will inform companies about how to proceed during each step of the registration process. This will be achieved by two-way contacts with companies, which will allow registrants to interact personally with ECHA, including question and answer sessions during webinars, one-to-one sessions at workshops and at ECHA's annual Stakeholders' Day and, where necessary, proactive telephone contacts regarding dossier submissions.

Through the HelpNet, national helpdesks will further develop the necessary knowledge in order to act as the first point of contact for companies. ECHA will continue to provide the members of HelpNet with the Helpdesk Exchange Platform (HelpEx) to discuss difficult questions, facilitate agreement on REACH and CLP FAQs to be published on the ECHA website, provide training on the ECHA IT tools and update them on the latest developments during the HelpNet Steering Group meetings and the webinars.

Furthermore, the first deadline for submission of applications for authorisation in February 2013 will also trigger questions for the ECHA Helpdesk. As the process is new to ECHA as well as to the stakeholders, the ECHA Helpdesk will be called upon to contribute to developing a clear understanding of the roles and responsibilities.

The year 2013 is also a transitional year for preparing for the entry into operation of the new Biocidal Products Regulation in September 2013. The ECHA Helpdesk will give advice to companies implementing this regulation and support the users of the B4BR system (or its ECHA-managed successor). In 2013, ECHA will need to integrate the national biocides helpdesks and other national authorities providing advice to companies on the Biocidal Products Regulation into the HelpNet.

Guidance

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

ECHA recognises that in the run-up to the 2013 REACH registration deadline (as in the case of the 2010 deadline) it is desirable to have stable guidance available which gives potential registrants confidence that the advice given will not change in the final run-up to the deadline, i.e. while they are preparing and finalising their new registration

dossiers. ECHA has therefore already published certain key guidance documents (notably e.g. a fully updated Guidance on Registration) a full twelve months ahead of the registration deadline and will adhere to a moratorium on publication of other new or updated REACH guidance documents starting six months before the deadline (i.e. by the end of November 2012). Consequently, whatever work (e.g. draft updates) on REACH-related guidance will continue during the moratorium period, respective updated final guidance documents will not be published before 1 June.

Since it may be assumed that registrants in 2013 will include a higher proportion of smaller companies with less experience in REACH, this group will be targeted to benefit from certain explanatory documents complementing guidance as well as “quasi-guidance” such as Guidance in a Nutshell and Practical Guides. ECHA will continue to support SMEs by providing its guidance releases in 23 EU languages.

From 1 June 2015 onwards, the obligations regarding mixture classification under the CLP Regulation will become mandatory. During 2013, ECHA will explore the needs for helping companies to comply with these provisions in order to provide companies with the necessary tools and guidance well ahead of this deadline. Of particular interest in this regard are formulators because of their position in the supply chain and the fact that their size and level of knowledge may vary significantly.

Existing guidance on the REACH and CLP Regulations will be updated to keep it aligned with new developments on nanomaterials and the possible adaptations to technical progress.

By the end of 2013 and supported by the Commission, ECHA aims to have finalised the first set of guidance documents for biocides in support of the entry into operation of the Biocidal Products Regulation on 1 September 2013. As the entry into operation of the Rotterdam Convention on Prior Informed Consent (PIC) is scheduled for 1 March 2014 when ECHA will take over the operational responsibility, ECHA aims to deliver supportive guidance by the end of 2013.

In addition, ECHA will continue to improve the accessibility of guidance for all interested parties by producing and maintaining supportive documentation and web pages (Question and Answer pairs, REACH Fact Sheets, web pages for specific REACH and CLP processes, the REACH Navigator tool, and the REACH terminology database (ECHA-term) in 23 EU languages (i.e. including Croatian with a view to the forthcoming accession of Croatia).

2. Objectives and Indicators

Objectives

1. Industry and the Member States receive timely and efficient support from the ECHA Helpdesk, and through high quality guidance documents, to fulfil its obligations under REACH and CLP.
2. Support is provided for the implementation of REACH and CLP in EU/EEA Member States via the training of trainers.

Performance Indicators & Targets

Indicator	Target in 2013	Means and frequency of verification
Percentage of ECHA Helpdesk questions answered within the established timeframe (15 working days).	80 %	Business Object report / monthly.
Level of satisfaction of users with quality of ECHA Helpdesk services.	High	Annual survey.
Percentage of feedback replies provided by ECHA to questions submitted to HelpEx by national helpdesks, within the timeframe set by the originator of the question.	80 %	Business Object report / monthly.
Level of satisfaction expressed in feedback from guidance users.	High	Annual survey.

3. Main OutputsECHA Helpdesk

- About 8 500 questions dealt with by the ECHA Helpdesk, including questions raised during webinars and one-to-one sessions at ECHA's Stakeholders' Day and Lead Registrant Workshops.
- HelpNet: two meetings of the HelpNet Steering Group, two updates of REACH and CLP FAQs and the first Biocides FAQ and training events for national REACH and CLP helpdesks (by various means, such as hands-on training, webinars, workshops).

Guidance

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

- Finalisation Guidance on the application of the CLP criteria (second ATP including sensitisation hazards);
- Guidance for Downstream Users;
- Update of the Navigator;
- Nutshell Guidance(s);
- Guidance on the Biocidal Product Regulation:
 - Guidance on data requirements (new);
 - Guidance on technical equivalence (new);
 - Regulatory guidance on the Biocidal Products applications (new).

Guidance projects to be initiated and which are to produce draft consultation documents during

2013 (all updates, unless indicated as "new"):

- Guidance on the preparation of CLH dossiers (specifications for industry dossier submitters);
- Guidance on the application of the CLP criteria (third & fourth ATPs);
- Guidance on PIC (new);
- Guidance on PPORD;
- Chapter R.11 (PBT assessment) of the Guidance on information requirements and chemical safety assessment (IR&CSA);
- Part C (PBT assessment) of the Guidance on IR&CSA;
- Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern.

Activity 6: Scientific IT tools

1. Main Challenges in 2013

The year 2013 will be extraordinary for the development of IT tools in ECHA. Besides supporting the second registration deadline, IT systems for receiving submissions under the Biocidal Products Regulation need to be available by 1 September 2013 and the preparations for taking over the tasks foreseen under the recast of the PIC Regulation in early 2014 will be in an active phase.

Supporting the 2013 REACH deadline

In 2013, ECHA has to face the second REACH registration deadline and a foreseeable peak in the post-registration tasks (dissemination and evaluation).

The IT tools necessary for registration and related dossier processing need to be fully functional. The applications will be maintained and supported, but only minor maintenance releases may be made available prior to the deadline. In particular, it is expected that far more registrants will use the intensively revised Chesar 2 for the second registration deadline, to prepare their chemical safety assessments and reports.

Pursuing the Data Integration Project towards integrated data and a single point of access for MSCAs

Further to the Enterprise Architecture study carried out in 2010, which disclosed risks associated to the fragmentation of data among several systems, in 2011 ECHA launched a data integration project with the view to better integrating the business applications. In 2013, ECHA will start the progressive release of a platform (data hub) for integrating the core data sources. A portal implementing enhanced functionality for MSCAs, to improve the usability of their access to ECHA's IT tools and data, as well as a new security and access management solution, will also be delivered.

In the context of the data integration project, a major technical revision of IUCLID will take place in 2013. IUCLID 6 will enhance the functional and non-functional properties of IUCLID 5 (e.g. to better meet the needs of different size organisations, interface with other applications, increase possibilities to configure security and scalability). IUCLID 6 will be progressively implemented in 2013 and is foreseen to go live in 2014, to avoid affecting the preparation of industry for the REACH deadline and ECHA's preparation for the entry into operation of the Biocidal Products Regulation.

Analogously, in the same project, REACH-IT will undergo a technical revision to comply with a new and easier to maintain architecture and to be prepared for enhanced multilingualism.

The IUCLID and Chesar tools will be reviewed in cooperation with relevant interested parties in the light of further developing chemical safety reports (CSR). With a more structured CSR, supported by a more comprehensive completeness check, ECHA enhances its ability to process, report and disseminate safety data in 2014.

Implementing the Dissemination roadmap

In 2013, ECHA will continue revisiting the approach to the publication of information on chemicals (dissemination) based on the stakeholder feedback (see Activity 1). Whilst the Dissemination portal will be maintained to ensure the publication of the new registration dossiers submitted by the 2013 deadline, a technical study will be conducted to plan for the implementation of the recommendations that emerged from the 2012 stakeholder requirements analysis. Attention will be also given to leveraging on the aforementioned data hub. This will run in parallel with preparatory activities related to the publication of new biocide dossiers that should kick off in 2014.

Extending the IT support to ECHA's workflows

To ensure higher levels of efficiency and the indispensable traceability of ECHA's regulatory action, ECHA will pursue the implementation of IT support for workflow management and document management in the context of the Enterprise Content Management (ECM) programme. In 2013, the workflows released in the previous years for the Evaluation processes and the SVHC process will be further enhanced to adapt to the new strategy set for the evaluation of dossiers towards targeted compliance checks. The increased capacity to tackle a faster implementation of the ECM programme will be provided by a new sourcing strategy in the form of a framework contract for the provision of ECM services established during 2012. Besides supporting the workflow for the evaluation processes and adapting to the new targeted compliance check approach, collaboration capabilities will be progressively developed to support the work of the Committees, with the aim of progressively replacing the current platform (CIRCA-BC).

Implementing IT systems for Biocides and PIC

In 2013, ECHA will continue preparing IT systems to support the new Biocidal Products Regulation and the recast of the PIC Regulation. ECHA will approach the new developments by extending the current databases and functionalities in as integrated a way as possible, to benefit from common mechanisms and building blocks.

To support the operational tasks under the Biocides Activity, ECHA will have to establish and maintain a Register for Biocidal Products (R4BP). This register will be an information system for industry to generate and submit their applications, and for applicants, ECHA, Member States, and the Commission to have access to the applications and to exchange information related to them and to authorisations. Non-confidential information in the register will be made publicly available by the Agency.

The more distributed nature of the biocides regulatory processes will require an enhancement of ECHA's information systems to adapt to more distributed processes spanning beyond its organisational borders to involve "partner" authorities.

To utilise technical and functional synergies in managing the three regulations, ECHA will develop a revised application architecture. During 2013, the new architecture will be used to develop the Register for Biocidal Products and EDEXIM systems. REACH-IT will be modified to use the same architectural components once the Biocides and PIC start-up has been secured.

2. Objectives and Indicators

Objectives

1. IT systems (particularly IUCLID, CHESAR, REACH-IT, Dissemination) adequately support industry and ECHA in processing dossiers for the 2013 REACH deadline and in disseminating the public information.
2. IT systems are adequate to support the first tasks foreseen for ECHA by the entry into operation of the Biocidal Products Regulation.

Performance Indicators & Targets

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

3. Main Outputs

- Maintenance and bug-fixing releases for all Business Information Systems already in production.
- The Data Integration project delivers on a data integration platform and a portal focused on the MSCAs usability and access needs.
- The technical revision of IUCLID and REACH-IT have reached the stage of prototype.
- Releases of the Data Integration Platform and of the Portal Dashboard focused on MSCAs needs.
- Prototypes of the first core components of the new generation IT Tools: IUCLID 6, REACH-IT 3.
- Maintenance of SVHC and ECM-DEP and its adaptation to the targeted compliance check.
- First deployment of the ECM Collaboration module.
- The IT functionalities necessary to support the tasks of ECHA at the entry into operation of the Biocidal Products Regulation are in place and operational.
- RIPE portal maintained and further enhanced.

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

1. Main Challenges in 2013

One of ECHA's strategic aims is to become a hub for the scientific and regulatory knowledge building of Member States, European institutions and other actors, and to use this new knowledge for improved implementation of the chemicals legislation. This will require increasing knowledge on chemicals so as to be able to respond better to questions raised by the policy institutions of the EU, benefiting from the vast information at its disposal after the first and second registration deadlines.

ECHA will continue a focused contribution to the OECD test guideline programme and its support to the development of alternative test methods both at the EU and international levels in order to improve the availability of such methods for the 2013 deadline and beyond, as more data gaps can be expected than for the high production volume chemicals subject to the first registration deadline.

ECHA wants to promote the use of data available for substances from the 2010 and 2013 deadlines to avoid unnecessary (animal) testing for the later registrations by applying alternative methods. Besides the further promotion of the development and use of QSAR, a specific focus will be put on promoting read-across and category approaches. The OECD QSAR Toolbox will be further developed to support registrants' efforts in these fields (see Activity 11). Moreover, ECHA will have a core team in place with expert knowledge on non-test method approaches, and supporting specialist software dedicated to providing support to ECHA processes such as evaluation and risk management. The software will exploit information available from the first registration deadlines to facilitate future assessments of chemical properties.

ECHA will advance its understanding of the assessment of hazard, exposure and risks as well as risk management and mitigation related to nanomaterials by carefully following all the developments and outcomes of EU and international programmes, so that it can efficiently address dossiers on substances with nanoforms under dossier evaluation, ensure a coherent approach to specific aspects of nanomaterials as part of REACH and CLP implementation, and support any review of REACH with regard to nanomaterials.

ECHA will gradually increase its efforts to efficiently manage endocrine disrupting substances under REACH, CLP, and the Biocidal Products Regulation. To that effect, ECHA will invest both in internal capacity building and in contributing more actively to the scientific developments of endocrine disruptors, including the development of criteria for identifying or prioritising them under the relevant regulatory processes. Furthermore, ECHA will intensify its work on the area of combination effects of chemicals, including the follow-up to the Commission communication on this topic and ensuring appropriate capacity building.

ECHA will continue to contribute to the follow-up of the first review of the Agency, which the Commission completed in summer 2012. In addition, and if so requested by the Commission, ECHA will prepare a contribution to support the review activities being carried out by the Commission in relation to REACH, in accordance with Article 138 of the regulation.

ECHA's active cooperation with the European Parliament and the Commission will continue in 2012 by, *inter alia*, regularly informing the institutions of its activities and through meetings in Helsinki and at the seat of the Institutions. Cooperation with other European agencies and scientific committees will continue through exchanges and visits,

and where necessary, memoranda of understanding (MoUs) may be established to provide a more formal framework for ECHA's cooperation and coordination with them. MoUs have already been established with EFSA and EU-OSHA.

2. Objectives and Indicators

Objectives

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

Performance Indicators & Targets

Indicator	Target in 2013	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

- Continue the capacity building programme in the fields of nanomaterials, endocrine disruptors, and combination effects to facilitate the regulatory debate and effective implementation of REACH, CLP, and BPR.
- Contribution to ongoing Commission initiatives in relation to nanomaterials, and coordination of the activities of the nanomaterials working group that is foreseen to start its activities in 2012.
- Participation and contribution to ongoing international scientific events, events and workshops will lead to an improved understanding of hazard, exposure and risk of nanomaterials.
- Software on non-test methods procured and made accessible, taking into account scientific developments, expert knowledge built up by training, practical experience and active exchange with experts outside ECHA.
- Contributions provided for the development of new test methods, mainly via the OECD Test Guidelines Programme.

Activity 16: Biocides

1. Main Challenges in 2013

The new Biocidal Products Regulation (BPR) which entered into force in July 2012 will enter into operation on 1 September 2013. This regulation extends ECHA's regulatory remit with regard to technical and scientific tasks related to the implementation of the BPR, in particular on the approval of active substances, Union authorisation of biocidal products, the Biocidal Products Committee and the secretariat of the Coordination Group, providing guidance and assistance through the helpdesk, awareness raising and communication, dissemination of data, assessment of technical equivalence and facilitating data sharing and development and maintenance of the IT systems (Register for Biocidal Products and IUCLID).

The preparatory work supported by the Commission's Joint Research Centre (JRC) will continue for the larger part of 2013, and as not all new tasks will start immediately after entry into operation, some parts of the preparatory work will continue for the full year. As REACH and the BPR have similar elements, leverage on the existing systems, experience and capacity will make the biocides preparation as effective and efficient as possible. Adequate recruitment of new staff, and their induction and training is key to the completion of the preparatory work and effective start of the biocide tasks.

To embrace the new legislative tasks efficiently and effectively, ECHA will ensure good progress in the preparatory activities so that the Agency will become operational for biocide tasks by 1 September 2013, including the establishment of adequate IT systems to receive and process submissions. Consequently, ECHA must be able to process incoming dossiers for active substances, product authorisation, and technical equivalence efficiently and with high quality as of 1 September. ECHA will prepare to take over the review programme of active substances from the JRC by the end of 2013.

The changes from the Biocidal Products Directive to the new regulation and the new role of ECHA will also imply changes for Member State competent authorities and industry. In order to facilitate the transition, good working relations with the national competent authorities are indispensable. The necessary contacts and networks with stakeholders should also be well established. Effective communication should maximise the awareness of the new regulation among them, in particular among SMEs.

2. Objectives and Indicators

Objectives

1. Agency is prepared and operational by 1 September 2013 to carry out all tasks conferred on it by the Biocidal Products Regulation.
2. From 1 September 2013, all dossiers are processed according to the standard procedures adopted by ECHA and within the legal deadlines or targets set.

Performance Indicators & Targets

Indicators	Target in 2013	Means and frequency of verification
Project success rate for critical preparatory activities in terms of availability of end products.	100 %	Evaluation of implementation project finalisations – quarterly monitoring.
Percentage of dossiers handled according to standard procedures and legal deadlines.	100 %	Quarterly monitoring (as from 1 September 2013).
Level of satisfaction with the quality of scientific, technical, and administrative support provided to the members of BPC, CG, and to the Commission and MSCA's. (also during preparations).	High	Annual survey.

3. Main Outputs

- Necessary procedures, IT systems and workflows are in place and operational for submission, handling of dossiers, applications for technical equivalence and inquiries to share data.
- Biocidal Products Committee and the Coordination Group are fully established and have taken up their tasks.
- Handover of the review programme of active substances from JRC completed.
- Contacts and networks with competent authorities and interested parties established.
- Secretariat for Coordination Group prepared to assume its duties.

Activity 17: PIC

1. Main Challenges in 2013

The PIC Regulation implements the international Rotterdam Convention into EU law. It applies to banned or severely restricted chemicals and provides for information exchange mechanisms regarding the export and import of those chemicals. The Regulation contains a Prior Informed Consent (PIC) procedure for chemicals that are specifically identified as PIC chemicals under the Rotterdam convention, and which are also listed in the regulation itself. The export of PIC chemicals requires the explicit consent of the importing country. The recast of the PIC Regulation has entered into force in August 2012 and certain tasks regarding the implementation of the regulation will be transferred from the JRC to ECHA by March 2014; it is duly expected that ECHA will manage some administrative tasks relating to export notification and the PIC mechanisms and will provide the Commission, upon request, with technical and scientific input and assistance with respect to the latter's role as a commonly designated authority of the European Union, and to the participation of the Union in the Convention.

In 2013, ECHA will work towards ensuring good progress in the preparatory activities. This includes, among other things, that significant progress is made in developing modern IT tools necessary to enable exporters and importers, Member States, the Commission and ECHA to carry out their work. ECHA will also prepare to be able to provide appropriate advice and support for companies via new guidance and manuals, as well as by initiating awareness-raising and communication activities related to the new legal obligations and ECHA's new role. In order to carry out the new tasks with regards to implementation of the regulation, ECHA will create the necessary network with Designated National Authorities of the Member States with a view to establishing procedures and practices for cooperation. In addition, as foreseen in the PIC Regulation, ECHA will start to provide scientific and technical advice to the Commission on the implementation of the Rotterdam Convention, where requested.

2. Objectives and Indicators

Objectives

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

Performance Indicators & Targets

Indicators	Target in 2013	Means and frequency of verification
Project success rate for the preparatory activities in terms of time, scope and resources.	80 %	Evaluation of project finalisations. Quartely monitoring.
Level of satisfaction with the quality of scientific, technical, and administrative support provided to the Commission and MS DNA's.	High	Annual survey.

3. Main Outputs

- Significant progress in designing the necessary procedures, workflows and IT

systems for submission and handling of notifications.

- Contacts and networks with Designated National Authorities and interested parties established.

2. ECHA's Bodies and Cross-cutting Activities

Activity 8: Committees and Forum

1. Main Challenges in 2013

The Committees - Member State Committee (MSC), Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) - are an integral part of ECHA and play an essential role particularly in providing valuable scientific and technical advice (i.e. agreements and opinions) as a basis for ECHA and Commission decision-making. In order for this advice to be based on the broadest possible expertise available within the Community, ECHA will have to continue its efforts to ensure that the Committees are adequately resourced with regulatory and scientific expertise from the Member States. Fluctuations in required expertise and peak workloads demand for flexible working methods where the ECHA Secretariat needs to manage and plan the process to fit the Committee outcomes to the regulatory needs.

The main challenge in 2013 will therefore be to continue managing a constantly high workload, while complying with the tight legal deadlines and maintaining a high quality of scientific and technical advice. Furthermore, the Committees need to maintain a high level of transparency whilst respecting confidentiality requirements and be prepared for possible legal challenges.

Member State Committee (MSC)

All processes of the MSC (i.e. SVHC identification, opinions on ECHA's draft recommendations for Annex XIV, dossier evaluation, substance evaluation) will be running at maximum volume in 2013. Dossier evaluation will continue at high volume with a shift from testing proposals to compliance checks, which may be more complex and thus more often trigger diverging views to be resolved by the MSC. Substance evaluation will continue with the adoption of the first update to the Community Rolling Action Plan (CoRAP) at the end of February 2013 and by concluding the first decisions requesting further information for substances from the first list. Seamless cooperation between ECHA and the Member States responsible for a draft decision will continue to ensure the robustness and harmonised content of the decisions.

The smooth operation of the MSC and the high throughput needed requires sufficient support from the Secretariat to facilitate efficient decision-making. To achieve this, the Secretariat needs to carry out preparatory work in exploring possible solutions in advance of agreement seeking or opinion formulation. Increased complexity of cases addressed by the MSC may require more discussion-time, but the use of preparatory meetings and written procedures can reduce the length of the resource intensive plenary sessions.

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

The Committees will deal with an substantially increasing number of new dossiers - especially authorisation applications as well as CLH, restriction proposals and any specific requests from the Executive Director - in addition to the proposals and requests carried over from the previous year. In parallel, an increasing support provided by the Secretariat to rapporteurs will be needed. This, together with continuous efforts from the ECHA Secretariat in collaboration with the RAC and SEAC in streamlining its procedures and working practices, will play a crucial role in meeting the high level of demand. Within this context, it is important to continue the good interaction and cooperation between the RAC and SEAC regarding the opinions on restrictions and authorisation applications.

In particular, in order to facilitate the risk assessment and socio-economic analysis of the RAC and SEAC respectively, the ECHA Secretariat will ensure high quality advice by using the best ways for communicating the risks and uncertainties and by providing adequate capacity building tools.

The Committees' opinions and other outcomes will continue to be widely disseminated among all the relevant actors and interested parties.

ECHA will further undertake cooperation activities with other EU risk assessment scientific committees and panels in order to continue preventing and solving potential divergences in the opinions.

Biocidal Products Committee (BPC)

The BPC will be responsible for preparing the Agency's opinion on seven different biocide processes with legally binding timeframes. The operating parameters may be quite challenging from the outset. Although the number of opinions to be delivered in 2013 is still low it is expected to increase rapidly thereafter, and therefore the Committee will have to operate very efficiently from the beginning. To handle the scientific aspects opinion development properly, Working Groups will be established as part of the BPC.

The Committee will become fully operational before September 2013 and the work plan, the key procedures and working practices will be established. Preparations are made for discussing the first dossiers from the review programme of active substances in early 2014.

Coordination Group

Under the BPR, a Coordination Group will be established that has a task to examine questions related to mutual recognition of national product authorisations. Though the Coordination Group is not established within ECHA, the Agency will provide its secretariat and facilitate the preparatory work until 1 September 2013.

Forum for Exchange of Information on Enforcement

The Forum for Exchange of Information on Enforcement provides a network of Member State authorities responsible for the enforcement of the REACH, CLP and PIC Regulations, with the aim of harmonising their approach to enforcement. Its role is also to closely cooperate with NEAs and MSCAs to ensure an appropriate coordination between their tasks. The ECHA Secretariat has a catalytic role in supporting the Forum in its harmonisation and coordination of enforcement activities. By 2013, the work of the Forum as well as interaction between ECHA, NEAs and MSCAs will have reached an even more operational stage. Identifying and designing the interlinks between ECHA, MSCAS and NEAs has been an important step to ensure effective and efficient enforcement; its practical implementation will further intensify.

The Forum will in the run-up of the 2013 registration deadline prepare the subsequent enforcement of the REACH and CLP Regulations by providing specific training packages for enforcers. Another focus in 2013 will be the gradual implementation and development of active communication between ECHA and NEAs on enforcement cases in order to ensure that the goals of both regulations are achieved. In this regard, ECHA will emphasise activities that support its strategic aim of improving the quality of data submitted in registration dossiers.

As outlined by the Forum, agreed harmonised enforcement will be further improved and promoted via the continuous development of the Manual of Conclusions. This tool will collect and summarise Forum's conclusions on practical enforcement issues.

The interlinks between ECHA, the MSCAs and NEAs will be implemented through an established Focal Point in the ECHA Forum Secretariat. The ECHA Focal Point will serve to dispatch information between the Agency and the Focal Points of each national enforcement authority in the context of enforcing ECHA decisions and ensuring the information flow between actors as identified by the Interlinks project, using the REACH Information Portal for Enforcement (RIPE) for secure communication with Member State Focal Points on enforcement related matters. This will notably contribute to the harmonised enforcement of decisions issued by ECHA. In that regard, it is of utmost importance that ECHA receives appropriate feedback from the MSCAs and NEAs regarding their enforcement activities, enabling ECHA to fulfil its tasks efficiently. Following its 2012 decision, ECHA will offer RIPE as an interim solution for an electronic information exchange system (EIES) to allow secure communication between enforcement authorities between Member States. In parallel, the ECHA Secretariat and Forum will investigate in detail the suitability of the Commission-owned ICSMS-system for the long term solution for EIES.

In 2013, the Forum will finalise its second coordinated enforcement project on the obligations of downstream users, in particular formulators of mixtures, and draw recommendations for inspectors based on its results. The third Forum coordinated REACH enforcement project on registration obligations, the verification of the registrations by Only Representatives and cooperation with the customs authorities will enter into the operational phase. To strengthen its project capabilities, the Forum will conclude its ongoing work to develop and implement a harmonised methodology to select, prioritise, conduct and evaluate Forum coordinated projects. On the basis of this methodology, the Forum will further explore priorities to define and launch a fourth Forum project in 2013.

Study visits as well as the development of suitable training programmes for inspectors will be continued in order to enhance the exchange and sharing of best practices. Furthermore, the ECHA Forum Secretariat will continue providing technical, scientific and administrative support to the Forum in the organisation of its Working Group meetings, its annual stakeholder workshop and its plenary meetings.

The Forum will continue to cooperate with RAC and SEAC to give advice on the enforceability of proposed restrictions on substances. This will require good coordination when dealing with restriction proposals, taking due account of the dialogues with the Committee members and the questions and opinions of RAC and SEAC.

Finally, the Forum will also address any need to coordinate a network of Member State authorities responsible for the enforcement of the PIC Regulation.

2. Objectives and Indicators

Objectives

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

- to further strengthen and harmonise the enforcement of the REACH and CLP Regulations in the EU/EEA Member States, while ensuring the necessary confidentiality, and
 - to promote harmonised enforcement.
3. Conflicts of opinion with scientific committees of other Community bodies are prevented and solved through the sharing of information and the coordination of activities of mutual interest.

Performance Indicators & Targets

Indicator	Target in 2013	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 (e.g. support, including training and chairing provided by ECHA, overall transparency, publication of the outcomes of Committee processes) and the Forum.	High	Survey.
Occurrence of conflicts of opinions with scientific committees of other EU bodies.	Only in well justified cases	Internal evaluation report.

3. Main Outputs

Member State Committee

- Unanimous MSC agreements on up to 30 proposals for identification of Substances of Very High Concern (SVHCs).
- Up to 250 unanimous MSC agreements on draft decisions on testing proposals and compliance checks.
- Preparation of up to 30 unanimous agreements on draft substance evaluation decisions.
- Opinion on ECHA's draft recommendation for Annex XIV.

- Opinion on the first draft update of CoRAP.
- Updates to the Manual of Decisions.
- The above to be achieved through
 - Six plenary meetings and additional working groups and other preparatory meetings.
 - Participation in workshops on dossier and/or substance evaluation and/or the authorisation process.

Committee for Risk Assessment

- Up to 70 RAC opinions on CLH dossiers.
- Up to seven RAC opinions on restriction proposals.
- Deal with a number of requests for opinion under Article 77(3)(c) of REACH.
- Development of RAC opinions on applications for authorisation (based on 20 expected applications).
- The above to be achieved through up to five plenary meetings.

Committee for Socio-economic Analysis

- Up to seven SEAC opinions on restriction proposals.
- Development of SEAC opinions on applications for authorisation (based on 20 expected applications).
- Deal with a number of requests for opinion under Article 77(3)(c) of REACH.
- The above to be achieved through four plenary meetings.

Biocidal Products Committee

- All Members appointed.
- Regular meetings established.
- Rules of Procedure, main working practices and principles, and work plan established.

Forum

- Report on finalised second coordinated enforcement project on the obligations of downstream users.
- Training for trainers on the enforcement of REACH and CLP in second half of 2012.

- Implementation of ECHA's decision regarding the EIES electronic information exchange system.
- Up to seven advices on enforceability on restrictions proposals.
- Harmonised methodology to select, prioritise, conduct and evaluate Forum coordinated projects; subsequently, development of further enforcement-related guidance.
- Updates to the Manual of Conclusions.
- Enhanced transparency of the Forum's work.
- Forum Work Programme 2014-2016.
- The above to be achieved through three plenary meetings and additional working groups.

Activity 9: Board of Appeal

1. Main Challenges in 2013

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).

It is expected that in the first months of 2013, prior to the second registration deadline, a higher share of registrations will be made by companies having less experience of, and expertise in, regulatory chemical requirements than was the case before the 2010 registration deadline. It is possible that this will result in a greater number of negative decisions from ECHA, reflecting problems that these companies may have with the registration process, and these in turn may lead to a number of appeals.

Decisions on appeals will help to clarify certain aspects of the registration process as well as those areas in the REACH Regulation that may create questions of interpretation. This can help improve the quality of data submitted by industry for registration purposes.

It is foreseen that there will be an increasing number of dossier and substance evaluation decisions, which could result in scientifically complex appeals. Such appeals might bring particular challenges to the work of the Board of Appeal.

The forthcoming Biocidal Products Regulation will require preparatory work, including reviewing aspects of the appeals system and the Board's internal procedures so that it is able to handle appeals resulting from both the REACH Regulation and the Biocidal Products Regulation. The new duties placed on the Board of Appeal will also require capacity building in this new field of competence. Raising awareness among interested parties on the scope of appeals under the new regulation will also need to be tackled.

2. Objectives and Indicators

Objectives

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

Performance Indicators & Targets

Indicator	Target in 2013	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 Board.

3. Main Outputs

- Procedural and final decisions adopted (dependent on the number of appeals lodged).
- 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 (dependent upon the number and type of appeals lodged and inquiries received).

Activity 10: Communications

1. Main Challenges in 2013

The Agency has defined its audiences and external communication needs in high-level policy documents which provide orientation to its activities in 2013.

During the first half of 2013, the Agency will be reaching out to companies, including SMEs, to ensure that they are aware of up-to-date information on how to prepare high quality dossiers and submit them by the second REACH registration deadline on 31 May 2013. Furthermore, the Agency will continue raising awareness amongst companies of their responsibilities under the authorisation process and drawing attention to public consultations. In addition, it will prepare for communication actions to raise awareness of the need to classify and label mixtures in accordance with the CLP Regulation as from June 2015. This will require the organisation of events, publication of information material, release of information on the ECHA website, establishment and use of promotional material, as well as other related tasks.

Continued cooperation with the Accredited Stakeholder Organisations will, even more than in previous years, enable the Agency to gather their feedback and to count on their channels to multiply its outreach towards industry, other actors and the general public. ECHA also intends to conduct a Stakeholders' Day in 2013 (giving due consideration to the workload created by the 2013 REACH registration deadline), as well as its regular workshop with Accredited Stakeholders. It will also conduct various stakeholder surveys to provide input that will be valuable to the Agency's efforts to continuously improve its services.

In 2013, the Agency will streamline and further improve its online presence by expanding the content and functionalities of ECHA's website and making appropriate use of social media when resources allow. It will also continue to engage with media representatives to extend awareness to new industrial sectors that are affected by the chemicals legislation as well as consumers.

Communication on the requirements of the Biocidal Products Regulation that will have begun at the end of 2012 will intensify in 2013. Awareness-raising will precede the implementation of these pieces of new legislation.

The Agency will continue to further develop effective internal communication to ensure that all staff in ECHA have the information they need to do their jobs well, that they feel part of a common corporate endeavour and are ready to be redeployed to meet the needs of an evolving organisation.

2. Objectives and Indicators

Objectives

1. ECHA's external audiences are communicated with effectively, in 23 EU languages where necessary, and ECHA benefits from an accurate and proportionate media presence.
2. Accredited Stakeholders are involved in ECHA's work and are satisfied that their views are heard and taken into account.

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

Performance Indicators & Targets

Indicator	Target in 2013	Means and frequency of verification
Level of reader satisfaction with ECHA's written output, including languages available, (website, e-News, Newsletter, Press Releases, News Alerts). This to be measured in terms of timeliness, content and usability.	High	Annual readers' feedback and surveys.
Level of Accredited Stakeholder satisfaction with the information they receive and their engagement with ECHA.	High	Annual survey.
Level of staff satisfaction with internal communications.	High	Annual internal communications survey.

3. Main Outputs

- Up to 200 translation requests - All material (whether online or offline) that is produced for SMEs or the general public published in 23 EU languages (including Croatian).
- Coordinated communication activities, e.g. on the submission of registration dossiers, on applications for authorisation and on the new Biocides and PIC legislation.
- Up to 25 press releases produced and three press briefings organised for the media.
- Up to 50 news alerts, 50 weekly e-News bulletins and a bimonthly newsletter produced for interested parties.
- Two Stakeholders' Days, one recurrent workshop for Accredited Stakeholder Organisations and adhoc stakeholder events held.
- ECHA's online presence further improved, e.g. by integrating the former ECB chemical databases and biocide related pages into the ECHA website.
- Joint communication actions with EU partners and Accredited Stakeholder Organisations to support industry, especially SMEs, in understanding their duties and the benefits of implementing the legislation.
- Follow-up the recommendations of the Commission's Article 34(2) CLP Report on the Communication of the safe use of chemicals

- Internal information provided daily on the intranet and internal information screens. Weekly internal highlights (ECHAnet Exchange) produced, annual Corporate Day and quarterly Staff Assemblies organised.
- Surveys to gauge satisfaction or to understand stakeholder experience (e.g. stakeholder satisfaction survey, readership survey, website user survey, internal communications survey and a survey of registrants who submitted dossiers successfully for the 2013 deadline).
- Increasingly efficient procedures – for example a new publishing tool to facilitate timely issuing and revision of ECHA's publications.

Activity 11: International Cooperation

1. Main Challenges in 2013

In 2013, ECHA will also live up to its international profile as a leading regulatory agency worldwide, mandated with the management of the most complex and sophisticated chemicals safety regime. This entails interacting with actors and authors beyond the confines of the European Union.

During the first half of 2013, ECHA will focus on intensifying its cooperation with Croatia in the immediate run-up to this country's accession to the European Union. With support provided under the European Union's IPA programme, the Agency will also continue to provide explanatory and training events in the field of regulating chemicals safety for the benefit of EU candidate countries and, depending on their needs and state of development, also of potential candidates.

The Agency will maintain its good and fruitful cooperation with regulatory agencies in the four countries outside the EU with whom it has concluded cooperation agreements (Australia, Canada, Japan, and the United States of America) in areas of relevance to ECHA, thereby focusing on exchanging information and best practice to mutual benefit. On the basis of experience gathered since establishing these agreements in 2010, ECHA may possibly in 2013 already review these agreements and their implementation.

At OECD level, ECHA will continue its involvement in the international level harmonisation process for the collection and exchange of structured information on chemical substances. This is key to facilitating the interoperability of IT platforms and the exchange of information between regulatory and industry actors, to avoiding the duplication of work by registrants and to increasing synergies between the regulatory actors. In 2013, ECHA will continue to chair the IUCLID Expert Group Panel and further promote the use of IUCLID as the standard for storing information on properties and uses of substances at international level. In particular, IUCLID will be expanded to enable reporting robust study summaries of tests done on nanomaterials. ECHA will also continue hosting the OECD eChemPortal, which is a major ECHA contribution to the EU commitment to identify and make information on chemical properties publicly available. In addition, ECHA will contribute to the maintenance and the further development of the OECD QSAR Toolbox. The development of controlled toxicology vocabularies on further endpoints is planned in order to improve data integration of experimental data from different sources in the QSAR Toolbox and thus facilitate grouping, read-across and data gap filling. This work is pivotal for supporting registrants of the later deadlines, especially those of 2018, to be able to provide scientifically valid justifications in their dossiers. It should also allow ECHA to verify whether waiving statements for certain data requirements for substances not meeting the criteria set in Annex III of REACH (CMR category 1 or 2, PBT or vPvB) are valid.

At their request, the Agency will continue providing technical and scientific support to the services of the European Commission in the conduct of the European Union's multilateral relations, in particular under relevant international conventions and other agreements. It can be expected that the Agency's involvement in this regard may further intensify in 2013 due to the new tasks in the area of the Rotterdam convention/PIC Regulation.

2. Objectives and Indicators

Objectives

1. The Commission receives high-quality scientific and technical support for its international activities, especially in multilateral bodies.
2. ECHA, within the scope of its responsibilities, builds up and maintains its bilateral relations for scientific and technical cooperation with key third country regulatory agencies that are useful for the implementation of REACH and CLP, and supports EU candidate countries and potential candidates within the framework of the IPA programme in an effective and efficient way.
3. ECHA, within the scope of its responsibilities, contributes to OECD activities related to chemicals with a view to promote harmonisation of approaches, formats and IT tools in order to increase synergies and avoid duplication of work whenever possible.

Performance Indicators & Targets

Indicator	Target in 2013	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	Annual survey.

3. Main Outputs

- Scientific and technical cooperation with the OECD (continuation):
 - Hosting and enhancing the eChemPortal according to the priority on possible improvements endorsed by the OECD Joint Meeting in 2012.
 - Scientific and technical support to the Commission as specified in the annual Work Plan for International Activities of ECHA for 2013.
 - Further development of OECD harmonised templates in particular for reporting information and results of studies on nanomaterials.
 - Collecting and prioritising users' feedback for the further development of IUCLID 6.
 - Further development of the OECD QSAR Toolbox, to improve reliability and usability and incorporate new needs such as modes of action.
 - Support to the OECD Test Guideline Programme.
- Provision of scientific and technical support to the Commission on UN GHS, including participation and input to the work at OECD and UN level.

- Continued cooperation with the regulatory agencies in the four countries outside the European Union with whom ECHA has concluded cooperation agreements.
- Capacity building activities targeted at EU candidate countries and potential candidates under the IPA programme and possibly targeted cooperation with the European Union's ENP partner countries under the ENPI programme.
- Presentations at seminars/workshops/conferences in key third countries (either in person or via video conference) and hosting of visits by representatives of such countries.

3. Management, Organisation and Resources

Activity 12: Management

1. Main Challenges in 2013

In 2013, ECHA will adapt its management process to address the strategic aims adopted by its Management Board in June 2012.

ECHA's highest decision making body is the 35-member Management Board⁵. It is assisted by a Secretariat provided by the Executive Director. The Management Board's core functions include adoption of the Agency's Multi-Annual and Annual Work Programmes, budget, and annual report, as well as the adoption and review of internal Agency rules. The Management Board is also the appointing authority for the Executive Director, the Chair and members of the Board of Appeal, and the members of RAC and SEAC. The Board has established dedicated working groups, for example on planning and reporting, transfer of fees and audit, which facilitate the decision-making process of the Board. In order to improve the Agency's efficiency, the Management Board will have revised its working methods in 2012 and the relevant changes will be implemented in 2013. In addition, through regular reporting provided by the Executive Director and specific topic related reports from the Secretariat, the Management Board will closely follow the performance of the Agency and the implementation of its strategic aims.

ECHA will keep a strong focus on independent decision making and will make sure that all processes include the necessary 'checks and balances' to avoid undue interests influencing the outputs of the Agency.

ECHA will strengthen relations with the Member State competent authorities and improve communication through correspondence, visits and an annual Competent Authorities Directors' planning meeting.

In order to efficiently facing peaks in several Activities and, at the same time, a reduction of resources, the management commits to improving working methods and to ensuring an efficient performance monitoring. An important element will be further development of the Integrated Quality Management System (IQMS) and the continued implementation of the roadmap towards ISO 9001 certification. Integration of the new tasks to the existing ones and thus creating maximum synergies will require a review of the organisation of the Agency. Clarity of the multi-annual planning will be emphasised. Risk management and the review of the implementation of the Internal Control Standards will also be used as a tool to improve the efficiency of the Agency. Management of information will be improved in order to guarantee that the production of records is traceable and can be audited, and to facilitate the work of the staff and ensure proper archiving.

ECHA has been entrusted with a large amount of information from the entire chemicals industry. Part of the information is by nature highly confidential (in particular due to the fact that the data contains confidential business information). Therefore, the level of protection of the information will be reinforced, and the protection of staff and premises will continue to be ensured. The capacity to face business disruptions will be improved through external data centres, ensuring a high level of business continuity. The integration of new information systems supporting the Biocidal Products Regulation in this security framework will be a priority in 2013. ECHA will continue to organise the meetings of the Security Officers' Network in order to support the secure implementation of access to confidential business information for old and new MSCAs, Mandated National

⁵ 36 after Croatia joins the EU.

Institutions, the Commission and the NEAs.

ECHA's Data Protection Officer will keep striving for the Agency to comply with all its statutory obligations to protect individuals with regard to the processing of their personal data. Training and information will be provided to staff on a regular basis.

Internal and external audits will be used to provide assurance to the Executive Director that the decisions taken within the Agency are in compliance with regulations and internal policies, procedures and instructions.

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 & Targets

Indicator	Target in 2013	Means and frequency of verification
Degree of fulfilment of the ISO 9001:2008 requirements for quality management system elements.	80 %	Quality Manager's assessment.
Percentage of very important audit recommendations implemented within the deadline (IAS).	100 %	Internal auditor's annual report.
Percentage of annual declarations of interest filled in by the members of the Management Board, the Committees and the Forum.	100 %	Annual internal report.

3. Main Outputs

- Four Management Board meetings and corresponding working groups organised in order to allow the Board to take all necessary decisions.
- One planning meeting for MSCA Directors organised.
- Strong legal support provided for the drafting of ECHA decisions and for their effective defence.
- Business continuity plans established for the new configuration of IT systems.
- Implementation of information management policies audited.
- One meeting of the Security Officers' Network organised.
- Data protection compliance in selected important processes audited.

- 400 access to documents requests handled.
- Further development of knowledge management.

Activity 13: Finance, Procurement and Accounting

1. Main Challenges in 2013

The overall objective of ECHA's financial management will continue to be assuring the best use of available financial resources in line with the principles of economy, efficiency and effectiveness. In 2013, the Agency's focus in the financial field continues to be on efficient liquidity management and firm budgetary discipline. Besides this, the second REACH registration deadline of 2013 will create a specific challenge within the accounting function, given the expected high numbers of fee invoices to be treated. A systematic checking of the correctness of the granted SME reductions, compared to the initial sample-based approach, will require specific prioritisation in 2013. With the new responsibilities for ECHA in the implementation of the Biocidal Products and PIC Regulations, a financial system will be operated that segregates the related fund sources.

A large number of invoices, although for relatively smaller amounts, are expected to be processed in connection with the REACH registration deadline of 2013. This will, besides the regular work for the accounting function, result in a level of workload in the accounting area that will need attention and management follow up. Besides this, other sources of REACH/CLP income will include fees stemming from authorisation applications, appeals, administrative charges, as well as interest revenue. The deadline of May 2013 is expected to yield considerably less fee income compared to the first one and it is therefore anticipated that the reserve built up from the fees and charges linked to the first REACH registration deadline of 2010 will be needed to finance the budgeted expenditure for the year. ECHA will have to plan in 2013 and be prepared for possible adaptations and changes to the fee regulation.

In 2013, the Agency will intensify its efforts to ensure that companies have correctly declared their size at the time of the registration and thus the correctness of the SME reductions. Given that the initial sampling approach, which was applied during 2011, revealed that 80 % of the declarations were not correct, a systematic verification approach has been decided upon. This activity will therefore be prioritised in the resource allocations within the 2013 Work Programme.

The implementation of the established cash investment policy and the overall liquidity situation will also be carefully monitored in 2013, while experiences from previous years will be drawn for a possible revision. The aim for ECHA is to maintain financial self-sustainability as long as possible for REACH through prudent management and investment of income and through a tight control of expenditure. While the REACH/CLP activities are expected to continue to be fully self-financed in 2013, a mixed funding regime is expected from 2014 onwards. Preparing and ensuring an orderly return to a mixed funding regime, where part of the expenditure will be covered from fee income and the rest balanced by an EU subsidy, is a key challenge and priority for 2013 in order to ensure appropriate funding of the REACH activities in the years following.

The financing of the biocides and PIC activities is expected to be achieved mainly through subsidies from the European Union budget along the lines of the agreed financial statements, while a small portion expected to be covered through biocide fee income. The Agency will separate its budgeting, accounting and reporting systems in order to cater for the need for a segregation of the funds from the REACH activities, as imposed by these two new legislations, i.e. the Biocidal Products Regulation and the PIC Regulation. In addition, ECHA will further foster the implementation of the Agency-wide cost accounting system to monitor the costs at the level of each Activity.

As regards procurement and contracting, ECHA will also in 2013 outsource part of its

activities to foster an efficient implementation of the regulations that it is responsible for. The establishment of appropriate contractual arrangements for this will continue to impose demands for efficient procurement. A considerable number of new procurement exercises and new contracts is also expected in 2013.

2. Objectives and Indicators

Objectives

1. The Agency has correct, sound and efficient financial management while applicable financial rules and regulations are complied with.
2. Cash reserves are managed prudently and diligently.
3. The Agency has effective financial systems to manage and report on several financially segregated legal bases.

Performance Indicators & Targets

Indicator	Target in 2013	Means and frequency of verification
Number of reservations in the annual report on financial and accounting issues of the European Court of Auditors.	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).	75% (*)	Annual report.
Carry over rate (% of committed funds carried over in 2013)	< 12 %	Annual report.
Compliance with MB guidance on cash reserves (MB/62/2010 final).	100 %	Annual report.

* for activities related to REACH/CLP

3. Main Outputs

- Rigorous budget and liquidity management.
- Complete asset inventory.
- Mechanism for managing and investing the Agency's cash reserves in operation and under close monitoring.
- Reporting established to ensure segregation of funds under different legislations.

- Further systematic verification of registrants' SME status and collection of revenue related to false declarations.
- Activity-based cost accounting system in implementation.
- Follow up and execution of the budget to reach a commitment rate of 95 %.
- Annual accounts for 2012 prepared in time.

Activity 14: Human Resources and Corporate Services

1. Main Challenges in 2013

Human Resources

The human resource strategy is evolving from an initial focus on growth towards enabling a more stable organisational environment that is effective, efficient and that maintains the flexibility to assume and integrate new tasks.

ECHA is committed to its five strategic HR objectives, as articulated in the Multi-Annual Staff Policy Plan, as follows: (1) to build a sustainable, high performing work environment that will facilitate a culture of teamwork, integration and adaptability of people; (2) to strategically align training needs identification with ECHA's organisational requirements and deliver appropriate learning and development interventions to improve staff contribution and organisational performance; (3) to develop the current, and future, managers and leaders to proactively influence, motivate and empower staff in the achievement of their objectives; (4) to attract, retain, recognise and motivate staff, and (5) to enhance staff engagement and well-being at all levels in the organisation.

The year 2013 will be a critical year for a number of core REACH activities, with the second registration deadline on 31 May 2013, an increase in the number of authorisation applications and a record number of dossier evaluations. This will require ECHA, supported by its HR Unit, to foster organisational adaptability to absorb these peak workloads through the temporary redeployment of staff. It can also mean that, on a temporary basis, specific efforts are expected from staff and that certain activities are temporarily reduced such as the number of training days that are planned per staff member (7.5 days per year instead of 10 days per year; including 2.5 days of on the job training per year). Additionally, there will be demand for achieving further efficiencies, for acquiring external capacities, as well as for providing specific training to successfully integrate the projected tasks.

In addition to the specific REACH context, 2013 will be the main year of capacity building for the implementation of the Biocidal Products and PIC Regulations. This will require new recruitments to facilitate the Biocides activities, as well as a need to seek synergies and mechanisms to ensure competency-sharing.

The operating environment in 2013 will continue to be impacted by the prevailing economic situation in Europe and the resource impact on national and EU public administrations. The staffing resources for established EU agencies such as ECHA are, at this stage, subject to a reduction of 5 % during the years 2013-2017. ECHA may thus be faced with a reduction of its core staff while workloads are peaking during 2013. An in-depth assessment, with the aim of achieving further efficiency gains, will be needed, to which the HR Unit will contribute. In addition, the HR Unit will assess, and implement, relevant elements of the reform package of the Staff Regulations.

Corporate Services

The Corporate Services function covers the management of the building and office infrastructure of the Agency; the physical security; the organisation of travel and meetings; and the provision of services such as mail registration, office supplies, archiving, and library management. The strategic aim is to provide sufficient, well maintained and secured premises that offer an efficient and safe working environment for the staff and that can support the meeting and communication requirements for the Agency's bodies and the stakeholders. The unit responsible aspires to a high level of quality for the services it provides, while adhering to safety, health and environmental

standards will continue to be a key driver in pursuing the objectives.

The year 2013 will specifically impact on corporate services with the REACH registration deadline in May 2013 and by the further capacity build-up in the area of the Biocidal Products and PIC Regulations. The preparations for the REACH registration deadline imply that contingency measures have to be set up and, depending on the developments with the registrations, might have to be deployed. The further building up of capacities for Biocides and PIC results in a growing number of staff to be hosted and supported with services, while it also increases the number of hosted meetings.

Following an overall assessment of adaptations and refurbishing requirements of ECHA's premises, which is conducted in 2012, a longer term programme for fitting out the premises will be concluded. The implementation of this multi-annual plan will start in 2013. Further improvements in some of the technical facilities will also be necessary in order to ensure the operability of the premises and to respond to business continuity requirements.

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 & Targets

Indicators	Target in 2013	Means and frequency of verification
Percentage of establishment plan posts filled at the end of the year for REACH/CLP.	97 %	Annual internal report.
Percentage of establishment plan posts filled at the end of the year for Biocides/PIC.	90 %	Annual internal report.
Turnover of Temporary Agents.	< 5 %	Annual internal report.
Average number of training and development days per staff member.	7.5	Annual internal report.
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 office facilities and logistics services.	High	Annual survey.

3. Main Outputs

Human Resources

- Payroll for statutory staff and other payments to staff, SNEs and trainees (approximately 650 persons).
- An estimated 10 selection procedures to be launched.
- An estimated 60 recruitments to be completed.
- An average of 7.5 specific training days per staff member.
- Performance appraisal and reclassification exercise for approximately 550 statutory staff.
- Administration of rights and obligations, working conditions, emoluments and social security of staff.
- Advice and assistance delivered to staff and management on HR matters, in particular on individual rights and wellbeing.
- Staff survey results analysed and follow-up plans developed.
- Implement special projects such as internal mobility.

Corporate services

- Timely purchase of equipment, materials and services through appropriate procurement procedures.
- Timely calculations and reimbursements of mission and travel reimbursements.
- Secure office facilities.
- Good support for meetings and conferences.
- Well-functioning audio-visual equipment with good support.
- Efficient mail services.
- Well-organised and correctly managed library and archives.
- Up-to-date and correct inventory of non-IT assets.

Activity 15: Information and Communication Technology

1. Main Challenges in 2013

In 2013, a foreseeable peak in the registration and post-registration tasks as well as the entry into operation of Biocides will put the ICT infrastructure under pressure for performance and high availability. The ICT infrastructure has to scale its capacity and performance to meet these challenges.

Besides ensuring the operations of the ICT infrastructure at the level required by the aforementioned peak conditions, the focus of 2013 will be on consolidating the IT Business Continuity Plan and outsourcing the management of critical systems that require 24/7 service and/or a level of resources that cannot be provided internally.

The progressive large-scale update to the latest version of the Office Automation environment for all internal users started in 2012 and will be completed in 2013.

In parallel, ECHA will engineer a solution for virtualisation of the end user environment (desktop virtualisation), for the purpose of enhancing operability, maintainability and security in the context of remote working.

Due to the growth of the Agency and the need for even more accurate programming and control over the use of resources, ECHA will further deploy management information systems to support its administrative processes and management reporting.

Focus will be put on a more efficient, integrated and powerful IT system that will improve the service levels of the HR function to the organisation. The transition towards a new Human Resources management system has to be prepared while the current system (LeaMa, MiMa, eHR) is still being maintained. The time management system will be enhanced and provide reports in line with the planning and reporting needs and practice of the Agency. The use of an Identity Management system (IDM), initiated in 2012, for the centralised management of users' credentials and groups, will be further used, allowing a progressive harmonisation of users management across existing applications.

To ensure higher levels of efficiency and the indispensable traceability of ECHA's regulatory action, ECHA will – in the context of its ECM Programme – start the implementation of a Records Management System to control and manage ECHA's key documents and records in a coherent and secure way. It will provide records management functionalities along the whole lifecycle of the records according to ECHA's filing plan, taxonomy, and classification and retention rules.

2. Objectives and Indicators

Objectives

1. The technical ICT infrastructure of the Agency is operated at a high service level and continuity, efficiency, and security is maximised for all supported business operations.
2. An IT Business Continuity Plan adequately covers the mission-critical systems.

Performance Indicators & Targets

Indicators	Target in 2013	Means and frequency of verification
Availability of mission-critical systems for external customers (i.e. uptime during service hours).	On average 98 % over 12 months	Data centre statistics.
Level of internal user satisfaction with IT services, relative to staff/support ratio.	High	Annual customer survey and adhoc feedback.
Level of coverage of mission-critical systems in the business continuity solution involving external data centre(s).	REACH-IT, the ECHA website, the email system and Internet connectivity are covered	Annual internal report.

3. Main Outputs

- Provisioning and availability of services by ECHA and its suppliers to keep the ICT infrastructure and ICT resources operational and at the appropriate level of performance.
- Further establishment of High Availability solutions for Business Continuity leveraging the outsourced hosting services, targeting mission-critical systems that serve external stakeholders.
- A first implementation of a Record Management System based on the records related to the Secretariat of the Management Board, the planning, monitoring and review process and the Director's coordination meetings.
- Running the Project Portfolio Office.
- Upgraded Office Automation environment.

4. Agency Risks

ECHA conducts an annual risk assessment exercise in order to identify, assess, and manage the potential events that could put the achievement of the objectives defined in the Work Programme at risk. Based on this assessment, ECHA's management identified the following main risks.

The Biocidal Products Regulation will bring new tasks to ECHA. Considering the tight deadlines and lack of timely resources for setting up biocides operations, including development of the IT tools, ECHA may not manage to achieve a smooth transition for biocides. To mitigate this risk, for the key biocides implementation projects ECHA will develop a "plan B" to ensure that essential services can be offered to industry and national authorities. The existing IT system (R4BP v2) will remain operational until at least 31 December 2013, should the new IT system not be available at that time. The Commission will maintain this system and partially update it according to new requirements.

At the time that this Work Programme was developed, an outstanding uncertainty was identified with respect to the level of available staff resources in 2013. If the budgetary authority, the European Parliament and the Council decide on a lower level of staff resources or biocides/PIC subsidy, compared to the level proposed by the Agency, or if the biocides fee income is considerably lower than currently estimated, the implementation of the Work Programme will be adversely impacted. ECHA will follow-up closely on the institutional process and will align the activity-level in the Work Programme with the staff resources that are allocated to ECHA for 2013. This would most likely result in delaying the recruitment of new staff, IT development, and the setting up of the new Biocidal Products Committee, and thus would negatively affect ECHA's capability of becoming fully operational on biocide activities by 1 September 2013.

Given that ECHA staff base comprises temporary posts - a considerable number of which are due for consideration for renewal in 2013 - and the continuing uncertainty on the number of posts that ECHA will have in 2013 implies that ECHA could risk a loss of key staff members in 2013. To reduce this risk, ECHA will follow the situation closely by continuing its focus on promoting a positive work environment; creating appropriate learning and development and career development opportunities and fostering internal mobility.

As in 2012, a record number of compliance checks will have to be conducted to meet the 5 % target. ECHA's ability to manage the processing efficiently is fundamental to the achievement of its objective in this regard. At the time of preparing this Work Programme, the efficiency of the process still poses a risk. Therefore, specific focus will be put on monitoring the efficiency of the dossier evaluation process and on implementing any necessary corrective action.

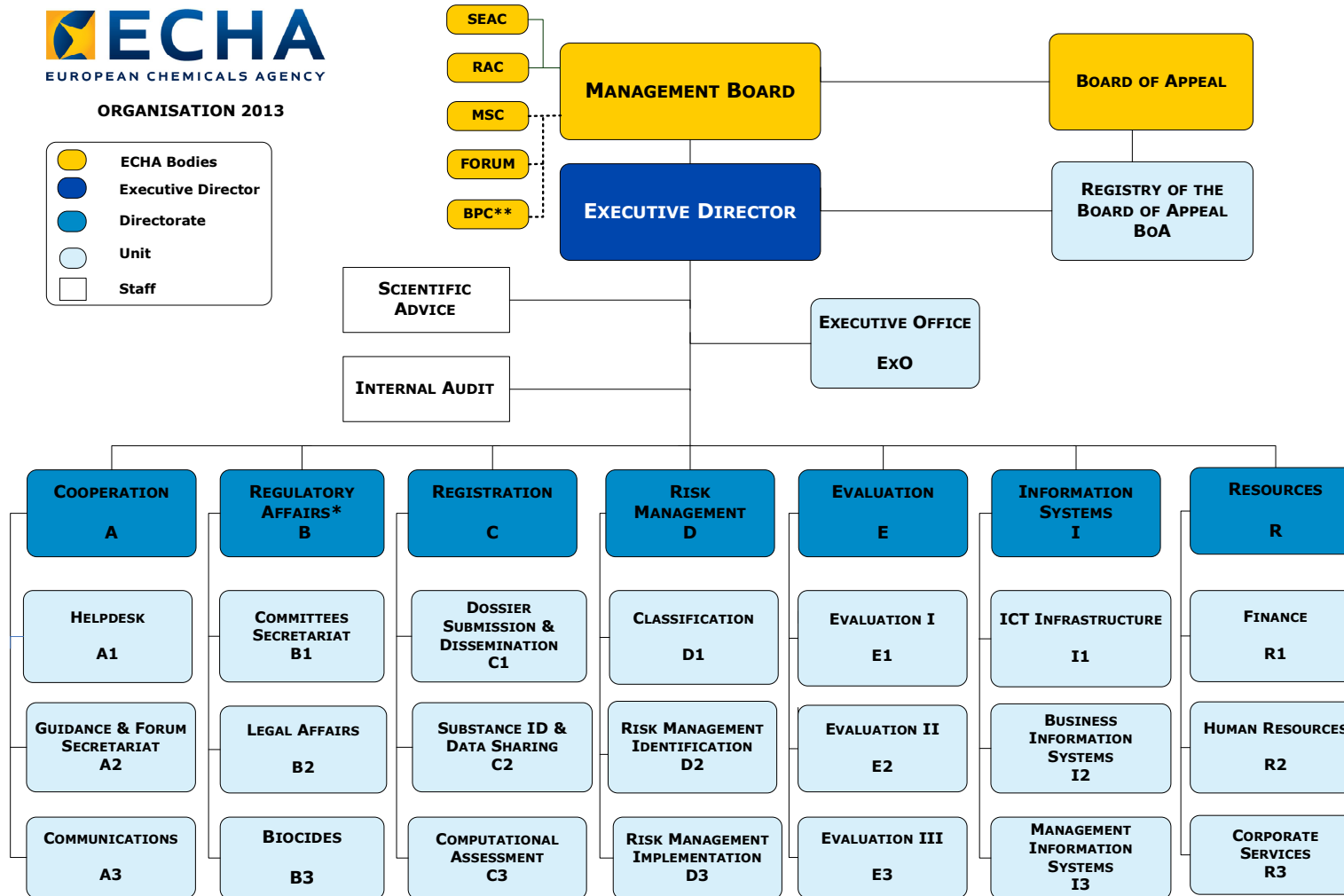
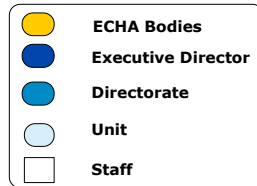
A number of Work Programme objectives are directly linked to the capacity of ECHA's Committees to deliver. If the dossier evaluation cases in the MSC increase or remain at the level of 2012, with the other new processes, its ability to ensure the expected output is at risk. If the workload is rising at risk level, the Secretariat will increase the use of pre-plenary discussions to facilitate agreement seeking, organise parallel sessions during plenaries, stopping discussions earlier, if no prospects for agreement (and accept that the case is transferred to COM), delay work where there are no legal deadlines. In addition, the Secretariat will facilitate common understanding with MSCA's on principles concerning proposals for amendments, which is a key workload driver for the MSC.

ECHA's activities rely heavily on efficient IT systems for the processing of the different types of dossiers received by the Agency. If the availability of an external data centre and suitable fail-over procedures are delayed, ECHA cannot guarantee an operational IT BCP well ahead of the 2013 deadline. This risk is mitigated through careful planning, monitoring and preliminary testing – as far as possible – of fail-over procedures.

ANNEX 1: ECHA Organisation 2013



ORGANISATION 2013



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

ANNEX 2: Baseline assumptions

Main drivers of REACH & CLP activities	Estimate for 2013
Dossiers arriving in 2013	
Registration dossiers (including updates)	15 200 ⁶
Testing proposals	410
Confidentiality requests	770
Access to data older than 12 years	240
PPORD notifications	400
Inquiries	1 200
Data Sharing disputes	33
Number of notifications under Article 7(2)	70
Number of reports/notifications under Article 38 of REACH	400
Restriction proposals (Annex XV)	8
Restriction proposals developed by ECHA	3
Proposals for harmonised classification and labelling (Annex VI of CLP Regulation)	70
Proposals for identification as SVHC (Annex XV)	30
SVHC proposals developed by ECHA	5
Authorisation applications	20
Alternative name requests	150
Substances on the CoRAP to be evaluated by Member States	50

⁶ Out of the 15 200 dossiers 8 000 are expected to be under the 2013 deadline.

Main drivers of REACH & CLP activities	Estimate for 2013
ECHA decisions in 2013	
Decisions on dossier evaluation	
- Number of decisions on TP	20
- Number of CCH concluded	560
• Out of which CCH decisions (30%)	350
- Number of substance evaluation decisions	30
Decisions on data sharing	3
Decisions on completeness check (negative, i.e. rejections)	470
Decisions on confidentiality requests (negative)	80
Decisions on access to documents requests	400

Main drivers of REACH & CLP activities	Estimate for 2013
Appeals submitted in 2013	36

Main drivers of REACH & CLP activities	Estimate for 2013
Others	
Draft CoRAP for substances subject to evaluation	1
Recommendations to the Commission for the Authorisation List	1
Questions to be answered/harmonised answers (REACH Advice, REACH-IT, IUCLID 5, others)	8 500
SME checks	300
Management Board meetings	4
MSC meetings	6
RAC meetings	5
SEAC meetings	4
Forum meetings	3
General enquiries by phone or email	3 300

Press enquiries	1 000
Press releases and News alerts	75
New CA posts to be filled for REACH/CLP	11
Recruitment due to turnover	25
Main drivers of Biocides/PIC activities	Estimate for 2013
Others	
Applications for new active substance approval	1
Applications for renewal or review of active substances	3
Applications for Union authorisation	9
Assessment of technical equivalence	25
BPC meetings	3
New TA/CA posts to be filled for Biocides	40
New TA/CA posts to be filled for PIC	2

ANNEX 4: Procurement Plan

13 December 2012

WP Activity	Sub-activity (where applicable)	Subject of the Contract	Estimated budget in EUR	Tentative procurement channel	Foreseen date for launching procurement	Foreseen date for contract signature
1.0: Registration, pre-registration and data-sharing	1.1. Pre-registration, 1.7 Data mining and intelligence, 1.9 CSA Development	Scientific consulting services (4 contracts)	363 400	FWC ECHA/2011/01	Q2	Q3
2.0: Evaluation	2.1 Dossier evaluation	Scientific consulting services	75 000,00	FWC ECHA/2011/01	Q1-Q2	Q3-Q4
3.0: Authorisations	3.2 Identification SVHC, 3.3 Recommendations Annex XIV	Scientific consulting services (2 contracts)	184 000,00	FWC ECHA/2011/01	Q1-Q2	Q2-Q3
3.0: Authorisations	3.5 Restrictions	Scientific consulting services (2 contracts)	302 040,00	FWC ECHA/2011/01	Q1-Q2	Q1-Q3
3.0: Authorisations	3.6. Horizontal risk management activity	Scientific consulting services (2 contracts)	184 000,00	FWC ECHA/2011/01	Q1-Q3	Q2-Q4
4.0: Classification and labelling	4.2 C&L notification and inventory	Scientific consulting services	150 000,00	FWC ECHA/2011/01	Q1	Q1
6.0: IT support to operations	6.1. IT Projects	IT consulting services for ECHA Projects: REACH-IT, IUCLID, CHESAR, Biocides, PIC, Dissemination, C&L, DIP, RIPE, CASPER, Odyssey, ECM (20 contracts)	10 753 700,00	FWC ECHA/2011/103, FWC ECHA/2012/150, SACHA II FWC	Q1-Q3	Q1-Q4
6.0: IT support to operations	6.2 Software servicing	SciSoft, Business Objects, Remedy, SharePoint (5 contracts)	795 000,00	SACHA II FWC, HANSEL, FWC ECHA/2011/103	Q1-Q4	Q1-Q4

6.0: IT support to operations	6.3 Software engineering	Hosting services (eCHEMportal, MOSS), Maintenance (ORACLE), IT testing (4 contracts)	2 116 000,00	FWC ECHA/2010/95N, SACHA II FWC, ORACLE FWC, ECHA/2012/135	Q1-Q4	Q1-Q4
7.0: Scientific and practical advice for the further development of legislation	7.1 Non Test methods	Production of video	45 000,00	FWC ECHA/2011/111	Q3	Q4
7.0: Scientific and practical advice for the further development of legislation	7.2. Test methods	Development of test methods	40 000,00	FWC ECHA/2011/01 or low value	Q3	Q4
10.0: Communication	10.2.Digital Communication and 10.3 Internal communication	Maintenance and development of ECHA website and ECHAnet (2 contracts)	470 000,00	FWC ECHA/2010/124	Q1-Q4	Q1-Q4
10.0: Communication	10.2.Digital Communication	Production of videos and other a/v material	270 000,00	FWC ECHA/2011/111	Q1-Q3	Q1-Q4
10.0: Communication	10.3 Internal communication	Corporate Day/ECHA Anniversary/Europe Day (2 contracts)	90 000,00	Low value negotiated procedures	Q1	Q2
10.0: Communication	10.4 External communication	Printing services (orders)	100 000,00	FWC ECHA/2011/183	Q1-Q4	Q1-Q4
10.0: Communication	10.4 External communication	Promotional material (orders)	50 000,00	ECHA/2010/66	Q1	Q4
10.0: Communication	10.5 Media relations	Media analysis, relations and news	80 000,00	FWC ECHA/2011/278	Q1-Q4	Q1-Q4
10.0: Communication	10.6 Stakeholder engagement	Stakeholders' Days (2 in 2013)	94 000,00	2012/ECHA/CEI-1	Q3 2013	Q1- Q4
11.0: International cooperation	11.1 Coordination of international relations	Ontology consulting services	60 000,00	FWC ECHA/2011/25	Q2	Q3
11.0: International cooperation	11.1 Coordination of international relations	QSAR, E-chem portal, OECD Toolbox (4 contracts)	380 000,00	FWC ECHA/2011/01, SACHA II FWC	Q2-Q3	Q4

12.0: Management	12.5 Quality Management, 12.6 Security and business continuity, 12.7 Information management, 12.8 Strategic Management 12.9 Internal audit, 12.12 Planning, Monitoring and Review	Management consulting services (7 contracts)	673 630,00	FWC ECHA/2010/93 and FWC ECHA/2011/103	Q1	Q2
6.0: IT support to operations	15.3 IT operations	Software maintenance (Splunk, Jira, Confluence, others)	100 000,00	FWC SACHA II	Q1-Q4	Q1-Q4
15.0: Information and Communication Technology	15.3 IT operations	Software licenses: EMC Documentum modules	160 000,00	DG DIGIT FWC	Q2	Q2
15.0: Information and Communication Technology	15.3 IT operations	MAINTENACE SOFTWARE: testing tools	45 000,00	FWC DIGIT/ HANSEL	Q1-Q4	Q1-Q4
		Total sum	17 580 770,00			
The procurement plan includes operational expenditure above EUR 15 000 Euros through procurement of the Agency foreseen for 2013						

