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WORK PROGRAMME OF THE EUROPEAN CHEMICALS AGENCY FOR 2012

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List of Acronyms

AD	Administrator
AST	Assistant
C & L	Classification and Labelling
CA	Contract Agent
Casper	IT Characterisation Application for Selection, Prioritisation, Evaluation and Reporting
CCH	Compliance checks
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
DG JRC	European Commission Joint Research Centre
DU	Downstream User
eChemPortal	Global portal to information on chemical substances
EC	European Commission
ECA	European Court of Auditors
ECHA	European Chemicals Agency
ECM	Enterprise Content Management
EEA/EFTA	European Economic Area/ European Free Trade Agreement
EFSA	European Food Safety Authority
EIES	Electronic information exchange procedure system
EMAS	Eco-Management and Audit Scheme
ES	Exposure Scenarios
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work
FAQ	Frequently Asked Questions
Forum	Forum for Exchange of Information on Enforcement
HelpNet	REACH and CLP Helpdesk Network
HR	Human Resources
HRMS	Human Resources Management System
IDM	Identity Management system
IPA	Instrument for Pre-Accession Assistance
IQMS	Integrated Quality Management System
ISO	International Organization for Standardization
ICT	Information Communications Technology

IR	Information Requirements
IT	Information Technology
IUCLID	International Uniform Chemical Information Database
IUPAC name	Systematic way of naming chemical compounds as recommended by the International Union of Pure and Applied Chemistry (IUPAC)
MB	Management Board
MS	Member State
MSC	Member State Committee
MSCA	Member State Competent 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 Products
(Q)SAR	(Quantitative) Structure-Activity Relationship
RAC	Risk Assessment Committee
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REACH-IT	REACH-IT is the central IT system providing support for REACH
RIPE	REACH Information Portal for Enforcement
RMO analysis	Analysis of the best Risk Management Option
R4BP	Register for Biocidal Products
SAICM	Strategic Approach to International Chemicals Management
SDS	Safety Data Sheet
SEAC	Socio-Economic Analysis Committee
SME	Small and Medium-sized Enterprises
SNE	Seconded National Expert
SIEF	Data Sharing & Substance Information Exchange Forum
SON	Security Officers' Network
SVHC	Substance of Very High Concern
TA	Temporary Agent
TAIEX	Technical Assistance and Information Exchange instrument for partner countries
TP	Testing Proposals
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 concerning chemicals placed on the European market before 1981; 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.

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

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 2012, which will be its fifth year of activity. The Multi-Annual Work Programme 2012-2014, adopted in June 2011 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.

In June 2009, the European Commission ("Commission") proposed a new Regulation concerning the placing on the market and use of biocidal products[1] which is currently in its second reading by the European Parliament and the Council. The proposed Regulation foresees additional tasks for ECHA – in particular, the review of applications for authorisation of certain biocidal products from 2013 onwards. As ECHA received additional funding for this purpose, prior to entry into force of the legal base, it has been able to start recruitment procedures, examining changes to its IT tools and building up expertise in relation to the Regulation, in 2011.

A recast of the PIC Regulation[2], which concerns the export and import of dangerous chemicals, was proposed by the Commission in May 2011, and is expected to be adopted in its first reading by the European Parliament and the Council. As of 2013, tasks will be transferred from the Joint Research Centre of the Commission to ECHA in the recast and hence it is expected that ECHA will provide the Commission, on request, with technical and scientific input and assistance. Moreover, ECHA expects to start preparing for the processing of export notifications prior to entry into force of the legislation, provided that it receives additional funding for this purpose.

The final ECHA budget and the establishment plan for human resources will be adopted in December 2011 by its Management Board, following the final adoption of the general budget of the European Union by the Budgetary Authority (European Council and Parliament). At the time of writing this Work Programme, it was uncertain whether ECHA would receive the 20 new posts for REACH and CLP that were foreseen in the legislative financial statement of the REACH Regulation in 2006. However, the Work Programme assumes that ECHA will receive these human resources in the form of 10 temporary and 10 contract agents. The activities corresponding to these human resources have been marked in italics. The final ECHA budget will be based on a re-estimate of the fee income available for the year. Should the total revenue or authorised staff figures differ significantly from the current estimates, the Work Programme will be adjusted accordingly.

[1] COM(2009)267.

2 Commission proposal of 5 May 2011 for a recast of Regulation (EC) 689/2008 of the European Parliament and of the Council concerning the export and import of dangerous chemicals

ECHA's challenges and priorities for 2012

The first challenge of the year is to ensure the readiness of ECHA for the second REACH registration deadline of 31 May 2013. This will include the support to registrants provided by the ECHA Helpdesk and the focusing of guidance updates on registration-related needs. ECHA will provide support to Lead Registrants to assist them in preparing high quality technical dossiers and chemical safety reports. Enhancements to the dossier submission processes and to existing tools will be necessary, as well as targeting communication and outreach activities. Feedback from the first registration deadline demonstrated that ECHA should have its IT registration systems and other tools ready in 2012, well in advance of the 2013 deadline.

A second challenge will be for ECHA to live up to the expectations on Evaluation. Evaluation together with industry's own responsibility should instil confidence with the EU citizens that industries' registration dossiers are of a good quality and meet the requirements. There will be a heavy workload in the domain of evaluating all testing proposals incorporated in 2010 phase-in registrations will need to be examined by 1 December 2012. Given ECHA's observation that the quality of the dossiers need improvement good progress needs to be made with regard to checks on the compliance of registration dossiers for high-volume chemicals. Furthermore, substance evaluation will need to begin via the adoption of the first Community Rolling Action Plan *and ECHA will need to assist Member State Competent Authorities in concluding on any information needs of the first batch of substances passing such evaluation.*

A third challenge will be in the area of authorisation, where the approaching application dates for the first substances on the authorisation list are likely to generate a much higher number of applications in 2012. The Commission has also set as a policy target a Candidate List containing 136 Substances of Very High Concern, by the end of the year. Achieving this target will require intensive co-operation between the Member States and the Commission in identifying the substances for which ECHA has been requested to provide support. Many of these substances will in the longer term pass to the Authorisation List.

A fourth challenge for ECHA will be ensuring its readiness for the expected entry into operation of the new Biocides Regulation in the course of 2013. ECHA will have to prepare the IT systems for the submission of different types of biocides dossiers in advance; to create and get operational the biocidal products committee; as well as to recruit and train scientific and other experts to process and assess the many dossier types. Moreover, ECHA will have to prepare its Helpdesk and those of Member States, to be able to handle questions from industry; develop guidance, manuals and other tools to assist industry; and set up a communication campaign to alert industry, Member States Competent Authorities and other stakeholders on the obligations resulting from the new legislation.

A fifth challenge, in the same vein as biocides but smaller in extent, is expected to result from the recast of the Prior Informed Consent (PIC) Regulation through which the EU implements the Rotterdam Convention. Through the recast, the technical implementation tasks of this Regulation are expected to be transferred from the Commission to ECHA. Although the workload impact on ECHA of this new regulation is much smaller than that of biocides, it nevertheless raises similar challenges since, based on the expected early adoption of this legislative proposal, the preparatory phase will also be short and partly overlap with that for biocides.

Apart from these five key priorities, many other challenges lay ahead. The main challenges listed below either intensify the current activities or are totally new:

- Complete the review of all confidentiality claims contained in the dossiers submitted by the first REACH registration deadline, to ensure that adequate justifications have been provided, and that the information is disseminated as soon as possible to the public, where this is not the case.
- Develop proposals for restrictions and provide the Commission with opinions on several restriction proposals.
- *Develop generic criteria to identify when there is a need to require registration by industry or to introduce risk management measures for substances of very high concern used in articles.*
- *Support Member States in the identification of substances of equivalent concern to SVHCs (such as endocrine disruptors and PBT-like substances and possible substances with sensitising properties).*
- Provide the Commission with opinions on the high number of dossiers for harmonised classification and labelling received in 2010 and 2011, implying a substantial increase of the RAC and ECHA Secretariat workload for formulating these opinions.
- Guidance updates, e.g. on information requirements and chemical safety assessments for nanomaterials under REACH.
- *Advise the Commission and Member States on those new alternative test methods that may merit changes to information requirements under REACH in advance of the 2013 REACH registration deadline.*
- Ensure that the IT system which contains the data submitted by industry is secure, more efficient, and provides Member States Competent Authorities and Enforcement Authorities with user-friendly access to fulfil their legal obligations.
- Work towards the first cooperation agreement(s) with third countries that permit the exchange of confidential information and of full assessments leading to synergy of efforts of authorities implementing REACH-compatible legislations.
- ECHA will contribute to the reviews set out in the REACH Regulation which the Commission is to carry out by 1 June 2012, *and assist the Commission in any follow-up.*
- ECHA will endeavour to assist SMEs to the greatest extent possible.

ECHA will, in 2012, become a unique agency as it will be financed from different legislative sources. The new Regulations are expected to enter into force at a moment when the tasks of ECHA under REACH and CLP are still increasing in volume so that any staff to be allocated for the new tasks cannot be deducted from its current workforce. That does not jeopardise ECHA's desire to achieve the highest possible synergy between the implementation of the different legislations so as to generate the smallest possible burden to industry and the European taxpayers.

1. Implementation of the REACH and CLP Processes

Activity 1: Registration, data-sharing and dissemination

1. Main challenges in 2012

Registration and dossier submissions

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 1 tonne or more per year need to demonstrate that they have assumed that responsibility by means of a registration dossier, submitted to ECHA. ECHA then verifies the completeness of the information provided and the payment of the registration fee, before assigning a registration number.

In terms of incoming registrations, 2012 should be a regular year: incoming dossiers are expected to be mostly updates of previously submitted registrations, and a lesser proportion of early registrations of phase-in substances by companies with a later registration deadline in 2013 or 2018, as well as new registrations of non-phase-in substances. The updates are expected to be due to either business or scientific reasons when, for example, the tonnage or the use of a registered substance has changed or new knowledge of the risks of the substance is available; or for regulatory reasons such as subsequent to a request for additional information further to compliance check decisions or assessment of confidentiality claims by ECHA. Moreover, the decision taken in 2011 to publish registrant names may lead companies to claim their names as confidential and trigger a volume of additional updates; a scenario which has not yet been quantified. Finally, it may also be the case that substances that have been registered as intermediates are found not to fulfil the requirements allowing for lighter information requirements, and thus respective dossiers would then have to be updated in order to contain a complete set of registration data.

Another important task for ECHA is to prepare for the 2013 REACH registration deadline. This will trigger a variety of activities, including the gathering of market intelligence for planning purposes; the provision of advice to registrants to enable preparation of high quality technical dossiers and chemical safety reports; undertaking enhancements to dossier submission processes and to existing tools; and finally, communication and outreach activities.

It was acknowledged after the 2010 deadline that the Directors' Contact Group (DCG), which brings together Directors of the Commission, ECHA and industry organisations, had played an important role in achieving a successful result: for this reason, the DCG decided to continue its work for the next deadline. Its primary goal in 2012 will be to observe and discuss the ongoing preparations for the 2013 deadline and the preparedness of companies, as well as to follow up work on DU issues and issues concerning the C&L inventory. The DCG will also confirm industry registration intentions, thus enabling ECHA to better plan its human and technical resources. *In addition the DCG will address new issues of concern when the need arises.*

It is foreseen that registrants in 2013 will include a higher proportion of smaller companies, but it is currently unknown whether this will result in a significant difference in the proportion of SME registrants in comparison to 2010. In this context, ECHA will optimise registration procedures and support mechanisms as far as possible, including updating the Guidance on Registration. In addition, by mid-2012, advice, guidance and

tools for industry, in particular Chesar, will need to be available to support industry, especially Lead Registrants, in the submission of CSRs of good quality with the second wave of registrations. These will be developed in connection with ECHA's programme for CSA development. ECHA is also prepared to respond to registrants' specific needs for support via, for example, webinars or the provision of specialised support to Lead Registrants, if such needs are expressed.

ECHA will intensify screening the registrations of intermediates in order to confirm that they meet the conditions imposed by Articles 17 or 18 of the REACH Regulation. Reduced information requirements apply only in cases where use is in line with the definition of intermediate use set out in Article 3(15) and where strictly controlled conditions are applied. Unjustified use of intermediate registration results in a lack of information relevant for ensuring the control of risks. Furthermore, it may result in a lowering of the priority of a substance for selection as an SVHC substance for inclusion in the Candidate List; could lead to the unjustified lower prioritisation of a substance from the Candidate List for further risk management; and could introduce the unfounded exemption of uses of substances in Annex XIV from Authorisation requirements. Therefore, ECHA will verify that the substance concerned is actually used as an intermediate or that strictly controlled conditions apply. *Where necessary, the registrant will be requested to submit existing data proving that the conditions are met. The Member State Competent Authorities and enforcement authorities are asked to act on cases concerning correspondence with such registrants in their country so that they can take enforcement actions where the conditions for intermediate status are not met. In cases where the conditions imposed by REACH Articles 17 or 18 are not met, decisions on compliance check may be further used to ensure that the dossier complies with the standard information requirements.*

In 2012, ECHA will continue to enhance all dossier submission processes. Specifically, authorisation applications and requests for the use of an alternative chemical name according to Article 24 of the CLP Regulation are expected to be implemented into REACH-IT.

Data sharing and substance identification

Companies manufacturing or importing the same substance shall submit their registration jointly after sharing their data and identifying further testing needs together, helping to avoid unnecessary animal testing and to reduce registrants' costs. REACH also gives registrants the possibility to use the so called read-across approach, that is, to predict the properties and effects of their substance from those of another substance within the same substance category. Successful joint registration, correct data-sharing and appropriate read-across are only possible if all parties have a clear understanding of substance identification under REACH. In effect, correct substance identification underpins all REACH and CLP processes, as both Regulations operate on the concept of substance.

Activity in substance identity is expected to remain high in 2012 as the identity of substances registered by the first deadline will become under scrutiny via other REACH processes. For example, testing proposals for a substance can only be evaluated if the substance has been identified in the registration dossier. To ensure consistency of substance identification throughout all REACH and CLP processes, ECHA will review all the processes from the substance identification viewpoint and document the approach and update guidance, if needed. ECHA will also support industry associations and registrants in clarifying the identification of their substance for the 2013 registrations, when appropriate.

Apart from substance identification, it is expected that companies, actively preparing their registrations for the 2013 deadline, are engaged in data-sharing and cost-sharing negotiations. ECHA will support these processes, based on lessons learned in 2010, to facilitate all parties' understanding of requirements under REACH and to promote best practice. This will be reflected in the update of the data sharing guidance planned for release in 2012. Specifically, ECHA wants to raise awareness among SMEs of their data-sharing rights within the REACH framework and to remind all companies that data sharing conditions, including costs, must be not only fair, transparent and non-discriminatory, but also proportionate to lower information needs for the second registration deadline. The aim is to minimise the occurrence of actual data sharing disputes.

Even with these planned efforts, it is expected that the number of new data sharing requests and disputes submitted to ECHA for arbitration is likely to increase in 2012 due to the run-up to the second deadline. ECHA has been given a fairly limited role in the process. In a nutshell, ECHA must assess the correspondence between the two parties and determine which was responsible for the failure of the negotiation by not making a reasonable effort to reach a positive outcome. However, based on experience gained in 2010, the Agency will review its procedures for handling disputes to make them as effective as possible for all involved parties. ECHA will also provide information to the MSCAs on the nature of the disputes as well as on the outcomes thereof.

Data-sharing activities via the inquiry process, including the provision of data older than 12 years to potential registrants, are also expected to remain at a fairly high level in 2012. The trend of receiving surprisingly high numbers of inquiries for phase-in substances that started in autumn 2010 seems to be continuing, and the more substances are registered, the more contacts need to be put together after an inquiry. Following the progress made in 2011, ECHA will maintain the level of inquiries processed within the target timeframe. For that, ECHA will further streamline the process for inquiries to ensure a fast procedure focusing more on the efficient sharing of data. Finally, companies manufacturing or importing phase-in substances for the first time in quantities of 1 tonne or more per year will continuously appear on the EU market. ECHA will receive late pre-registrations from these companies up to one year before their registration deadline and offer support to (pre-) SIEF activities whenever appropriate, especially with regard to newly formed SIEFs and Lead Registrants.

Dissemination – Electronic public access to information

Making information on chemicals publicly available, free of charge, on the ECHA website will continue to be a priority for ECHA in 2012, as it is a clear ambition of REACH to better inform citizens on the potential risks of the chemicals that they are using. In 2012, ECHA will enhance its procedures to more swiftly disseminate information on chemical substances from the different types of dossiers it receives. Furthermore, ECHA will complement the information already published with the registrants' identity and the registration numbers assigned to those substances, as well as more information about their properties – such as the result of the PBT assessment. Moreover, ECHA will also continuously improve the usability and user-friendliness of the data displayed on the dissemination website. Specifically, investigations will be made regarding how to make the data more easily accessible to users from the general public unfamiliar with reading data in the IUCLID format. To give the widest possible audience access to the data disseminated by ECHA, information disseminated on the ECHA website will continue to be linked to the OECD eChemPortal in a timely manner.

REACH allows companies to request the confidentiality of certain elements of their dossiers in order to protect their confidential business information. Confidentiality claims made in dossiers are assessed according to established, transparent criteria and

information deemed to be confidential is not disseminated. Furthermore, if the IUPAC name is claimed confidential, the public name proposed by the registrant is verified by ECHA to ensure that it adequately displays the chemical character of the substance. The assessment of all confidentiality claims submitted by the 2010 deadline will be completed by early 2012, so that ECHA can disseminate maximum information to the public.

2. Objectives and Indicators

Objectives

1. All dossiers, inquiries and data sharing disputes are processed, and confidentiality claims assessed, according to the standard procedures adopted by ECHA and within the legal deadlines or targets set. Decisions are well justified and of a high technical and scientific quality.

2. The public has easy access to information from all dossiers of registered substances within a reasonable time after the registration.

Performance Indicators & Targets

Indicator	Target in 2012	Means and frequency of verification
Percentage of registrations, PPORD notifications, and data sharing disputes processed within the legal timeframe.	100%	Time recorded in REACH-IT monthly reporting
Percentage of inquiries processed within the target timeframe (20 working days).	80%	Time recorded in REACH-IT monthly reporting
Level of assessing the confidentiality requests deriving from the registration dossiers that had received a registration number by the end of 2011.	100%	Assessment recorded in the workflow system. Monthly monitoring
Percentage of public information published from all registration dossiers received by ECHA since entry into operation.	90%	Rate of publication recorded. Monthly monitoring
Level of satisfaction of interested parties with the quality of the scientific, technical and administrative support provided.	*High*	Annual survey

3. Main outputs

- Approximately 5000 registrations and 200 PPORDs processed.
- Approximately 1800 inquiry dossiers and 75 data sharing disputes processed.
- Up to 750 confidentiality claims assessed, covering the remaining claims from the 2010-2011 period and 320 new claims.
- Information from the registration dossiers published on the ECHA website and linked to the OECD eChemPortal.
- Up-to-date manuals and other relevant information in place.

- Practical advice to registrants (including workshops and training) on how to improve the quality of their CSRs and the quality of the exposure scenarios communicated down the supply chain. This includes good quality examples for a CSR.

Activity 2: Evaluation

1. Main challenges in 2012

Dossier Evaluation

Dossier evaluation comprises both the examination of testing proposals and compliance checks. The purpose of the compliance check is to examine whether registration dossiers are in compliance with the requirements of the REACH Regulation, while the examination of testing proposals aims at ensuring that the generation of information on a given substance is tailored to real information needs and that unnecessary animal testing is avoided. Dossier evaluation involves scientific decision-making using expert knowledge from a variety of scientific disciplines. ECHA decisions will be under scientific and legal scrutiny by the registrants concerned and by the Member States. This in turn requires that the scientific judgements, resulting in legally sound decisions, are well founded. This is a major challenge for the ECHA Secretariat, especially in combination with the requirement for a high throughput of hundreds of dossier evaluations per year, and a decision making process involving all Member States and multiple procedural steps.

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 2012, ECHA will continue to examine the testing proposals included in the registrations submitted for the 2010 deadline, for which the draft decisions must be ready by 1 December 2012. In addition, for testing proposals for all registered non-phase-in substances, draft decisions must be prepared within 180 days. Considering the high number of testing proposals in the 2010 registration dossiers, ECHA will have to dedicate a major part of its resources for evaluation to examining testing proposals.

Compliance check is the regulatory task that ECHA uses to meet the objectives set in recital (65) of REACH, namely to instil confidence in the general quality of the registrations and the compliance with the REACH requirements. This task has become more important given that ECHA has observed that there was a general need to improve the quality of the registration. ECHA is obliged to carry out compliance checks on at least 5% of the registrations submitted per tonnage band. With regard to the dossiers submitted by the first registration deadline in 2010, ECHA has committed itself to achieving the 5% target by the end of 2013. On the basis of this plan, 250 compliance checks should be concluded in 2012. The priority setting for compliance checks will also include dossiers for substances which have been registered in nanoform or are known to be used in nanoform.

The Article 117(3) report on the implementation of alternative methods to fulfil the information requirements of the REACH Annexes, published in 2011, revealed that information requirements for longer term testing have often been filled by read across and by arguments to omit the standard information requirements. At the same time, compliance check results indicate that the quality of the read across and the arguments to omit studies are often insufficient and not adequate for classification and labelling and/or risk assessment. The prioritisation and targeting for future compliance checks will take these facts into account. ECHA will promote higher quality of registration dossiers and pay, in its 2013 registration campaign, particular attention on quality of registration dossiers (e.g. justification for exposure-based waiving and for use of alternative methods), where registrants often fail to meet expectations, and will continue inviting registrants to proactively update their registration dossiers.

The continued scientific and administrative capacity building of ECHA staff will be necessary as the high production volume phase-in substances that were registered by 1

December 2010 contain the highest level of information per dossier. ECHA's experience so far has shown that a considerable part of this information has not been generated using current standard and quality assured testing methodology. In addition, the Article 117(3) report on the use of alternative methods demonstrated that a high number of read across and grouping approaches have been applied by registrants to fill information requirements for the more complicated hazard endpoints, which would have entailed high costs and high animal use if standard information requirements were to be met. This will inevitably complicate the evaluation of the dossiers and raise complex and scientifically challenging questions. With the resources currently planned for, and under current assumptions, ECHA expects to be able to handle about 600 dossier evaluations in parallel per year.

The general results of the evaluation processes from 2011 will be contained in the annual progress report delivered by ECHA at the end of February 2012. 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. To contribute to the overall success of the REACH Regulation, and to the safe use of substances along the supply chain, ECHA will generate and communicate necessary information. *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 dossier evaluation. In the context of dossier evaluations, ECHA will also communicate its findings and recommendations for improvements of the quality of Chemical Safety Reports and exposure scenarios to industry at large, as appropriate.*

The next registration deadline of May 2013 will require increased communication and interaction with (sectors of) industry in order to improve the quality of the registrations in light of the knowledge gained with registrations from the first deadline. Continued further communication with other stakeholders 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 stakeholders.

Substance Evaluation

Substance evaluation aims at verifying whether a substance constitutes a risk for human health or the environment. Substance evaluations are performed by the Member State Competent Authorities (MSCAs) and involve an assessment of all available information and requests for further information from registrants, if appropriate. The 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.

Community Rolling Action Plan

ECHA has a principal role in establishing and updating the Community Rolling Action Plan (CoRAP) for the substances to be evaluated. The first CoRAP will be adopted by 28 February 2012 and will contain the list of substances and their corresponding evaluating Member States for the years 2012, as well for the years 2013 and 2014 to the extent available. The CoRAP shall be updated annually by 28 February; the first annual update is foreseen by 28 February 2013.

For each annual update, ECHA will apply a stepwise selection and ranking procedure. In 2012, further refinement and implementation of the adopted 2011 CoRAP selection criteria will be a high priority. The selection of candidate CoRAP substances will rely on the application of IT prioritisation tools which will be continuously refined in 2012. Both

selection and ranking will require substantial expert and manual verification of registration dossiers that will be selected by the IT tools. Similar expert advice will be needed to generate supporting documents to justify the selection of new candidate CoRAP substances. ECHA will also ensure adequate inter-linkage of the CoRAP development in general with other processes which could lead to the establishment of (Community-wide) risk management measures (Authorisation, Restriction, C&L).

The cooperation with Member States on the CoRAP annual updates may include capacity building and interaction with MSCAs in order to achieve the necessary synergies for the selection and ranking process.

Substance evaluation process

ECHA will further act as a coordinator in the overall substance evaluation process. After the publication of the first CoRAP by 28 February 2012, MSCAs will start their respective evaluation work. *Since it is the first time that this process is being performed, MSCAs may wish to get support and training to perform their work. During 2012, ECHA will continue to provide clear process support. ECHA will, together with the MSCAs, define the appropriate steps for the process and make available necessary templates for recording the work as well as instructions. In 2012, the process for substance evaluation will be fully deployed in practice and further procedural developments will be identified, together with the MSCAs, through pragmatic and efficient dialogue.* Based on the capacity indicated by MSCAs in 2011, it is estimated that around 40 substances may undergo substance evaluation in 2012. *During an ECHA workshop on substance evaluation held in May 2011, MSCAs expressed their wish for legal and scientific support through the form of specific seminars and training events for MSCA staff, particularly in 2012, which is the first year that this new process is being implementing.*

As a result of substance evaluation, MSCAs may propose a draft decision requesting information requirements to clarify the detected concern. As is the case for dossier evaluation, the decision making process involves all 27 Member States and also the Member State Committee, if Member States propose amendments to the draft decision of the reporting Member State. In the end, however, in cases of unanimity in the MSC, ECHA takes the final decision. If there is no unanimity, the decision is taken by the Commission. ECHA therefore will endeavour to ensure that the draft decisions on information requirements are completed within the legal time frame and that they are scientifically consistent and legally sound. ECHA will be a catalyst for these first 40 substances that may be processed by MSCAs. It is estimated that this will result in up to 40 reports and 30 draft decisions which will need to be screened by ECHA staff for legal and scientific consistency.

Furthermore ECHA will also coordinate the substance evaluation process in administrative terms. This will involve, *inter alia*, establishing individual service contracts between ECHA and individual MSCAs (within the existing framework contract); assignment of the Substance evaluation tasks to be carried out and documented by the MSCA; and processing of the invoices sent to ECHA. In certain cases, a pre-payment of 25% of the total sum is foreseen after signature of the service contract.

Communicating the achievements of substance evaluation to registrants and the general public is also a task under ECHA's responsibility. The criteria for selecting CoRAP substances and the adopted CoRAP-list will be published in 2012.

2. Objectives and Indicators

Objectives

1. Scientifically and legally sound draft decisions on dossier evaluation, in compliance with the legal requirements and the multi-annual planning, are prepared.

2. ECHA has ensured an effective start to substance evaluation by publishing the first CoRAP and has ensured adequate coordination of and support to the MSCAs performing the actual evaluation work.

Performance Indicators & Targets

Indicator	Target in 2012	Means and frequency of verification
Percentage of compliance checks treated within the legal timeframe.	100%	Monthly internal report
Percentage of testing proposals examined 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.	35%	Quarterly internal report
Percentage of the draft decisions accepted unanimously by the MSC.	90%	Monthly internal report
Level of satisfaction of MSCAs with ECHA's support for substance evaluation.	*High*	Annual survey

3. Main outputs

- 360 testing proposals examined and draft decisions prepared.
- 250 compliance checks concluded.
- First CoRAP published by 28 February 2012.
- Up to 40 substance evaluations initiated by the Member States according to the CoRAP so that the evaluations can be concluded according to the legal timeline (February 2013) and the process is successfully steered and coordinated by ECHA.
- The REACH Article 54 report for evaluation published by 28 February 2012.
- Communication and Interaction with industry to prepare for the next registration deadline.

Activity 3: Risk Management

1. Main challenges in 2012

Authorisation

The authorisation process under REACH aims at ensuring the good functioning of the internal market, while assuring the risks from substances of very high concern (SVHCs) are properly controlled and that these substances are progressively replaced by suitable alternatives, if these are economically and technically viable.

Identification of SVHCs and Annex XIV recommendations

In order to fulfil the policy objective announced by European Commission Vice-President and Commissioner for Industry and Entrepreneurship Antonio Tajani and Commissioner for Environment Janez Potočnik, during their visit to ECHA in March 2010, more than 60[3] SVHC dossiers need to arrive at ECHA in 2012. ECHA will continue to fulfil its commitment to support the Commission in identifying the best possible candidates and to prepare at least five dossiers.

Processing of the SVHC dossiers will eventually lead to updates of the Candidate List by mid-year and just before the end of the year. ECHA will also continue to provide Member States with tools and the means to co-ordinate their work on SVHCs, and to provide training and other support in preparing Annex XV dossiers for SVHCs, with the aim of facilitating the submission of good quality dossiers from as many Member States as possible. *Furthermore, ECHA will support Member States when identifying substances of equivalent concern to SVHCs (such as endocrine disruptors and PBT-like substances and possible substances with sensitising properties).*

In 2012, ECHA will start a new priority setting process, eventually leading to a new recommendation for inclusion of substances in Annex XIV of REACH (the list of substances subject to authorisation, or the "authorisation list") that will be submitted to the Commission by the end of 2012.

Authorisation applications

ECHA expects to receive up to 30 applications for authorisation before the end of 2012 considering that the latest application dates for the first five substances of the Authorisation List are between February and August 2013. *While ECHA has planned for these applications, it is clear that – as was the case for the first registrations of substances – the applicants, ECHA, as well as stakeholders will be "learning by doing". Therefore, on the basis of the applicants' notifications, ECHA plans to 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. A particular challenge will be to be ready to cope with an increasing number of applications from 2013 onwards and to gradually build up the IT (workflow) system.* Overall, the main challenge for ECHA, including its Committees, is to successfully manage these applications and to develop *high* quality opinions on applications that can effectively support the Commission's decision-making on granting or refusing an authorisation.

[3] This number will be verified after the final decision on the inclusion in the CL in December.

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 health or to 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.

If requested, ECHA will provide technical support the Commission in the adoption of decisions on the first four restriction dossiers[4], for which opinions of the RAC and SEAC were forwarded to the Commission in 2011.

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 or finalise the preparation of up to three Annex XV restriction dossiers in 2012.

ECHA is planning to work on two to four opinions on Annex XV restriction dossiers. They would be provided to the Commission in 2012 and 2013. This, however, depends on the number of Annex XV restriction dossiers received in 2011[5]. The ECHA Secretariat will continue to provide high quality and timely support to the RAC and SEAC as they develop these opinions.

ECHA will support the Member States in further improving Annex XV restriction reports through workshops, training or further guidance, based on the needs identified in a survey carried out in 2011.

Other activities related to risk management

ECHA will continue to increase the knowledge on the practical application of Socio-Economic Analysis. The results of projects started in 2011 on willingness-to-pay and costs of using alternative substances as well as estimates for quality/disability adjusted life years will have become available and will be shared and discussed with relevant stakeholders. In addition, ECHA will provide further support to the selection of the best Risk Management Options for SVHCs and other substances for which risk management is considered necessary.

ECHA will continue to develop approaches to screening the information generated by REACH processes to identify potential concerns and whether further risk management is needed. This will include the screening of information relevant for substances in articles and the development of generic criteria for identifying when there is a need to consider further risk management measures for substances of very high concern (Annex XIV) used in (imported) articles. Based on work started in 2011, ECHA will further develop a framework for the identification of restriction needs or other risk management actions with the aim of discussing this with the Member States and the Commission in the first quarter of 2012.

[4] These proposals relate to (1) the use of Dimethylfumarate in treated articles, (2) Lead and its compounds in jewellery, (3) manufacture, placing on the market and use of Phenylmercury compounds and (4) placing on the market and use of Mercury for sphygmomanometers and other measuring devices in healthcare and in other professional and industrial uses.

[5] At the time of writing, Denmark has submitted an Annex XV restriction report on four classified phthalates and the Commission has indicated that it would be requesting that ECHA prepare Annex XV restriction reports on three substances.

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In 2012, ECHA will continue to support industry (registrants as well as downstream users) in building capacity to develop good quality exposure scenarios (ES) to be included in their chemical safety reports (CSR) and safety data sheets (SDS),that can be implemented in practice to ensure the safe use of chemicals. In particular, work will be carried out to derive a robust methodology and examples for substances used in mixtures and in consumer products, as well as the service life and waste life cycle stages. ECHA will develop/improve its evidence-base from which to target its support for industry (registrants as well as downstream users) by more systematically reviewing the available CSRs and SDSs.

ECHA will promote initiatives such as seminars and trainings to increase the awareness and capability of stakeholders on ES-related issues, and also to promote the communication and sharing of information amongst industry and authorities on the effective implementation of ES principles. In this respect, the "ECHA-stakeholder exchange network on exposure scenarios" that was set up in 2011 will play a key role.

ECHA will explore possibilities to work collaboratively with other organisations and committees to identify opportunities for the effective and efficient implementation of the exposure scenario in REACH with other legislative frameworks, notably in the fields of worker, consumer and environmental protection and in specific industrial sectors.

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 2012	Means and frequency of verification
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

- Two updates of the Candidate List published.
- On the basis of the screening of available information on substances, substances identified for further work on risk management, for selected substances a RMO analysis completed.
- Upon request by the Commission, five Annex XV dossiers for substances of very high concern prepared.
- Development of a new recommendation for inclusion of SVHCs in the authorisation list (Annex XIV).
- At the request of the Commission, up to three Annex XV restriction dossiers prepared and submitted to the Committees for the formulation of opinions.
- Development of the criteria for requiring producers and importers of articles to register substances in articles and development of the approach to conclude whether Annex XIV substances in articles pose an unacceptable risk.
- A database or other information on costs of using alternative substances established.
- Training events, workshops and advice delivered to Member States to help them to fulfil their tasks in preparing Annex XV dossiers and in responding to comments received during public consultations.
- Practical examples of exposure scenarios i) for substances through the life cycle stages and ii) for substances with consumer use and for mixtures, including recommendations on how to address DUs' specific needs.
- Two to three meetings held of the "ECHA-stakeholder exchange network on exposure scenarios"

Activity 4: Classification and labelling (C&L)

1. Main challenges in 2012

Handling proposals for harmonised Classification and Labelling (CLH)

The process of harmonised classification and labelling ensures that for certain substances the classification and labelling is derived correctly and harmonised at EU level. Member State Competent Authorities (MSCAs) can submit proposals for harmonised classification and labelling (CLH proposal) for substances that are CMRs, for respiratory sensitisers, and, on a case-by-case basis, for substances that have other hazardous effects with a justification for action on a Community-wide basis. Additionally, manufacturers, importers and downstream users may submit CLH proposals to an MSCA, for hazard classes of substances for which no harmonised entry exists. ECHA received a first such industry submission of a CLH proposal in 2010.

For active substances in Plant Protection Products (PPP) and in biocidal products, a full harmonisation of the C&L is required. ECHA will continue its co-operation with the European Food Safety Agency (EFSA), the Commission and MSCAs and continue efforts to align the authorisation process for active substances in PPP with the process for harmonisation of the Classification and Labelling.

ECHA assumes that about 60 proposals will arrive each year. As the completion of the process will often take more than 18 months, the number of proposals in the various stages of the process will amount to about 150. It is anticipated that this number will be reached for the first time during 2012. *A substantial increase of the current resources as well as major gains in efficiency is necessary to cope with the increasing workload.*

Classification & Labelling Inventory (C&L Inventory)

The main objective of the Classification and Labelling Inventory is to promote agreement between companies on an adequate classification and labelling of their substances. The classification and labelling inventory contains information about hazardous substances placed on the EU market. It gathers substances which have been self-classified by manufacturers and importers as well as substances for which a harmonised (legally binding) classification exists (Annex VI CLP). The inventory will also contain cases where different classifications for the same substance have been submitted. The CLP Regulation requires manufacturers and importers to make every effort to come to an agreed entry in the inventory unless there is a valid reason for a different classification.

During 2011, ECHA will have published the first version of the public inventory. When publishing the data, ECHA, due to confidentiality constraints, will not be able to disclose information on the identity of manufacturers and importers. This will require ECHA to develop other mechanisms to allow manufacturers and importers to contact each other and agree on a classification. ECHA will analyse the scope of the problem in 2011, and where possible start implementing mitigation measures. This work will be continued in 2012.

In 2012, the C&L inventory will be further updated *and improved*. While the bulk of the notifications will have been received by that time, it is anticipated that the inventory will still grow by several thousands of new notifications each year. Maintenance and updating of the inventory will be a continuing task.

Evaluating requests for the use of alternative chemical names

Under specific conditions, companies can request the use of an alternative chemical name for a substance in a mixture, on labelling and in the Safety Data Sheet, in order to protect confidential business information. ECHA is responsible for deciding on such requests when the mixtures are classified, labelled and packaged according to the CLP Regulation. Any application must be assessed and decided upon within six weeks.

ECHA launched this process in 2011, and at the time of writing, there is no experience to allow development of precise estimates for how many requests may be submitted to ECHA per year. In addition, applicants can choose whether they submit such requests to ECHA or to Member State Competent Authorities in case they want to use the 'old' classification according to the Dangerous Preparations Directive, which creates additional uncertainty. For planning purposes, ECHA assumes that around 50 decisions will be taken in 2012.

ECHA will carry out a study, in consultation with MSCAs and stakeholders, on the communication of information to the general public on the safe use of substances and mixtures and the potential need for additional information on labels.

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 is maintained and kept updated.

Performance Indicators & Targets

Indicator	Target in 2012	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 interested parties with the Classification and Labelling Inventory.	*High*	Annual survey
Level of satisfaction of Commission, MSCAs and RAC with the quality of the scientific, technical and administrative support provided.	*High*	Annual survey

3. Main outputs

- Provision of timely support, of a high scientific quality, to both submitters of proposals for harmonised C&L, and to the RAC and its rapporteurs for their development of opinions, and provision of scientific background documents for such proposals.
- Publication of improved and updated versions of the C&L Inventory.
- Release of a communication platform to be used by notifiers and registrants of a same substance with the aim of harmonising the classification and labelling of that substance.
- 50 decisions on requests for the use of alternative chemical names.
- Report of the study on the communication of information to the general public on the safe use of substances and mixtures and the potential need for additional information on labels.

Activity 5: Advice and assistance through guidance and helpdesk

1. Main challenges in 2012

Helpdesk

The ECHA Helpdesk provides authoritative advice to those who have obligations under the REACH and CLP Regulations. This encompasses advice on REACH and CLP obligations, support to users of ECHA's IT tools (such as IUCLID and REACH-IT), and information on individual submissions to ECHA.

ECHA provides the Secretariat of the REACH and CLP helpdesk network (HelpNet). HelpNet supports national REACH and CLP helpdesks to exchange best practice for the operation of helpdesks; to arrive at a common understanding of REACH and CLP implementation; and to familiarise themselves with ECHA's IT tools for industry users. HelpNet aims at harmonising replies to companies by providing up to date information on REACH and CLP implementation, discussing difficult questions in HelpNet Exchange and agreeing on REACH and CLP FAQs to be published on ECHA's website.

In 2012, the ECHA Helpdesk will contribute to ECHA's preparations for the 2013 registration deadline, but it will also support national helpdesks' activities to raise awareness on upcoming REACH and CLP obligations. The HelpNet Secretariat will organise two HelpNet Steering Group meetings in 2012, one of them combined with a workshop allowing hands-on training on ECHA's IT tools, and several training webinars.

The ECHA Helpdesk expects to continue to receive some individual and complex questions on authorisation in 2012, given that the first deadline for authorisation applications falls in early 2013.

Questions on the dissemination of data in the public C&L inventory are still foreseen. The deadline for the re-labelling and repackaging of substances on 1 December 2012, and the updates of SDSs are expected to prompt questions to the ECHA Helpdesk. IUCLID support continues to be an important task since new versions are expected to be made available during the year (5.4 in Q1 and 5.5 in Q2), along with the relevant updates of all plug-ins. Moreover, REACH-IT will be updated following the new IUCLID releases; new types of dossier submission will be included for industry users and MSCAs. New functionalities for MSCAs will also be made available.

Guidance

ECHA helps industry and MSCAs to comply with their duties under the REACH and CLP Regulations and to ensure the safe use of chemicals. To this end, its guidance provides an accurate and authoritative reference framework.

The main challenge during 2012 will be to consolidate the work started in 2011 which needs to be completed in time for the 2013 REACH registration deadline in order to be useful to all registrants in general and SMEs in particular.

ECHA aims to 'freeze' the Guidance on registration, substance identification data sharing and the CLP Regulation at least six months before the deadline in order to ensure that duty holders can work on the basis of stable guidance documents for the 2013 registration deadline. ECHA will continue to expand its guidance activities for downstream users. Furthermore, the Guidance on information requirements and chemical safety assessments will be aligned with the developments of the IT-tool Chesar and amendments to the REACH and CLP Regulation.

The processes for the collection of feedback from relevant stakeholders and guidance users will be continuously improved in order to enhance input into guidance updates or new guidance developments.

Existing guidance will also be kept aligned with new developments on nanomaterials assessment and other relevant aspects. Based on output from the REACH Implementation Projects (RIPoNs), key research projects, international cooperation of appropriate quality and usefulness resulting from the Commission's work and from other relevant developments on nanomaterials, ECHA will update respective guidance, e.g. on information requirements and chemical safety assessment for nanomaterials

With regard to information requirements, ECHA's guidance follows the balance in the legislation which aims at generating reliable and high quality information to ensure the safe use of substances while minimising the need for additional animal testing. This will be further improved through amendments of related guidance.

ECHA will seek, in 2012, further ways to improve the accessibility of the guidance to all stakeholders by finalising the re-design of the guidance website and by simplifying guidance where practical. ECHA will continue to produce so-called 'quasi guidance' (which includes Frequently Asked Questions, Fact Sheets, Guidance in a nutshell, Practical Guides and new dedicated internet pages for specific REACH and CLP processes), the REACH Navigator tool, and the REACH terminology database (ECHAterm) in 22 Community languages.

REACH training

The objectives of ECHA's external training activities are to provide high quality training for national REACH and CLP helpdesks in order to enable them to reply to questions and to foster a common understanding of the REACH and CLP Regulations. The training supports MSCAs regarding, in particular, their use of ECHA's IT tools, such as REACH-IT and IUCLID5. Moreover, the training also supports inspectors from MS enforcement authorities with their use of RIPE. Training is also provided to and in third countries while addressing such requests in a fair and transparent manner.

2. Objectives and Indicators

Objectives

1. Industry receives timely and efficient support from the 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 2012	Means and frequency of verification
Percentage of resolved Helpdesk questions answered within the established timeframe (15 working days).	80%	Business Object report / monthly
Level of satisfaction with quality of Helpdesk services provided to interested	High	Annual survey

parties.		
Number of FAQ updates agreed with HelpNet and published on the web.	At least 3	Annual report
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
Percentage of guidance documents published on the web according to the plan.	80%	Annual report
Level of satisfaction expressed in feedback from guidance users.	High	Annual survey
Level of satisfaction with quality of REACH training events.	High	Participants feedback / Annual

3. Main outputs

Helpdesk

- 7000 individual and collective replies to questions made by industry and national helpdesks.
- Two meetings of the HelpNet Steering Group.
- Two trainings for the national REACH and CLP Helpdesks.
- 3 updates of REACH and CLP FAQs.

Guidance

- Finalisation of guidance activities initiated in 2011:
    - IR&CSA (including Chapter R.7 , R.9 & Part E) (relevant for authorisation applications)
    - Guidance on registration
    - Guidance on data-sharing
    - Guidance on dossier and substance evaluation
    - Guidance on identification and naming of substances (relevant for authorisation applications).

- Guidance update projects to be initiated in 2012
    - IR&CSA (including Chapter R.6 granulometry and nanomaterials)
    - Guidance on the application of the CLP criteria (sensitization hazards)
    - Guidance on the preparation of CLH dossiers (specifications for industry dossier submitters).

REACH and CLP Training

- Annual work programme on external REACH and CLP training.
- Training for national helpdesks, MSCAs, enforcement authorities, and external stakeholders according to the annual work programme on REACH and CLP training.

Activity 6: Scientific IT tools

1. Main challenges in 2012

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

The main challenge for 2012 will be to make sure that both industry and ECHA have the best possible functionalities in place for the registration deadline of 2013. This means further development of REACH-IT, IUCLID and Chesar in 2012. REACH-IT will continue to be a key application in the Agency and needs to be continuously enhanced. Any significant changes relevant to the 2013 registration deadline should be introduced into REACH-IT before the end of 2012, in order to provide industry with a stabilised system with which they can familiarise themselves.

In parallel, REACH-IT will be developed to be the single point of dossier submission to ECHA. In other words, ECHA's aim is that by the end of 2012 all dossiers submitted to the Agency, including Member State proposals for substances of very high concern, restrictions, or harmonised classification and labelling; industry applications for authorisation; and downstream user notification of authorised use, *inter alia*, arrive via REACH-IT. This means that the application will become the single hub for communication as well as the fees management software of the Agency.

ECHA will also develop the functionalities of REACH-IT to better serve the Member States, the Commission and small and medium sized companies. Specifically, the preparatory work of Member States for substance evaluation, Annex XV and CLH dossiers will be enhanced by providing them with advanced information gathering functionalities, and several on-line submission possibilities, e.g. downstream user reports or notifications of substances in articles will be published for SMEs so that they can fulfil their legal obligations easily.

IUCLID needs to be maintained and further developed to meet the increasing requirements of users, not only related to REACH and CLP, but also regarding other chemicals related regulations such as the future Biocides Regulation. ECHA plans to partially redesign the system for increased performance, usability, ability to integrate with other systems and added security. As IUCLID is a key system for registrants to prepare their dossiers, no changes affecting the registration will be introduced for industry after June 2012.

The Chemical Safety Assessment and Reporting tool, Chesar, will be extensively developed in the first half of 2012 based on the experience and feedback gained from the previous REACH registration deadline. The objective is to further promote the use of Chesar to make it the preferred industry standard. Ensuring further standardisation will increase the quality of CSAs/CSRs and will bring efficiency for both industry and authorities, including ECHA. The revised version of Chesar should therefore further support companies in preparing their chemical safety assessments and in the supply chain communication (exposure scenario generation).

The dissemination portal will continue to be maintained, and incoming substance information published swiftly on the website. Specifically, ECHA will initiate the development of the dissemination website to allow for a single point of access per

substance across the different regulatory processes. This will require considerable development of the underlying IT and the analysis will begin during 2012.

In 2012, ECHA will gather the initial experiences of users of RIPE, the Registration Information Portal for Enforcement authorities, and plan the further development of the tool.

Odyssey, a decision support system for Evaluation processes, will be maintained or further developed.

To utilise the valuable information held in ECHA databases, a system for data analysis and business intelligence – Casper – has been in place for a few years. The analysis and reporting functionalities will be continuously developed to satisfy the information needs of the Agency and of stakeholders.

ECHA will also continue to respond to the results of the Enterprise Architecture study which revealed a need to undertake technical changes to many of the current systems and their data models. Benefits of this investment will be:

i) an integrated and up-to-date visibility of all substance information currently spread over several systems and databases;
ii) an ability to provide this consistent view to internal and external users via a unified web portal which also consolidates the current points of access;
iii) easier maintenance of the systems and more controlled dependencies between them.

Based on the outcome of the needs and feasibility study on how to enhance SME communication with the Agency, which will be finalised at the end of 2011, and on consideration on how to facilitate SMEs compliance with their legal obligations, ECHA will improve the usability of REACH-IT and may include additional multilingual user interface elements.

2. Objectives and Indicators

Objectives

1. ECHA receives and successfully processes all dossiers and notifications and disseminates the public information, in accordance with the legislation, with the assistance of a well functioning IT tools.

2. Specialised IT tools and targeted user manuals and workshops have efficiently supported the stakeholders in meeting their legal obligations.

Performance Indicators & Targets

Indicator	Target in 2012	Means and frequency of verification
Project success rate in terms of time, budget and scope.	80%	Each project is evaluated as part of its closure activities. Summary reports prepared quarterly for follow-up.

Level of satisfaction of external users with the IT tools (IUCLID, REACH-IT, Chesar and RIPE).	High	Annual survey

3. Main outputs

- REACH-IT usability and user friendliness is enhanced, specifically addressing the needs of SMEs.
- REACH-IT modifications for the 2013 deadline will be implemented and released, at the latest, six months before the REACH registration deadline.
- A IUCLID release is published by summer 2012 to allow sufficient time for registrants to prepare for the 2013 deadline.
- A version of Chesar is published by summer 2012 which enables registrants to prepare their safety assessments and submit their CSRs for the 2013 deadline.
- IT solutions for Member States to access dossier and substance data are progressively delivered.
- Support and maintenance for applications in production is provided in a timely manner.

Activity 7: Scientific activities and technical advice to EU institutions and bodies

1. Main challenges in 2012

Drawing on from the vast amount of information at its disposal after the first REACH registration deadline, ECHA will considerably increase its knowledge on chemicals *so as to be able to respond better to questions raised by the institutions of the EU.*

ECHA will continue its 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 deadline to avoid unnecessary (animal) testing for the 2013 and 2018 registrations by applying alternative methods. Besides the further promotion of the use of QSAR, a specific focus will be put on promoting read-across and category approaches. Moreover, ECHA will have a core team in place with expert knowledge on non-test method approaches, and supporting specialist software dedicated to provide support to ECHA processes such as evaluation and risk management. *The software will exploit information available from the first registration deadline to facilitate future assessments of chemical properties.*

ECHA will *significantly* advance its understanding of the assessment of hazard, exposure and risks as well as risk management and mitigation related to nanomaterials by following carefully all the developments and outcomes of EU and international programmes, so that it can efficiently start addressing dossiers on substances with nanoforms under dossier evaluation and update relevant guidance for nanomaterials in time for the 2013 registration deadline*,* 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 *increase its efforts to* manage *efficiently* endocrine disrupting substances under REACH and CLP. 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 REACH and CLP processes.*

ECHA will continue to carry out its programme for CSA development, which was launched in 2011. *Based on the analysis of registrants' CSRs from the first REACH registration deadline, ECHA will focus on further developing methods and tools for exposure assessment in those areas where major gaps exist. Assessment challenges in the context of substance evaluation, authorisation and restriction will also be addressed in these developments.* ECHA will also clarify the communication obligations incumbent upon downstream users and promote best practice for their implementation. Practical advice for downstream users on how to perform their own chemical safety assessments will be developed.

ECHA will continue to contribute to the first review of the Agency, which is due to be completed by June 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, exposure assessment, testing methods and the use of alternative methods.

Performance Indicators & Targets

Indicator	Target in 2012	Means and frequency of verification
Level of satisfaction with the quality of the scientific, technical and administrative support provided to the Commission and MSCAs.	*High*	Annual survey

3. Main outputs

- Analysis *and further development* of existing exposure estimation tools, in order to support safety assessments under REACH. *Improved* methods for exposure from service life of substances in articles. Practical methods to address conversions products of substances reacting on use in the CSA.
- Information from the registration dossiers extracted to advance the use of (Q)SARs and the application of grouping and read-across.
- The application of computational methods is integrated into routine work processes to support efficiently ECHA's tasks under REACH.
- Software on non-test methods procured, taking into account scientific developments, expert knowledge built up by training, practical experience and active exchange with experts outside ECHA.
- *Increased* contributions to the scientific and regulatory developments concerning endocrine disrupting chemicals.
- *Improved* capacity for addressing nanomaterials under REACH and CLP processes.
- Contributions to the Agency review and reviews of various REACH provisions under Article 138 of REACH.

2. ECHA's bodies and cross-cutting activities

Activity 8: Committees and Forum

1. Main challenges in 2012

In 2012, the Committees will face an increasingly high workload. It will be a challenge to meet the tight legal timelines, and to maintain the high scientific and technical quality and to ensure that the Commission can take decisions efficiently with the advice provided by the Committees. The Committees need to maintain a high level of transparency whilst respecting the required confidentiality. The Forum will, with the help of the secretariat, intensify MS efforts in effective enforcement of REACH and CLP, making use of the new tools and projects.

The 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 start running at maximum capacity in 2012. Substance evaluation will be initiated with the adoption of the first Community Rolling Action Plan (CoRAP) which is foreseen at the end of February 2012. Based on proposals prepared by MS, the MSC will adopt an opinion on the first draft CoRAP as advice to ECHA. Close cooperation between ECHA and the MS responsible for a draft decision will continue to ensure a harmonised approach to and the robustness of the decisions.

The Committee for Risk Assessment (RAC) and the Committee for Socio-Economic Analysis (SEAC)

The Committees will need to handle an increasingly large number of dossiers, including those carried over from the previous year, (CLH, restriction proposals, authorisation applications, and any specific requests from the Executive Director), which will be combined with the support provided by the Secretariat to rapporteurs. The RAC, in particular, is likely to be placed under a very high level of demand and must be prepared to meet this demand by streamlining its procedures and working practices, and by receiving the necessary support from the MSCAs and the ECHA Secretariat. The RAC will therefore continue the work started in 2011 to improve and streamline its processes.

The conclusions and recommendations of the Committees, as presented in their opinions and other outcomes, should be widely disseminated among all the relevant actors and interested parties.

To ensure that the REACH processes function effectively, the interaction and cooperation between the RAC and SEAC needs to continue and evolve further in the light of experience from restrictions and authorisation applications, and in particular, the best ways for communicating risks and uncertainties, in order to facilitate socio-economic analysis.

ECHA will further improve cooperation with other EU Risk Assessment Scientific Committees and Panels in order to avoid and solve potential divergences in the opinions.

Forum for Exchange of Information on Enforcement

The Forum is an integral part of ECHA and plays an essential role in ensuring harmonised enforcement. The Forum functions as a platform for Member States to exchange information and to coordinate and develop their enforcement activities.

The Forum will, in 2012, finalise its second coordinated enforcement project on the obligations of downstream users, in particular formulators of mixtures. Further recommendations will be made on the basis of the outcome of this project.

A third coordinated Forum REACH enforcement project, in cooperation with customs authorities, will be launched in 2012. Its aim is to ensure a common understanding with a view to harmonised enforcement guidance and training materials for inspectors, as well as to provide training to national coordinators.

To increase the effectiveness of the harmonisation of enforcement, the Forum will continue to develop the RIPE portal and EIES electronic information exchange procedure system to facilitate communication amongst the enforcement authorities. A new version of the RIPE portal, with additional functionalities, will be rolled out in 2012.

A first coordinated exchange of inspectors will take place in 2012 and study visits will intensify from 2012 onwards. The Forum will collect and examine proposals for the training programme for inspectors, with regard to the exchange and sharing of best practice. This will be an asset for the work of the Forum. In 2012, the Forum will continue to develop and implement indicators to allow effective measurement of the progress of the work of the Forum.

In order to warrant and improve coordination, cooperation and communication amongst the different actors to ensure that the Forum will fulfil its duties effectively, the Forum will further develop *and implement* the best available ways to interlink with the ECHA Secretariat, the Member State Competent Authorities, and the national enforcement authorities. It will elaborate a position document considering the most efficient ways of communication between ECHA and Member States taking due account of relevant REACH and CLP processes.

The Forum will continue to cooperate with the RAC and the SEAC to give advice on the enforceability of proposed restrictions on substances. The activities of the Forum will be conducted with good coordination when dealing with restriction proposals, taking into account the dialogue with the Committee members and the questions and opinions of the RAC and SEAC.

In 2012, the Member States will report to the Agency under Article 46 (2) of the CLP Regulation, summarising the results of official controls and other enforcement measures, and ECHA will submit their compilation to the Commission. The ECHA Secretariat will be devoting increasing attention and effort to promoting enforcement via participation in events such as the Enforcement Conference organised by the European Commission.

2. Objectives and Indicators

<u>Objectives</u>

1. The Secretariat will support 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 support and facilitate the work of the Forum *efficiently and effectively* and in a transparent manner so that it will have been able to strengthen and harmonise further the enforcement of the REACH and CLP Regulations in the EU/EEA Member States, while ensuring the necessary confidentiality.

3. Conflicts of opinions with Scientific Committees of other Community bodies are prevented through the sharing of information and the coordination of activities of mutual interest.

Performance Indicators & Targets

Indicators	Target in 2012	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 ECHA stakeholders on the added value of the Forum activities.	High	Annual survey
Level of satisfaction of the Members and other participants with the support (including training and chairing) provided by ECHA to the Committees and the Forum.	*High*	Survey
Level of satisfaction of stakeholders, Competent Authorities and Members of the Committees with the overall transparency and publication of the outcomes of Committee processes and Forum activities.	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 (or opinions) on up to 40 proposals for identification of substances of very high concern (SVHC).
- Up to 130 unanimous MSC agreements on draft decisions on testing proposals and compliance checks.
- Preparation of unanimous agreement on draft substance evaluation decisions (timing of the first decisions still open at this point of time).
- Opinion on ECHA's draft recommendation for Annex XIV.

- Opinion on draft CoRAP.
- Updates to Manual of Decisions.
- The above to be achieved through
    - Six plenary meetings
    - Two working group meetings (drafting of opinion on draft recommendation for Annex XIV).
    - Two working group meetings (drafting of opinion on draft Community Rolling Action Plan (CoRAP).
    - Participation in two workshops on evaluation of dossiers/substances.

Committee for Risk Assessment

- Up to 70 RAC opinions on CLH dossiers (based on the expected 60 CLH dossiers received each year).
- Up to 4 RAC opinions on restriction proposals.
- Updated RAC Manual of Conclusions and Recommendations.
- The above to be achieved through to up seven plenary meetings.

Committee for Socio-Economic Analysis

- Up to 4 SEAC opinions on restriction proposals.
- Updated SEAC Manual of Conclusions and Recommendations.
- The above to be achieved through four plenary meetings.

Forum

- Report on the second Forum enforcement project.
- Updated RIPE and EIEP (Electronic information exchange procedure).
- Training of country coordinators for third REACH enforcement project.
- Interlinks between ECHA, Member State Competent Authorities and national enforcement authorities.
- Training of enforcement trainers' event.
- The above to be achieved through three Forum plenary meetings.

Activity 9: Board of Appeal

1. Main challenges in 2012

The Board of Appeal was set up to provide the possibility of legal redress by deciding on appeals lodged by any natural or legal person affected by the decisions of the Agency referred to in Article 91 of the REACH Regulation.

Over the course of 2012, the pending appeals lodged in 2011 will need to be examined and decided upon. More evaluation-related appeal cases, involving more complexity from the scientific point of view, are expected as a consequence of the evaluation work on dossiers after the first registration deadline. This will be taken into account in the Board's proactive knowledge management activities.

Companies having less experience of, and expertise in, regulatory chemicals issues are expected to be involved in preparing for the 2013 registration deadline. It is also anticipated that there will be a greater need to generate new data for 2013 registrations than was the case for the 2010 registration deadline. This may result in more data-sharing disputes between potential registrants as well as a greater number of questions on the compliance of registration dossiers, thereby generating appeal cases in the future.

If the workload requires it, the Board of Appeal will work together with the alternate and additional members in an effective and efficient manner.

2. Objectives and Indicators

Objectives

1. High-quality decisions adopted by the Board without undue delay.

2. Maintain stakeholder confidence in the REACH provisions for legal redress.

Performance Indicators & Targets

Indicators	Target in 2012	Means and frequency of verification
Percentage of cases concluded within target time[6] set for each type of appeal.	90%	Annual report of the Board
Percentage of Board of Appeal decisions appealed before the General Court.	Less than 20%	Annual report of the Board
Level of stakeholder confidence in the appeal procedure.	High	Survey among stakeholders

3. Main outputs

- Decisions adopted (dependent on the number of appeals lodged).
- A robust body of high-quality decisions related to the specific legal issues resulting from the REACH Regulation published on-line.

[6] Target time is defined as the time within which 75% of previous cases of the type of appeal have been closed (minimum 10 cases being closed to define target time).

- Effective communication with the (potential) parties in relation to appeal proceedings (dependent upon the number and type of inquiries received).

Activity 10: Communications

1. Main challenges in 2012

In 2012, the Agency will be reaching out to companies who need to register substances in 2013 to ensure that they are aware of up-to-date information on guidance and tools that will help them to comply with their legislative obligations. By providing an extended support to Lead Registrants, including a new Lead Registrant workshop, ECHA wishes to contribute actively to the generation of higher quality dossiers for the second registration deadline. Raising awareness amongst companies of their responsibilities under the Authorisation and Restriction processes, and drawing attention to public consultations to maximise participation will be another important communication task. ECHA will continue its cooperation with other relevant actors and, in particular, the European Commission.

Around the end of 2011, the Agency will launche a fully revamped website that will provide improved access to all web products published by ECHA. After the launch, an important task in 2012 will be to guide web users through support material to the available information and the new features of the website.

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 22 EU languages where necessary, and ECHA benefits from an accurate and proportionate media presence.

2. 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

Indicators	Target in 2012	Means and frequency of verification
Level of website customer satisfaction.	High	Annual user survey, quarterly web statistics
Level of staff satisfaction with internal communications.	High	Annual staff survey
Level of reader satisfaction with publications.	High	Annual customer surveys
Level of stakeholder satisfaction with their involvement.	High	Stakeholder Day surveys and Annual

		Stakeholder survey
Publication of translations of new documents relevant for small and medium sized enterprises or for the general public (within an average period of three months after publication of the original document, without validation).	100%	Internal quarterly report

3. Main outputs

- Communications campaigns carried out (e.g. on authorisation requirements and procedures; SIEF formation for the 2013 deadline), including activities targeting industry and the general public.
- All material (whether online or offline) that is produced for SMEs or the general public published in 22 EU languages.
- Internal information provided daily on the intranet and internal information screens. Weekly internal highlights (ECHAnet Exchange) produced, periodic internal newsletter (ECHO) printed. Annual Corporate Day and quarterly Staff Assemblies organised.
- Multi-media Press Releases and weekly e-news bulletins produced, two press briefings organised, network of press officers in the Member States embedded.
- Stakeholder Day and *ad hoc* Stakeholder events held.
- A procedure for dealing with public enquiries established.
- New ECHA website further enhanced.
- Additional websites (e.g. IUCLID5, Chesar, etc.) migrated and adapted to the same common web management system.
- ECHAnet (ECHA's intranet) further improved.
- Risk and Crisis Communications Strategies executed.

Activity 11: International cooperation

1. Main challenges in 2012

With interest increasing amongst candidate countries in the implementation of the EU's chemicals legislation – and with at least one nearing the end of accession negotiations – as well as in the context of involvement under the IPA (Instrument for Pre-Accession Programme) and targeted TAIEX activities, ECHA will need to continue to meet demands for capacity-building measures from these countries, within the resources available, to make them acquainted with the operations as well as the scientific work of various ECHA bodies. Similar demands, but to a lesser extent, will come from potential candidate countries.

The Agency will *build up and maintain* bilateral cooperation with third countries' regulatory agencies through cooperative agreements, including supporting steps towards the first bilateral cooperation agreements that permit the exchange of confidential information. ECHA will further contribute to the exchange of know-how for handling data on chemical substances between ECHA and other regulatory bodies. This will promote consistent decision making internationally and improve the efficiency of the REACH processes.

ECHA will continue to contribute to the harmonisation process for the collection and exchange of structured information on chemical substances at the OECD level, particularly in view of the second registration deadline, and subsequent implementation in IUCLID. Existing formats may need to be updated and new formats might be added, for example for nanomaterials.

Moreover, ECHA will continue its collaboration with the OECD on two large projects: the eChemPortal (global portal to information on chemical substances) and the QSAR Application Toolbox by funding their development and the hosting of the eChemPortal. In 2012, the Portal will be enhanced with information on ongoing and planned assessment work, with the aim to avoid duplication among countries/regions and increase efficiency whenever possible. The QSAR Toolbox will need further development both in terms of its robustness and functionality, in order to ensure sufficient support for registrants for the upcoming deadlines.

Finally, ECHA will remain available to provide technical and scientific support to the Commission services in the conduct of the EU's multilateral relations, in particular under relevant international Conventions.

2. Objectives and Indicators

<u>Objectives</u>

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 those third country regulatory agencies that are useful for the implementation of REACH and CLP, and supports EU candidate countries and potential candidates within the framework of the IPA programme in an effective and efficient way.

Performance Indicators & Targets

Indicators	Target in 2012	Means and frequency of verification
Level of satisfaction of the Commission with the support given by ECHA on international activities.	High	Annual survey
Increase in the visits to the eChemPortal from previous year.	20%	Internal annual report
Level of implementation of the annually planned modules of QSAR Application Toolbox.	90%	Internal annual report

3. Main outputs

- Scientific and technical support to the Commission as specified in the annual Work Plan for International Activities of ECHA for 2012.
- Bilateral cooperation arrangements with interested third country regulatory agencies and continued cooperation with those whom ECHA has already concluded such arrangements.
- Attendance at international convention meetings in support of the Commission.
- Functioning of the eChemPortal and QSAR toolbox.
- Provision of support of a high scientific and technical quality to the Commission on GHS and amendments and adaptations to the CLP Regulation, including participation and input to the work at OECD and UN level.
- Scientific and technical cooperation with the OECD (continuation):
    - Participation in the OECD steering group of the eChemPortal (review and prioritisation of new user requirements for potential further development).
    - Participation in the OECD QSAR Toolbox Management Group and coordination of the development and release of the software modules for the third version of the QSAR Toolbox.
    - Chairing of the IUCLID User Group Expert Panel with a view to prioritising users' requirements for implementation into IUCLID. Participation in the work of the OECD groups linked to the IUCLID activity: Expert Group on the Electronic Exchange of Pesticides Data; Transport Subgroup of the above OECD group; Harmonised Templates for Reporting Study Summary Results Group.
    - Task force on hazard assessment.
    - Task force on exposure assessment.
    - Working party on manufactured nanomaterials.
    - Working Group of the National Co-ordinators for the Test guidelines. Programme.
- Capacity-building activities targeted at EU candidate countries and potential candidates under the IPA project, if continued.
- Presentations at seminars/workshops/conferences in, and visit received from, third countries.

3. Management, organisation and resources

Activity 12: Management

1. Main challenges in 2012

ECHA's highest decision making body is the 35-member[7] Management Board. 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 the 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. The Management Board follows the performance of the Agency closely through regular reporting provided by the Executive Director and specific topic related reports from the Secretariat. Four plenary meetings are planned for the year, as well as several working group meetings.

Supporting the Member States in the consistent implementation of the REACH and CLP regulations is one of ECHA's aims. ECHA will strengthen relations with the Member State Competent Authorities and improve communication through correspondence, visits and an annual Competent Authorities Directors' planning meeting.

ECHA's organisational structure went through a major change in 2011 to shift from preparatory activities towards multiple science-based decision and opinion making. Further work will be necessary to ensure adaptation of management processes to a larger organisation and to ensure the efficient coordination of cross-Directorate activities. This will require, among other things, mature planning of activities at each level of the organisation and will require development of tools to integrate planning, resource allocation, performance monitoring and management of Agency risks. The tasks deriving from new legislations will be an additional management challenge.

ECHA has been entrusted with a large amount of information from the entire EU 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 ensuring security – for information, premises and staff – will continue to be a priority. The security management system that has been established will be further developed. Moreover, ECHA will also continue to organise meetings of the Security Officers' Network in order to support the secure implementation of access to confidential business information for Member State Competent Authorities, Mandated National Institutions, the Commission and the National Enforcement Authorities.

The business continuity plans developed in 2011 will be tested and improved in 2012, in order to guarantee the better protection of ECHA assets and the smooth operation of ECHA processes in the case of a crisis during the run-up to the 2013 deadline.

Furthermore, ECHA information management guidelines will be finalised and knowledge management projects initiated.

[7] The members include 27 EU Member States, 6 representatives appointed by the European Commission, including 3 individuals from interested parties, and 2 members appointed by the European Parliament. In addition, Iceland and Norway participate as EEA/EFTA country observers.

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 to staff will be provided on a regular basis.

The assessment of the maturity of the Integrated Quality Management System (IQMS) and its compliance with requirements, done in 2011, will further stimulate optimisation and continual improvement. The roadmap leading to certification according to ISO 9001 will be defined. In addition, implementation of the Eco-Management and Audit Scheme (EMAS) will be initiated.

Legal expertise will be further strengthened in order to guarantee that the growing numbers of ECHA decisions and contracts are legally sound and in order, to be able to manage possible complaints and court proceedings, including those related to ECHA's intellectual property.

As part of its overall risk management, ECHA will monitor the implementation of its risk mitigation plan, and continue to improve its capability to face crises and to implement the Business Continuity strategy.

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 quality of outputs.

Performance Indicators & Targets

Indicators	Target in 2012	Means and frequency of verification
Percentage of statutory documents submitted to the Management Board within legal deadlines.	100%	Quarterly internal report
Percentage of quality documents in place according to annual plan.	80%	Quality Manager's annual report
Number of "critical" findings by the auditors relating to the internal control system in place.	0	Internal auditor's annual report
Percentage of important audit recommendations implemented within the deadline.	100%	Internal auditor's annual report
Number of security incidents for which an inquiry by ECHA's security services identified a leak of confidential information.	0	Internal reports

3. Main outputs

- 4 Management Board meetings and corresponding working groups organised in order to allow the Board to take all necessary decisions.
- 1 Inter-Agency network meeting organised (Heads of Agencies and Heads of Administration).
- 1 MSCA Directors' planning meeting organised.
- Strong legal support to ECHA's decisions and their effective defence.
- Business continuity plans tested.
- Roadmap for ISO 9001 certification.
- 1 SON meeting organised.
- 300 Access to documents requests handled.

Activity 13: Finance, Procurement and Accounting

1. Main challenges in 2012

The Agency's primary focus in the financial field will continue to be on efficient liquidity management and rigorous budget discipline. With regard to REACH/CLP activities, the Agency will continue, in 2012, to be fully self-financed, mainly utilising the reserves built up from the fees and charges linked to the first REACH registration deadline of 2010. Other sources of income will include fees stemming from authorisation applications, fees related to the upcoming registration deadlines, and interest revenue. The implementation of the established cash investment policy and the overall liquidity situation will need to be carefully monitored. For the financing of the Biocides and PIC activities, European Union subsidies are expected to cover the necessary preparatory activities to be carried out ahead of the expected entry into operation of the respective legislations.

The Agency will face the challenge of adapting its budgeting, accounting and reporting systems in order to cater to the need for a full separation of funds imposed by these two new legislations, i.e. the Biocides regulation and the PIC regulation. In addition, it is foreseen to start off with the implementation of an Agency-wide cost accounting system to monitor the costs at the level of each activity. With respect to the volume of financial transactions, the number of incoming fee payments is foreseen to be rather modest in 2012, while it is expected that the Agency will have some 500 financial commitments and close to 4500 outgoing payment transactions as a result of its operational activities. In addition, the Agency will need to prepare revised estimates as regards the expected revenue from the 2013 registration deadline and other sources.

In 2012, the Agency will continue its efforts to verify that companies have correctly declared their size at the time of registration and consequently paid the correct fee amount. In view of the fact that fee reductions can be up to 90% for the smallest category of companies, it is important that the reductions are granted on a legitimate basis – not only to safeguard sufficient financing for the Agency but also to ensure a fair and equitable treatment of companies.

The main procurement actions in 2012 are expected to focus around further IT systems development, implying the procuring for a new generation of IT framework contracts. Competition will be reopened within the new framework contract for scientific services and new procurement actions will be launched in the area of administrative services e.g. setting-up of security framework contracts. The 2012 procurement plan is annexed to this document.

2. Objectives and Indicators

<u>Objectives</u>

1. The Agency has sound and efficient financial management.

2. Cash reserves are managed diligently.

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

Performance Indicators & Targets

Indicators	Target in 2012	Means and frequency of verification
Number of reservations in the annual report of the European Court of Auditors.	0	ECA reports/ annual
Commitment rate.	95%	Monthly financial report / annual
Payment rate.	75%	Monthly financial report / annual
Carry over rate (of committed funds).	< 20%	Annual internal report
Number of Court rulings against ECHA procurement procedures.	0	Annual internal report
Compliance with MB guidance on cash reserves (MB/62/2010 final).	100%	Quarterly internal report

3. Main outputs

- Rigorous budget and liquidity management.
- 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 verification of registrants' SME status and collection of revenue related to false declarations.
- Activity-based cost accounting system put into implementation.
- Follow up and execution of the budget to reach a commitment rate of 95%.
- Annual accounts for 2011.

Activity 14: Human resources and corporate services

1. Main challenges in 2012

Human resources

Having completed the initial growth and development phase for the REACH and CLP activities, the Agency will focus on creating a culture of continuous learning and development for its staff, in 2012. These efforts will foster career opportunities for individual staff members as well as enhance the long-term competency basis for the Agency.

Following the fast growth of the Agency in previous years, specific focus will be given to strategic organisational development as well as to consolidating the management capacity of the Agency. This includes the provision of appropriate support to managers to equip them with the tools to fulfil their people management responsibilities and to contribute to the organisational development of ECHA.

In 2012, a number of the Temporary Agent staff will have completed five years of service with ECHA. The HR Unit will lead the development of an appropriate contract renewal policy.

Continued and dedicated attention will be given to promoting the wellbeing of the staff and their families, with the objective of facilitating a healthy work/private life balance.

ECHA will further develop its new graduate scheme in the field of EU chemicals policy to help graduates plan their careers and find training and professional development, with a view to being better qualified to fill vacancies as regulatory affairs professionals dealing with REACH and CLP.

During 2012, it is anticipated that the activities with respect to the new regulations – Biocides and PIC – will commence. This will demand additional recruitment, deployment of capacity, and the further development of staff competency.

The building of a Human Resources IT system, which commenced in 2011, will reach the development phase in 2012. This will require a continued focus on the implementation of the project; managing the transition; systems testing; as well as training the HR staff and the end-users of the system.

Corporate services

The Corporate Services function covers the management of the building and office infrastructure of the Agency; physical security; the organisation of travel and meetings; and the provision of administrative services such as mail registration, office supplies, archiving, and library management.

Some refurbishment of the Agency's premises, following decisions taken in 2011 linked to changes in the organisational structure, will be required and are planned to take place in 2012. Some further improvements in the technical infrastructure will also be necessary in order to ensure the operability of the premises.

At the request of the European Parliament, a purchase option for the building was included in the lease contract between ECHA and its landlord. In 2012, ECHA will further explore, with the Budgetary Authority, whether the opportunities to execute this clause would merit further consideration.

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 2012	Means and frequency of verification
Percentage of establishment plan posts filled at the end of the year.	95%	Annual internal report
Percentage of selection procedures planned for the year completed.	90%	Annual internal report
Turnover of Temporary Agents.	< 5%	Annual internal report
Average number of training and development days per staff member.	10	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, (numbering approximately 600 persons overall).
- An estimated 10 selection procedures to be launched.
- An estimated 70 recruitments to be completed.
- An average of 10 training days per staff member.
- Performance appraisal and reclassification exercise for close to 500 statutory 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.
- Active development of the people and performance management processes and methods.

Corporate services

- Timely purchase of equipment, materials and services through appropriate procurement procedures.
- Timely calculations and reimbursements of 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 2012

In 2012, ECHA will pursue the further enhancement of its IT operations by implementing the outsourcing of the hosting services for its ICT infrastructure; the main objective being to progressively provide enhanced Business Continuity for the mission critical IT-services. REACH-IT, the ECHA website, the e-mail system, and Internet connectivity will receive the highest priority, in 2012, since they are at the core of ensuring continuity of service for the 2013 REACH registration deadline. The outsourced services will also provide a new and more secure storage location for the regular off-site back-ups.

IT Security management in relation to network connections, data access, monitoring, incidents management and designing secure software will be constantly improved and fine-tuned to meet ECHA's challenging confidentiality obligations vis-à-vis the constant evolution of information systems, and to mitigate external threats.

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:

- introducing a Human Resources Management System (HRMS) – work on which began in 2011;
- enhancing the time management system;
- completing the introduction of an Identity Management system (IDM), initiated in 2011, for the centralised management of users' credentials, groups and distribution lists, and the provisioning and de-provisioning of users' accounts. Harmonisation of users management across existing applications will be tackled to consolidate the current application-specific solutions;
- leveraging on the basis set in 2011 for cost-accounting, work planning, time management and on the existing targeted reporting tools, ECHA will investigate a consolidated corporate model for planning and reporting potentially supported by information systems.

In 2011, ECHA established a precise sourcing strategy for the advancement of its ECM programme; in 2012, the challenge will be to scale up operations to tackle a faster implementation of the ECM roadmap with increased capacity. Besides completing workflow support to the Evaluation processes started in 2011, ECHA will tackle two additional areas and, in particular, the external collaboration processes (e.g. the processes related to the Committees' operations) with a view to starting a progressive replacement of the IT functions currently covered by CIRCA.

Engineering of ICT processes and services will be an ongoing effort in order to meet the challenges of providing high quality IT support to a complex and modern administration.

2. Objectives and Indicators

<u>Objectives</u>

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. A consistent and common corporate architectural approach is assured; best practice in governance and management of IT projects, fostered; and professional, competent and timely responses to any of the planned or recurring business activities, ensured.

Performance Indicators & Targets

Indicators	Target in 2012	Means and frequency of verification
Availability of mission-critical systems for external customers (i.e. uptime during attended service hours).	99%	Data centre statistics
Level of internal user satisfaction with IT services, relative to staff/support ratio.	High	Annual customer survey and *ad hoc* feedback
Level of coverage of mission-critical systems in the business continuity solution involving external data centre(s).	REACH-IT, the ECHA website, the e-mail system and the Internet connectivity are covered	Annual internal report

3. Main outputs

- Provision of services to keep the ICT infrastructure and ICT resources operational and at the appropriate level of performance.
- Establishment of an IT-Security management function.
- Establishment of a Business Continuity solution for mission-critical IT systems leveraging on the outsourced hosting services (priority is given to the systems which are core to the 2013 REACH registration deadline).
- Extending the coverage of operational and administrative workflows in the Enterprise Content Management programme.
- Running the Project Portfolio Office.
- Implementation of an HR management information system.
- Deployment of a time recording system.
- Completion of the implementation of an Identity Management System.
- ECM capacity fully operational according to the new sourcing strategy, and two new areas covered in the ECM programme roadmap.
- The solution for the external collaboration processes (e.g. the processes related to the Committees' operations) is defined for implementation with a view to starting a progressive replacement of the IT functions currently covered by CIRCA.

4. Activity 16: Biocides

1. Main challenges in 2012

The new Biocides Regulation is expected to be adopted in mid-2012 with entry into operation in September 2013[8]. This Regulation will considerably extend ECHA's regulatory remit with regard to technical and scientific tasks related to the implementation of the Regulation. The foreseen timetable leaves twenty months in which to prepare for the foreseen tasks, which is a considerable challenge for ECHA.

In 2012, ECHA has to extend the so far very limited preliminary preparations into a full preparatory programme, while avoiding any adverse effects on the implementation of REACH and CLP. This will include the following key challenges:

- Ensuring that ECHA will be ready in time to receive and handle applications on active substances, take over the Review Program from the European Commission (DG JRC) and on Union authorisation of biocidal products, following the timelines and transitional periods in the Regulation.
- Analysis of how to adapt REACH-IT and IUCLID to biocides needs to be finalised to build up the Register on Biocidal Products (R4BP) and the first stage of implementation needs to start.
- Work on biocides guidance and manuals has to progress very quickly in order to enable companies to have key guidance in place well in advance of the new provisions becoming operational.
- ECHA also needs to contribute to a series of implementing and delegated acts to be issued by the Commission, including the new Biocides Fee Regulation.
- ECHA needs to be prepared to handle other tasks related to biocides, and in particular, concerning data sharing, the so-called free riders, and establishing the technical equivalence, including the related appeal procedures. Submission pipelines will need to be developed for these different tasks.
- The Biocidal Products Committee needs to be established and the working practices and relevant rules and procedures developed to enable it to start its routine work as from 1 September 2013. Informal preparatory meeting(s) may need to be organised in the second half of 2012. Also the secretariat function of ECHA for the Coordination Group needs to be established.
- A communication plan has to be developed to raise the awareness of companies and stakeholders about their new responsibilities, and implementation of the plan needs to start. This will focus on the new obligations for companies, as compared to the current Biocidal Products Directive (the so-called 'free riders', technical equivalence and Union authorisation). A key element in the communication will be the establishment of a dedicated website for biocides, including the smooth handover of the relevant web-sections from the DG JRC, which will need to begin in 2012.

Rapid recruitment of new staff, and their induction and training is key to the effective start of the biocide tasks.

[8] The proposal initially envisaged that the date of applicability of the Regulation would be 1 January 2013. However, the Commission, in its Communication on the Council position at the first reading, proposed that the applicability date be postponed to 1 September 2013.

2. Objectives and Indicators

Objectives

1. Ensure preparedness of ECHA to start new biocides operations from the date of application in an effective and successful way.

2. Setting up of new procedures, tools, and organisational structures as well as selection and capacity building of new biocide experts.

Performance Indicators & Targets

Indicators	Target in 2012	Means and frequency of verification
Not applicable in 2012.		

3. Main outputs

- Analysis and design of Register for Biocidal Products (R4BP) is finalised and implementation has started.
- Incorporation of biocides features in foreseen IUCLID5 release including an inventory of additional user requirements for IUCLID6.
- First draft key guidance documents are developed, a comprehensive program for developing other biocides guidance is established.
- Draft procedures and necessary documentation have been developed to carry out the tasks of the ECHA Secretariat to handle applications, including regarding cooperation with Member States and industry.
- Draft procedures and necessary documentation have been developed to deal with tasks related to data sharing, free riders, and technical equivalence.
- Appointment of Members, provision of Chair and Secretariat, and organisation of first informal meeting(s) of the Biocidal Products Committee, if necessary. Establishment of ECHA secretariat for Coordination Group.
- Preliminary work plan and the necessary rules of procedures for the Biocidal Products Committee.
- Training program for new biocides staff is developed and its implementation is started.
- Staff model is further developed including the organisational setting within ECHA of the biocides activities.

5. Activity 17: PIC

1. Main challenges in 2012

In May 2011, the European Commission adopted a proposal for a recast of the Regulation concerning the export and import of dangerous chemicals (Regulation 689/2008, the so-called PIC Regulation). An important element of the proposal is to move the scientific and technical aspects of the implementation of the Regulation from the Commission Joint Research Centre to ECHA. It is foreseen that the adoption of the Regulation could take place in 2012 with expected entry into operation in 2013.

In order to ensure a successful implementation of this new regulatory task, ECHA needs to undertake a series of preparatory activities, while avoiding any adverse effects on the implementation of REACH and CLP. The most urgent and extensive of these will be to carry out an analysis, in cooperation with DNAs, and start implementing new IT-functionalities to deal with the export notifications in an effective way, also taking into account the strict deadlines in the legislation. In addition, ECHA will need to set up new guidance and manuals, as well as initiate awareness-raising and communication activities related to the new legal obligations and ECHA's new role.

Furthermore, ECHA needs to quickly set up internal capacity to deal with the new responsibilities, through the recruitment and training of new staff. This is needed to support the implementation of the new operational tasks as well as to provide scientific and technical advice for the Commission in the implementation of Rotterdam Convention. ECHA also will start creating the network with Designated National Authorities of the Member States and with third countries, with a view to agreeing on common principles and practises of cooperation.

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.

2. Ensure setting up of new procedures and tools, as well as the capacity building of staff implementing the new tasks.

Performance Indicators & Targets

Indicators	Target in 2012	Means and frequency of verification
Not applicable in 2012.		

3. Main outputs

- Significant progress in the development of export notification submission procedures, IT tools, and related manuals for export notifications procedures in cooperation with DNAs.
- Significant progress in developing procedures to deal with the explicit import consent procedure.

- Necessary contacts with the Member States and third countries are established.
- Recruitment of new staff is started and capacity building program is developed.

6. Agency risks

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

ECHA is subject to many external pressures and expectations which can force the Agency to change its priorities or add new ones on top of the existing ones. This could lead to inefficient use of resources and delay the achievement of objectives. As a mitigating measure, any resource implications from reprioritisation or from the assumption of new tasks, will have to be calculated carefully before being accepted.

As in 2012, a record number of testing proposals will have to be examined and also an ambitious number of compliance checks conducted; ECHA's ability to manage the processing efficiently is fundamental to the achievement of its objectives 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. As the workload of the Committees is rapidly increasing, their ability to ensure the expected output is at risk, if their members do not get the adequate level of support from the Member State Competent Authorities, as required by REACH. ECHA will therefore reinforce its dialogue with the Member States, especially in relation to the input and contribution it needs from the MSCAs for the implementation of the Work Programme.

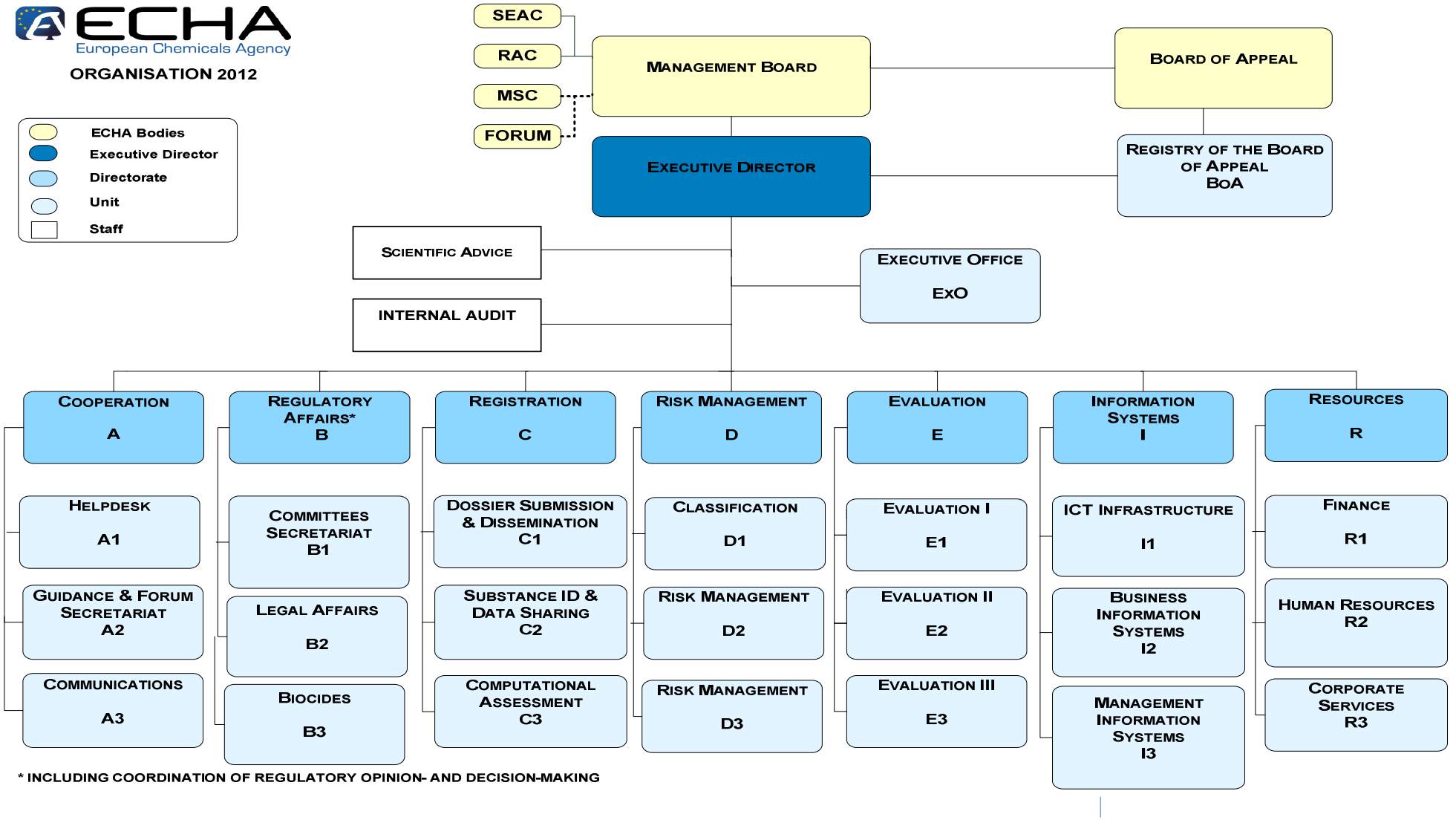
This Work Programme and ECHA's longer term planning is based on the so-called baseline figures presented in Annex 2. These figures derive from the original estimates of the Commission developed when the REACH Regulation was prepared, and from subsequent updates made by ECHA in cooperation with industry and other stakeholders. Due to the high uncertainty linked to these figures, an important risk remains in relation to the planning of its human resources, both quantitatively and qualitatively. Moreover, based on a sound staff model developed in 2011, ECHA will make the best use of available resources. As regards the two new legislations, Biocides and PIC, avoiding any delays in the recruitment of new staff is the only way to ensure that ECHA will be able to prepare itself for its new tasks.

ECHA's activities rely heavily on efficient IT systems for the processing of the different types of dossiers received by the Agency. Any problems or delays in IT development could threaten the achievement of objectives as planned. In order to mitigate this risk, ECHA has put in place a long term IT development plan in 2011, including a resource plan. However, the risk remains in particular with regard to the efficiency gains expected through the IT tools.

An additional human resource risk that ECHA has identified relates to the retention of its scientific capacity in the long term. At the time of writing, ECHA is still growing rapidly in terms of new staff, but recruitment will slow down considerably from 2012 onwards. Inevitably, some staff members will begin to consider alternatives after having worked for the Agency for a number of years; therefore, ECHA intends to emphasise the development of a strategy to retain its high scientific capacity in the future.

A longer term risk that has been identified, relates to the resources available to the Agency after 2013. It is estimated that ECHA will need an EU subsidy after 2013 and its needs should be taken into account in the financial perspectives to be negotiated for the EU for 2014-2020.

ANNEX 1: ECHA Organisation 2012



ANNEX 2: Activity levels used for the Work Programme

Baseline figures for 2012

Main drivers of ECHA activities	Estimate for 2012
Dossiers arriving in 2012	
Registration dossiers (including updates)	5100
Testing proposals	10
Confidentiality requests	320
Access to data older than 12 years	120
PPORD notifications	200
Inquiries	1800
Number of notifications under Article 7(2)	70
Number of reports/notifications under Article 38 of REACH	11 700
Restriction proposals (Annex XV)	10
Restriction proposals developed by ECHA	3
Proposals for harmonised classification and labelling (Annex VI of CLP Regulation)	60
Proposals for identification as SVHC (Annex XV)	40
SVHC proposals developed by ECHA	5
Authorisation applications	30
Alternative name requests	50
Substances on the CoRAP to be evaluated by MS	40
ECHA decisions in 2012	
Decisions on dossier evaluation - no. of decisions on TP - no. of CCH concluded o Out of which CCH decisions (30%)	 360 250 75
Decisions on data sharing	75
Decisions on completeness check (negative, i.e. rejections)	10
Decisions on access to documents requests	300
Decisions on confidentiality requests (negative)	30
Appeals submitted in 2012	40

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)	7000
SME checks	300
Management Board meetings	4
MSC meetings	6
RAC meetings	7
SEAC meetings	4
Forum meetings	3
New TA/CA posts to be filled REACH/CLP	*20*
Recruitment due to turnover	25
New TA/CA posts to be filled for Biocides	19
New TA/CA posts to be filled for PIC	4

ANNEX 3: Estimated resources for 2012

	Staff resources WP2011			Final Budget 2011	Staff resources 2012			Budget 2012
The numbering below refers to the WP 2012, not to the numbering in the budget	AD	AST	CA		AD	AST	CA	
Implementation of the Regulatory Processes (operational budget)								
Activity 1: Registration, data-sharing and dissemination	34	11	7	1 151 289,00	34	11	8	1 229 800,00
Activity 2: Evaluation	81	13	2	440 198,00	85	13	4	2 964 050,00
Activity 3: Risk management	32	7	2	1 496 675,00	36	7	7	1 269 000,00
Activity 4: Classification and labelling	13	3	2	230 258,00	14	3	4	287 500,00
Activity 5: Advice and assistance through guidance and helpdesk	26	11	5	967 469,00	24	10	6	904 460,00
Activity 6: IT support to operations	28	8	0	12 793 811,00	28	8	2	12 777 850,00
Activity 7: Scientific activities and technical advice to EU institutions and bodies	5	0	1	308 623,00	8	0	3	724 700,00
ECHA's bodies and supporting activities								
Activity 8: Committees and Forum	21	8	3	1 868 183,00	21	8	4	2 071 120,00
Activity 9: Board of Appeal	9	6	5	362 801,00	7	5	2	191 000,00
Activity 10: Communications	10	9	8	7 739 753,00	10	9	8	6 765 480,00
Activity 11: International cooperation	4	0	0	777 845,00	5	1	0	684 840,00
Management, organisation and resources								
Activity 12: Management	24	14	3	1 603 095,00	25	15	4	2 255 150,00
Total REACH and CLP	**287**	**90**	**38**	**29 740 000,00**	**297**	**90**	**53**	***32 124 950,00***
Activities 13-15: Organisation and resources (Title II: Infrastructure)	24	55	28	15 587 000,00	24	55	30	**14 619 700,00**
Title I (staff expenditure)[9]				54 473 000,00				**55 921 350,00**
Total	**311**	**145**	**66**	**99 800 000,00**	**321**	**145**	**83**	**102 666 000,00**
In Establishment plan:	**456**				**466**			
Activity 16: Biocides	NA		NA	NA	11	0	8	2.756.500
Activity 17: PIC	NA		NA	NA	1	2	1	1.470.300

[9] It is assumed that ECHA gets a subsidy and therefore does not need to pay the pension contributions.

ANNEX 4: Procurement Plan

[To be inserted in December 2011]