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WORK PROGRAMME OF THE EUROPEAN CHEMICALS AGENCY FOR 2011

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(Document adopted by the Management Board)

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List of Acronyms

AD	Administrator
AST	Assistant
C & L	Classification and Labelling
CA	Contract Agent
CARACAL	Competent Authorities for REACH and CLP
CASPER	IT Characterisation Application for Selection, Prioritisation, Evaluation and Reporting
CHESAR	Chemical Safety Assessment and Reporting tool
CLP	Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic or toxic to Reproduction
COM	European Commission
CoRAP	Community Rolling Action Plan
CSA	Chemical Safety Assessment
DU	Downstream user
DCG	Directors' Contact Group
eChemPortal	Global portal to information on chemical substances
EA	Enterprise Architecture
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
EMAS	Eco-Management and Audit Scheme
ERP	Enterprise Resource Planning
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work
FAQ	Frequently Asked Questions
Forum	Forum for exchange of enforcement information
HR	Human Resources
IPA	Instrument for Pre-Accession Assistance
IQM	Integrated Quality Management
ISO	International Organization for Standardisation
IPPC	Integrated Pollution Prevention and Control
ICT	Information Communications Technology
IT	Information Technology
IUCLID	International Uniform Chemical Information Database
MB	Management Board
MoU	Memorandum of Understanding
MSC	Member State Committee

MSCA	Member State Competent Authority
OECD	Organisation for Economic Cooperation and Development
Odyssey	ECHA's tool in support of 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
SAICM	Strategic Approach to International Chemicals Management
SEAC	Socio-Economic Analysis Committee
SLA	Service Level Agreement
SME	Small and Medium-sized Enterprises
SIEF	Data Sharing & Substance Information Exchange Forum
SVHC	Substance of Very High Concern
TA	Temporary Agent
UN GHS	United Nations Global Harmonised System of classification and labelling of chemicals.
vPvB	very Persistent and very Bioaccumulative
WFD	Water Framework Directive
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 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's mission is
- to manage all REACH and CLP tasks by carrying out or coordinating the necessary activities, in order to ensure a consistent implementation at EU level
- to provide Member States and the European institutions with the best possible scientific advice on questions related to the safety and the socio-economic aspects of the use of chemicals.

This is achieved by ensuring a credible and consistent decision-making process, using the best possible scientific, technical and regulatory capacities in order to achieve compliance with the REACH and CLP Regulations.

ECHA's Vision

ECHA's vision is to become *the* internationally recognised Agency on any question related to the safety of industrial chemicals, and a source for reliable and high quality information on chemicals for the benefit of all citizens.

ECHA will be a benchmark regulatory authority that attracts highly motivated and talented staff by applying the most modern administrative practices and staff policies. Industry should perceive ECHA as a reliable partner providing advice and assistance as needed.

ECHA's values

As a modern public administration, ECHA's values are transparency, impartiality, accountability and efficiency; it will manage the REACH and CLP operations in a secure, professional and science-based manner.

ECHA attaches importance to its independence from all external interests, while at the same time closely cooperating with all stakeholders, the European institutions, and Member States. The Agency pursues a strong policy of equal opportunities and environmental friendliness.

Introduction

This Work Programme outlines the European Chemicals Agency's objectives for 2011, which will be its fourth year of activity. The Multi-Annual Work Programme 2011-2013, adopted in June 2010 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 fifteen Activities. Each Activity has a set of objectives and outputs, as well as performance indicators, with which achievements can be followed up.

Due to the time limits set down in the REACH Regulation, this Work Programme was first adopted in September 2010 at a time when the first REACH registration deadline, falling at the end of 2010, was still some months ahead. As the end result of the registrations in terms of number of dossiers submitted, testing proposals and confidentiality claims was decisive for ECHA's workload and finances in 2011, the Work Programme has been reviewed in December 2010. It should be underlined, however, that the baseline numbers relating to other activities, in particular authorisation, restrictions and appeals are still subject to a high degree of uncertainty.

The budget and the establishment plan for human resources, which are the basis for the Activity based allocation presented in Annex 3, have been adopted in December 2010 by the Management Board. However, the budget shall become final only following the adoption of the general budget of the European Union. Also the establishment plan will need to be adopted by the budgetary authority i.e. European Parliament and Council.

ECHA's challenges and priorities for 2011

A first challenge for ECHA in 2011 will be to successfully finalise the processing of the registration dossiers received by the first REACH registration deadline of 30 November 2010.

Making information on the chemicals registered publicly available, free of charge, is expected to have a positive impact on health and environmental protection in Europe and worldwide. Therefore, a core activity in 2011 will be to process the information on substances registered in 2010, assess whether requests for confidentiality provided by the registrants for certain parts of their dossiers are justified, and publish the non-confidential parts of the registration dossiers on the ECHA website.

Following the November 2010 registration deadline, the main challenge for ECHA will be the evaluation of the registered dossiers. The high-production-volume phase-in substances that will be registered by the first deadline will contain the highest level of information per dossier and many testing proposals. Due to the fixed deadlines for these evaluations, ECHA will have to focus its evaluation capacity in 2011 on testing proposals. Furthermore, ECHA will make sure that the first draft Community rolling action plan will be submitted well before the end of 2011.

As Annex XIV of REACH, which sets out a list of substances subject to authorisation, is expected to be adopted and published by the Commission in early 2011, ECHA will ensure its readiness to receive and process authorisation applications from industry.

Another challenge derives from the deadline of 3 January 2011 relating to classification and labelling notifications. After the deadline, ECHA will maintain the C&L inventory, develop it further and publish a non-confidential version of it on the ECHA website.

In line with the policy target set by the Commission earlier in 2010, the number of proposals for identification of substances as SVHCs is expected to increase. This will mean that, together with a higher number of restriction proposals and the first authorisation applications to be submitted by industry, the Secretariat and ECHA's scientific committees will be faced with increase in workload in 2011.

ECHA will step up, in 2011, its scientific and technical advice to the Commission and the Member States, making full use of its scientific platforms and its evaluation and risk management work. This will concern, in particular, questions related to nanomaterials and endocrine disruptors.

As far as the provision of scientific and technical advice to industry via guidance and helpdesks is concerned, special emphasis will be put on helping SMEs to prepare for the second registration deadline in 2013. Awareness-raising and providing information on obligations will be important elements in helping companies to prepare properly. The experiences gained from the first registration and notification deadlines will help ECHA to further develop its advisory capacity, in particular with a view to avoiding unnecessary animal testing and to simplifying guidance. Focus will continue to be put on translating guidance and other documents aimed at SMEs and the general public.

Given that the success of the REACH and CLP Regulations also depends on harmonised and effective enforcement, the support provided by the ECHA Secretariat to the Forum will continue to receive prominent attention in the Work Programme.

Implementation and enforcement of the REACH and CLP Regulations require a wide range of IT systems; their further development and maintenance will continue to be crucial for ECHA's operations. Based on the experience gained in 2010, ECHA will be in a position to develop intensively, and/or revamp where appropriate, the existing systems to make them more efficient and user friendly, with REACH-IT and IUCLID5 remaining the cornerstone applications of the Agency.

Based on reporting obligations in the REACH Regulation, ECHA will draw up the first five-year report for the Commission on the operation of the REACH Regulation, and in this context will also make suggestions for improving the workability of the Regulation. In addition, ECHA will draw up the first three-year report for the Commission on the status of implementation and use of non-animal test methods and testing strategies.

The pace of growth of the Agency, in terms of staff, will have peaked by the beginning of 2011. To ensure sound and consistent decision-making, a major reorganisation will take place at the start of year. It will be an important management challenge to ensure that this takes place smoothly, in particular by adapting management processes to a more decentralised organisational structure, and by ensuring their effective coordination and implementation. The primary focus of the ECHA management in the financial field will be on efficient liquidity management and rigorous budget discipline, as the Agency will be fully self-financing through fees and charges with regard to REACH and CLP activities over the period 2011-2013 while having, at the same time, to reimburse the EU subsidy received in 2010. Human resource management will steer its emphasis from the massive recruitment exercises of previous years towards staff retention, with reinforced attention to learning and development, innovative strategies in organisational development, and dedicated care for the wellbeing of staff.

1. Implementation of the REACH and CLP Processes

Activity 1: Registration, data-sharing and dissemination

1. Main challenges in 2011

Registration

REACH is based on the principle that the responsibility for the identification and management of risks from a substance lies with the company that manufactures, imports, markets, or uses the substance. Companies that manufacture or import substances in quantities of 1 tonne or more per year need to demonstrate that they have taken 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 regulation fee, before assigning a registration number.

The first REACH registration deadline of 30 November 2010 is for registration of high volume substances (1 000 tonnes/year or more) and for certain types of substances of concern. By that date ECHA received almost 25 000 registration dossiers, a number matching the original Commission estimate and the baseline scenario foreseen by ECHA. ECHA will have until 28 February 2011 to process these dossiers, but due to successful automation of some major steps in the dossier processing, the task will be completed earlier. The number of re-submissions is expected to be low as a very low proportion of the registration dossiers are failing the completeness check, thanks to the tool provided by ECHA for the industry to perform a completeness check test before submitting the dossier. ECHA will continue monitoring registration-related issues with its partners, including through the Directors' Contact Group (DCG)[1], that are relevant for registrants and downstream users even after the first registration deadline. A steady number of registrations for new substances and dossier updates are expected throughout 2011.

Information on the first wave of registrations, including an assessment of the joint submission process and of the reasons for submitting information separately, will be part of the first report of ECHA to the Commission on the operation of the REACH Regulation, due on 1 June 2011[2]. In addition, the registration process and related data sharing processes will be reviewed, also together with the DCG, in light of lessons learned (including appeals) to prepare for the next registration deadline of 2013.

From 1 June 2011, ECHA will begin to process the notifications of substances in articles[3] where the substances appear on the candidate list and fulfil the criteria set out in the legislation. ECHA will prepare principles and procedures for evaluating these notifications with a view to identifying when a full registration will be requested to promote effective risk management. Administration of downstream user (DU) reports will also start in 2011. DUs need to report uses not covered by their supplier's registration and for which a chemical safety report is required or where the DU relies upon a specific exemption. These reports are expected to be submitted in very large numbers (baseline estimate: 45 000). Lastly, the work associated with PPORDs in 2011 is expected to remain at the level of 2010.

[1] The Directors' Contact Group (DCG) consists of representatives from the European Commission, ECHA and industry associations. The objective of the group is to find practical solutions to issues which are seen as barriers to registration..

[2] REACH Art. 117(2).

[3] If they are present in quantities totalling over one tonne per producer or importer per year and present in those articles above a concentration of 0.1 % (w/w).

Data sharing

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. Successful data sharing, and hence the success of REACH, is very dependent upon a clear understanding of substance identity. Data on the "same" substances can be shared, while data cannot be shared for different ones. However, information on substance identity also underpins "read across", grouping of substances and (Q)SARs (Quantitative Structure Activity Relationships) which are all ways of using the information available on one substance (or group of substances) to fill data gaps for another different one, without resorting to further testing on vertebrate animals. The need to provide advice and support to industry on substance identity and upon the opportunities for "read across" to underpin data sharing are expected to increase in 2011, as more registrants, often with limited data sets, seek to prepare for registration for the later deadlines.

Data sharing requests and disputes (should they occur) can be divided into those following inquiries concerning non-phase in substances and those arising from disagreements within SIEFs. There was an unexpected increase in the number of inquiries in the last three months of 2010, mostly due to inquiries for phase-in substances. Despite steps taken to optimise the inquiry process, it is expected that a part of backlog will be carried over to 2011. It seems also reasonable to assume that the number of inquiries will remain on a relatively high level in 2011, taking also into account that many of them need to be resubmitted due to poor quality of initial submission.

Data sharing within SIEFs is different. From 2011 onwards, ECHA support to data sharing will increase further: in particular to help companies preparing for the 2013 deadline who are trying to obtain the contact details of previous registrants, in order to be part of a joint registration. Requests to share data may arise before a registration for a substance has been submitted or afterwards. The latter will predominate in 2011 as those SIEF members that manufacture or import less than 1000 tonnes/year seek to register when the lead registrant submitted before the 2010 deadline. In case of disagreement, companies may request ECHA's intervention. Where agreement on the sharing of a study involving testing on vertebrate animals cannot be reached, ECHA may in certain cases take a decision or give permission to refer to the information already submitted. These lower tonnage registrants are more likely to be SMEs. Whatever ECHA's decision, appeals from the other party can be expected, and preparing ECHA's legal defence could require a substantial amount of work. Lastly, existing IT systems and procedures will be re-examined to seek improvements based upon the experience of working on pre-registration in 2008 and registration in 2010.

Dissemination

Making information on chemicals publicly available, free of charge, on the ECHA website is expected to have a positive impact on health and environmental protection in Europe and worldwide. One core activity in 2011 will be to process the information on substances registered in 2010, assess whether requests for confidentiality provided by the registrants in their dossiers are justified, and publish the non-confidential information on the ECHA website. Based on the registration dossiers for which ECHA has already granted registration number, it seems that 2% of the phase-in substance registrations and 35% of the non-phase-in substance registrations contain confidentiality requests. The assessment of confidentiality requests submitted by 30 November 2010 would therefore nearly be finalised in 2011. In any case, priority will be given to dossiers with a testing proposal or under compliance check. Moreover, ECHA will streamline the automated extraction of non-confidential information from the registration dossiers and – in the

context of the renovation of the ECHA website – will also renovate the dissemination website so that usability and user-friendliness are significantly improved.

2. Objectives and Indicators

Objectives

1. All dossiers and data sharing disputes are processed, and PPORD notifications and confidentiality claims assessed, according to the standard procedures adopted by ECHA and within the deadlines set in the REACH Regulation.
2. Inquiries are processed according to the standard procedures adopted by ECHA, within the target timeframe of 20 working days.
3. Decisions on registrations and PPORD notifications are of a high technical and scientific quality.
4. Public information from all dossiers of substances registered before the first registration deadline is published on the ECHA website.

Performance Indicators & Targets

Indicator	Target in 2011	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 established timeframe (20 working days).	≥ 90%	Time recorded in REACH-IT monthly reporting
Percentage of assessed confidentiality requests in the registration dossiers submitted for the 2010 the registration deadline.	≥ 90%	Recorded in REACH-IT, quarterly reporting
Percentage of registration dossiers (non-confidential information) published on the ECHA website.	≥ 80%	Annual internal report
Number of appeals made by registrants and notifiers against decisions.	≤ 10% of decisions	Monitoring responses to decisions monthly

3. Main outputs

- Dossiers for phase-in substances deriving from the 2010 deadline processed, invoices sent and payments received, and data sharing disputes processed according to the appropriate deadlines.
- Registration dossiers for non phase-in substances, inquiry dossiers, intermediates and Product and Process Oriented Research and Development (PPORD) notifications, received and processed.

- Registrations for phase-in substances with later deadline but for the same substance for which the lead registrant has successfully registered by the 2010 deadline, processed.
- 250 new confidentiality requests (from registration dossiers for non-phase-in substances, registration dossiers for phase-in substances submitted in 2011, and updates of registration dossiers in 2011) and 1000 confidentiality requests deriving from the 2010 registration deadline, assessed.
- Established principles and procedures for requesting registration of substances in articles.
- Procedure and systems put in place to process downstream user reports for uses not supported by their suppliers (Article (38) of the REACH Regulation) and manufacturer/importer notifications for non supported uses identified by downstream users (Articles 37(3) and 38 of the REACH Regulation).
- Information from the registrations received in 2010, published on ECHA website and linked to the OECD eChemPortal.

Activity 2: Evaluation

1. Main challenges in 2011

Dossier Evaluation

Dossier evaluation comprises both examination of testing proposals and compliance checks. It involves scientific decision-making using expert knowledge from a variety of scientific disciplines. ECHA decisions will be under scientific and legal scrutiny by the affected registrants and by the Member States. This in turn requires that the scientific judgements are well founded and also that they are converted into legally sound decisions. It is evident that this poses major challenges 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. The workload driver for the examination of testing proposals is the number of substances registered, since it is expected that data sharing obligations will lead to the joint submission of testing proposals per substance. For non-phase-in substances, the draft decision should be prepared within 6 months and for phase-in substances registered by 1 December 2010, a draft decision must be ready by 1 December 2012.

In addition, ECHA is obliged to carry out compliance checks on at least 5% of the submitted registrations per tonnage band. The workload driver for compliance checks is therefore the number of dossiers received per tonnage band. However, due to the large variation in the number of dossiers registered per year, with a bulk of registration dossiers expected in the years 2010, 2013 and 2018, the legislator has not defined a timeframe within which the 5% target should be met. On the basis of the number of testing proposals and the number of registration dossiers submitted, ECHA will further develop its multi-annual timetable for achieving the target of not less than 5 % for compliance checks by the end of 2013.

Continued scientific and administrative capacity building 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, and ECHA expects that a considerable part of this information will not have been generated using current standard and quality assured testing methodology. 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 initiate approximately 500 and conclude 350 testing proposal examinations and compliance checks in 2011. As all 580 dossiers with testing proposals submitted in 2010 will have to be evaluated within the deadlines described above, they will be given priority and the remaining capacity will be used for compliance checks, noting however that a proportion of testing proposal examinations are also likely to trigger a parallel compliance check to react to shortcomings of high priority.

As part of the compliance check activities, ECHA will also continue to evaluate dossiers registered as intermediates with a view to confirming that the status as an intermediate or the application of strictly controlled conditions is correctly documented and adequate proof is provided in the dossier, and issue draft decisions when appropriate.

The general results of the evaluation processes from 2010 (described above) will be contained in the annual progress report provided by ECHA in line with Article 54 of the

REACH Regulation, at the end of February 2011. 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. In addition, ECHA will use other 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 pay attention to the quality of Chemical Safety Reports and exposure scenarios and communicate its findings and recommendations for improvements to individual registrants or to industry at large, as appropriate. These activities will contribute to the overall success of the REACH Regulation, and to the safe use of substances along the supply chain, by generating the necessary information while avoiding unnecessary animal testing.

The Chemical Safety Assessment (CSA) is a core element of REACH. For ECHA, it will be a challenge to process the Chemical Safety Reports (CSRs) submitted with the registration dossiers, to evaluate and use the information contained in the CSRs, and to support industry in improving their quality. In the coming years, concepts and methods related to the CSA need to be further developed. Consequently, ECHA has identified the need to set up an internal cross-cutting programme on CSA development, in order to provide guidance and tools to industry to generate high quality CSA/Rs, ensure consistency and efficiency of decision-making in the Agency, and to further develop its methodology related to CSA.

Substance Evaluation

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

The first draft Community rolling action plan (CoRAP) for substances subject to substance evaluation has to be submitted by the ECHA Secretariat to the Member States by 1 December 2011, and will be updated annually. ECHA will develop criteria for prioritising substances for substance evaluation in cooperation with the Member States. The MSCAs will select substances from the CoRAP and subsequently start their evaluations. ECHA has a coordination role in establishing and updating the CoRAP; the Agency also ensures the consistency of decisions on information requests. Building on preparatory work undertaken in 2010, ECHA will continue to work in dialogue with the Member States to submit the first draft CoRAP. The main conclusions of a workshop on priority setting organised at the end of 2010 will be the basis for the development of the CoRAP list by the end of 2011.

2. Objectives and Indicators

Objectives

1. Scientifically sound draft decisions in compliance with the legal requirements are prepared.
2. ECHA has an updated multiannual plan for evaluation.
3. ECHA has created the foundation for an effective start to substance evaluation.

Performance Indicators & Targets

Indicator	Target in 2011	Means and frequency of verification
Percentage of compliance checks treated within the legal timeframe.	100%	Quarterly internal report
Percentage of testing proposals examined within the legal timeframe.	100%	Quarterly internal report
Percentage of the draft decisions accepted unanimously by the MSC.	90%	Annual internal report
Number of appeals lost.	0	Annual internal report

3. Main outputs

- Evaluation started or completed for up to 500 dossiers (compliance checks and testing proposals).
- 350 completed dossier evaluations leading to a draft decision, quality observation or no further action.
- First draft Community Rolling Action Plan for substance evaluation by 1 December 2011.
- Update of the multiannual plan for dossier evaluations.
- Publication of the annual report on evaluation as required by the REACH Regulation.
- Continued capacity and knowledge building for dossier evaluation, including integration of additional staff, implementation of specific training programmes and seminars on selected topics in the fields of toxicology, eco-toxicology and exposure assessment.
- Further development and utilisation of the network of external experts to provide up-to-date scientific expertise in evaluation processes.

Activity 3: Authorisation and restrictions

1. Main challenges in 2011

Authorisation

As a consequence of policy statements made by Commission Vice-President and Commissioner for Industry and Entrepreneurship Antonio Tajani and Commissioner for Environment Janez Potočnik on authorisation, during their visit to ECHA in March 2010, it is likely that in 2011 a significantly higher number of SVHC dossiers than in previous years will arrive at ECHA by the agreed submission deadlines in February and August.

The Commissioners, amongst others, agreed that the guidance document on authorisation applications should be amended and finalised by providing further clarity on the role of substitution and analysis of alternatives in the authorisation process. They also agreed on the revision of the PBT and vPvB criteria (draft proposal for revising Annex XIII of REACH) indicating that all available information is to be considered within a so-called 'weight of evidence' approach when assessing whether substances fulfil these criteria. Furthermore, the Commissioners agreed that the speed by which SVHCs should be identified and included in the candidate list needs to be accelerated, and discussions with Member States and ECHA have started on a roadmap to substantially increase the number of dossiers to be developed over the next few years.

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 has informed the Commission that it can prepare 15 dossiers over a period of 2.5 years and will support the Commission in identifying the best possible candidates. ECHA will also provide training for the Member States in preparing Annex XV dossiers for SVHCs to facilitate the submission of good quality dossiers from as many Member States as possible.

In 2011, under the condition that a sufficient number of new substances have entered the candidate list, ECHA will start a new priority setting process, eventually leading to a new recommendation for inclusion of substances in Annex XIV of REACH (list of substances subject to authorisation, or “authorisation list”) that will be submitted to the Commission by the end of 2011.

As regards the handling of authorisation applications in 2011, ECHA will finalise and streamline the procedures, formats and (technical) guidance/manuals which were initiated in 2010. Although there is still uncertainty as to when industry will submit its first authorisation applications, it is expected that some of these will arrive during the course of 2011, after the publication of the first authorisation list in early 2011. ECHA’s challenge will be to successfully manage these applications in the limited time available, and for the Secretariat, the challenge will be to provide high quality support to the RAC and SEAC in developing their opinions in a coherent manner.

Restrictions

In 2011, public consultation over four restriction dossiers[4], will have been finalised. The ECHA Secretariat will continue to provide high quality and timely support to the RAC and SEAC as they develop their opinions. The opinions are scheduled to be adopted towards

[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.

the autumn of 2011. Following which, ECHA will submit the opinions, with the relevant background information, to the Commission for final decision.

On the basis of the experience gained with the first restriction dossiers, ECHA will further improve the efficiency and effectiveness of dossier handling procedures and, if relevant, improve (parts of) the guidance and formats. ECHA expects a further ten restriction proposals to be submitted in 2011.

In 2011, ECHA will develop a framework for the identification of restriction needs (e.g. on CMRs in consumer articles or Annex XIV substances in (imported) articles) with the aim of coming to an agreement with the Member States and the Commission on a work plan for the development of Annex XV restriction dossiers for substances for which concerns have been identified (e.g. as a result of reviewing incoming registration dossiers).

Other activities related to Community risk management measures

For both the authorisation and restriction processes, ECHA will continue organising training events and workshops and provide advice to Member States on how to fulfil their tasks in preparing Annex XV dossiers for substances of very high concern or for restrictions, and in processing the comments received during public consultations. ECHA will also continue providing support and training to Member State Competent Authorities, in order to increase knowledge of the practical application of Socio-Economic Assessment and to provide further guidance on the selection of the best Risk Management Options for SVHCs and other substances for which risk management is considered necessary. There is also a need to support industry to ensure good understanding of their obligations with regard to the restriction and authorisation processes, and of their and third parties' possibilities to contribute effectively to these.

In 2010, ECHA has started to analyse in detail the interconnections between REACH and some other pieces of EU legislation (e.g. IPPC, WFD directives, workers protection legislation, product specific legislation) with the aim of developing closer relationships with the responsible policy services and relevant executive organisations (e.g. Agencies, IPPC bureau). Through these contacts, ECHA should be in a better position to explain how relevant information arising from REACH processes could be used effectively by others. Likewise, this will allow ECHA to provide better support to the Member States and the Commission during their discussions on risk management options, as well as to ECHA's RAC and SEAC during their assessment of authorisation and restriction proposals. Moreover, ECHA plans to organise a workshop on the interface between the REACH Regulation and occupational safety and health legislation together with the Commission towards the end of the year.

In 2011, ECHA will continue its activities to improve its knowledge of methodologies and estimates of the health and environmental impact of identified risks, e.g. through better understanding of the population at risk. This will increase capacity to assess the health and environmental benefits of using alternative chemicals or technologies in the context of socio-economic analyses. ECHA will also develop methodologies and collect estimates of disability/quality adjusted life years and willingness-to-pay to avoid negative health impacts from substances. Furthermore, ECHA will start a new activity to increase its knowledge and capability of assessing abatement and other costs related to restricting or not authorising the use of substances.

2. Objectives and Indicators

Objectives

i). Authorisation

1. An updated candidate list of substances of very high concern (SVHCs) is prepared within five months of receipt by ECHA of dossiers from Member States, or the finalisation of dossiers prepared by ECHA on the request of the Commission.
2. ECHA provides support of a high technical and scientific quality, and within the legal timeframe, to the Commission, in the selection of substances from the candidate list for authorisation and in the authorisation application process.
3. ECHA adequately and efficiently manages the authorisation application process within the legal timeframe.

ii). Restrictions

1. ECHA prepares restriction proposals at the request of the Commission and handles all dossiers in the restriction process to a high degree of scientific and technical quality and within the legal timeframe.

Performance Indicators & Targets

Indicator	Target in 2011	Means and frequency of verification
Percentage of SVHC dossiers treated within the legal timeframe.	100%	Quarterly internal report
Percentage of restriction dossiers treated within the legal timeframe.	100%	Quarterly internal report
Percentage of applications for authorisation treated within the legal timeframe.	100%	Quarterly internal report
Level of satisfaction of the Commission, MSCAs and ECHA Committees with the quality of the scientific, technical and administrative support provided.	High	Annual survey

3. Main outputs

- Two updates of the candidate lists published.
- Upon request by the Commission, Annex XV dossiers for substances of very high concern prepared.
- Depending on the availability of new substances on the candidate list, preparation of the submission of a new recommendation for inclusion of SVHCs in the authorisation list (Annex XIV).
- Conformity reports on Annex XV restriction dossiers produced and submitted to the Committees for opinion formulation.
- If requested by the Commission, Annex XV restriction dossiers prepared and submitted to the Committees for opinion formulation.

- High quality and timely support provided by the Secretariat to the RAC and SEAC for opinion development on restriction proposals and authorisation applications.
- A register of downstream users' notifications of their use of authorised substances established, and access to this database granted to MSCAs.
- Framework on identification of restriction needs established.
- A database of 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.
- Workshop on the interface between the REACH Regulation and occupational safety and health legislation.

Activity 4: Classification and labelling (C&L)

1. Main challenges in 2011

Classification & Labelling Inventory (C&L Inventory)

Classification reflects the hazards of chemicals, and labelling helps to ensure that substances and mixtures are manufactured, used and disposed of safely.

For 2011, the main challenge will be to establish and update the C&L inventory for chemical substances. The deadline for notifications of substances on the market is 3 January 2011, but even after this date notifications will be submitted to ECHA in order to update earlier notifications, or to include substances placed on the market only after 1 December 2010. ECHA will also start analysing the information in the inventory and publish a first version of the non-confidential information by mid-2011.

Different notifiers may indicate different classifications for the same substance. The notifiers will then have to make every effort to come to an agreement on the C&L of the substance. ECHA will analyse what practical possibilities it has to support this goal and initiate necessary activities.

Handling proposals for harmonised Classification and Labelling (C&L)
ECHA estimates to receive and/or process up to 90 proposals for the harmonisation of C&L of substances, resulting in RAC opinions on the proposed classification. ECHA will continue its co-operation with the European Food Safety Authority to set up procedures that allow the opinion on harmonised C&L to be developed for active substances in Plant Protection Products (PPP), within the stringent timelines for PPP authorisation.

Evaluating requests for use of alternative chemical names
ECHA is also in charge of handling requests for the use of alternative names. Companies can request the use of an alternative chemical name for a substance in a mixture in order to protect confidential business information.

Working procedures will be developed for handling requests from industry for use of alternative chemical names. The preparation of manuals and guidance will be finalised, and the modest number of requests expected to be received in 2011 will be reviewed within the legal timeframe.

2. Objectives and Indicators

<u>Objectives</u>

1. All proposals for harmonised C&L submitted by MSCAs and industry are processed within the legal timeframe and to a high degree of scientific quality.
2. Any request for the use of an alternative chemical name is processed within the legal timeframe.

Performance Indicators & Targets

Indicator	Target in 2011	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 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 of scientific background documents for such proposals.
- All notifications received by 3 January 2011 included in the classification and labelling inventory by mid-2011.
- Publication of the C&L Inventory based on the notifications received by the 3 January 2011 deadline.
- Requests for use of alternative chemical names evaluated and decisions made.

Activity 5: Advice and assistance through guidance and helpdesk

1. Main challenges in 2011

In 2011 the provision of scientific and technical advice via guidance and helpdesk activities will be reframed and simplified on the basis of lessons learned from the first registration and notification deadlines.

During 2011, the ECHA Helpdesk will continue providing timely and high quality support to industry on REACH and CLP, focusing, in particular, on providing advice on the forthcoming REACH processes on evaluation, authorisation and restrictions. Special emphasis will be given to SMEs in view of the next registration deadline, for which awareness-raising and information on obligations will be important elements in helping companies prepare properly. The Helpdesk will also intensify its activities of coordinating the HelpNet, the network of national helpdesks on REACH and CLP, and the use of its information exchange tool (HelpEx) as well as publishing harmonised replies by means of the publication of FAQs.

The provision of advice to industry and authorities via guidance from ECHA has been an operational task of the Agency since its inception and will continue to be a priority. In particular, 2011 will be mainly devoted to the integration of experiences learned from the first years of guidance activities while finalising and completing guidance updates initiated in 2010. Special emphasis will also be put on ensuring that those guidance documents that are needed for the forthcoming deadlines (such as updating the registration guidance) are accessible, particularly for the benefit of SMEs, in 22 official EU languages[5]. ECHA will communicate its guidance planning schedules to stakeholders.

Helpdesk

It is expected that the need for helpdesk support to questions raised by industry and national helpdesks in 2011, while lower than in 2010, will be much wider in scope and of a higher complexity than in 2009-2010. Questions related to the REACH Regulation are expected to refer progressively to the forthcoming processes of evaluation, authorisation and restriction, while questions regarding the CLP Regulation are expected to increase.

The workload of ECHA's Helpdesk will also be determined by newly developed IT tools and new functionalities in existing IT tools needed for the submission of data (e.g. updates of REACH-IT, IUCLID 5, CHESAR, etc).

Planned helpdesk activities will also consist of ECHA providing support and coordination to HelpNet, the network of national REACH and CLP helpdesks. After its consolidation in 2010 with the integration of the national CLP helpdesks, the HelpNet has now not only to integrate the experiences learnt from the first registration and notification deadlines into its work but also to be prepared to provide harmonised replies on new topics related to REACH and CLP processes such as evaluation, authorisation, restriction and labelling, among others.

Guidance

At the outset of 2011, ECHA will have or will take up the publication of guidance (updates) after the moratorium of the second half of 2010.

[5] Translations from English are provided in all official languages except Irish.

Before updating other guidance documents or developing new guidance, priority will be given in 2011 to implementing experience gathered by ECHA over the last two years in providing advice via guidance to stakeholders. In particular, an analysis of lessons-learned from the first registration and notification deadlines and how to apply them to the further development of guidance documents, with a special emphasis on simplification of the guidance on registration, will be made. Furthermore, a planning of further guidance activities with estimated timeframes will be made available with a view to having guidance published within specific timeframes (e.g. a maximum of three to four times per year). ECHA will also consider feedback from its stakeholders when setting priorities in its planning.

The collection of feedback from relevant stakeholders and guidance users will be structured and analysed before a guidance update or new guidance is begun. The possible sources being considered include the feedback provided via questions addressed to the ECHA helpdesk (e.g. via a web-form on ECHA's website) or through any other route, (such as direct contacts with stakeholders and, in particular, SMEs).

Focus will be placed on improving the accessibility of guidance through revision of the guidance web pages on ECHA's new website – due in 2011 – as well as on providing information particularly targeted at SMEs (fact sheets, guidance in a nutshell, practical guides, manuals, etc. in 22 official EU languages).

Furthermore, ECHA will continue providing advice to industry and authorities through guidance documents, particularly in relation to evaluation, authorisation and restrictions processes. ECHA will also apply the results of the Commission's work and of other relevant developments on nanomaterials to launch an update of the guidance on information requirements and chemical safety assessment as soon as such results of an appropriate quality become available and the parties concerned have been consulted.

REACH training

Training events on REACH matters will continue to be organised in 2011 with a focus on forthcoming processes such as evaluation and authorisation. Training activities on IT tools and CLP matters will be enhanced and in particular targeted at the network of national helpdesks (HelpNet).

In addition to providing support via training to authorities and industry, 2011 will also see the Agency organise, as far as possible, training activities intended for wider audiences, such as MSCAs, third countries and others, in charge of implementing the legislations, with the aim of achieving common implementation standards for REACH and CLP. By using on-line tools (such as webinars, video tutorials, etc.) or other technological means, wider coverage of the activities will be ensured.

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 2011	Means and frequency of verification
Percentage of resolved Helpdesk questions answered within the established timeframe (15 working days).	Not less than 75%	Business Object report / monthly
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.	Not less than 75%	Business Object report / monthly
Percentage of guidance documents published on the web according to the plan.	Not less than 75%	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

- "One-stop shop" approach to ECHA customer support on REACH and CLP obligations, including phone service, to be progressively established.
- Provision of timely and consistent replies and support to industry, explaining their obligations under the REACH and CLP Regulations, IT tools, and ECHA-related processes.
- Two meetings of the HelpNet Steering Group organised.
- Two workshops/training sessions particularly targeted at REACH and CLP national helpdesks organised.
- Update and publication of FAQs on REACH and CLP-related matters following identification, discussion and agreement by HelpNet.
- Managing the update and publication of FAQs on REACH IT and contribution to the update of FAQs on IUCLID5.

Guidance

- Finalisation of guidance initiated in 2010:
  - Information Requirements and Chemical Safety Assessment (scope of exposure assessment, exposure based adaptation and strictly controlled conditions)
  - Safety Data Sheets
  - Application of the CLP criteria (for labelling)
- Initiate the update in particular of the following guidance:
  - Guidance on registration and related issues
  - Substance identification

- Data sharing
- Initiate the revision of guidance with regard to nanomaterials
- Organise a “discussion platform” with Member States and the European Commission on guidance-related matters within the framework of the preparation of the revision of the scope of REACH in 2012.
- Update the Navigator pathfinder on the web.
- Publish further guidance in a nutshell and fact sheets, practical guides and FAQs as well as translations, to make relevant documents more accessible to SMEs.

<u>REACH Training</u>

- Further development of REACH/CLP training for trainers in EU/EEA Member States and in third countries.

Activity 6: Scientific IT tools

1. Main challenges in 2011

Implementation of the REACH processes requires a wide range of IT systems; their further development and maintenance will continue to be crucial for ECHA's operations. After the regulatory deadlines at the end of 2010, ECHA will go into 2011 with the experience gained from that work and will be in a position to intensively develop and/or revamp, where appropriate, existing systems to make them more efficient. To that end, ECHA has initiated an Enterprise Architecture (EA) project in 2010 in order to prepare its IT landscape and a roadmap to implement the plan in the forthcoming years. Consideration will be given to improving the integration between systems and to enhancing the user-friendliness of applications targeted at ECHA's external stakeholders.

REACH-IT is and will remain the cornerstone application of the Agency. So far, its development has mostly focused on enabling registration. Additional development will concern increasing the automation level and building interfaces with other systems. Further areas of work will be related to adjusting the application to additional and/or new legal requirements, e.g. the management of downstream user notifications or applications for authorisation.

Complementary to REACH-IT, an Enterprise Content Management (ECM) system will provide fundamental support to ECHA's operational processes. Further to the work initiated in 2010 to support the evaluation and identification of substances of very high concern processes, the ECM system will be extended to support other REACH processes, notably harmonised classification and labelling and authorisation processes, and also ECHA's quality management and procurement. The system will be tightly integrated with REACH-IT to allow seamless and efficient processing of incoming dossiers. Implementation of a secure platform for collaboration with external stakeholders, starting with the Member States Committee, will initiate a gradual replacement of the CIRCA system being used to share confidential information.

In 2011, ECHA will enhance the user-friendliness of the dissemination website by providing easy access to all published information on chemical substances, linking registration data with information submitted in the context of processes other than registration. In addition, information on registered substances will be made available through the OECD eChemPortal (Global Portal to Information on Chemical Substances).

With regard to software aimed at supporting industry with the preparation of registrations, ECHA will continue to develop two key systems: IUCLID5, viewed as an international tool for gathering data on the intrinsic and hazardous properties of chemicals, and Chesar, a tool designed to help companies to prepare exposure scenarios and produce their chemical safety reports. In 2011, ECHA will upgrade IUCLID5, in close contact with the OECD and the Commission, by integrating new harmonised templates or adapting existing ones for nanomaterials and enhancing the functionality for preparing applications for authorisation. Chesar will be adapted to support substance evaluation and authorisation needs within the Agency, and integration with other existing exposure estimation tools will continue.

ECHA will significantly improve the accessibility to relevant information needed by the MSCAs through REACH-IT. Moreover, ECHA will continue to provide tools and information for the enforcement work performed by the Member States. To fulfil this task, ECHA has initiated a project with the objective of publishing in 2011 a portal where

enforcement authorities can check information on substances registered in their respective countries (the so-called RIPE tool). Information security plays an important role in the architecture and implementation of the system as disclosure of confidential information beyond intended audiences needs to be strictly prevented. Training will be provided for national administrators and trainers of users.

ECHA will also further develop tools for ECHA's internal use - Casper (priority setting and reporting tool) and Odyssey (decision-support system for evaluation activities). Although Casper is a generic tool with a wide range of functions, in 2011 both Casper and Odyssey will be mostly developed and used to support the evaluation activities that will peak after the first REACH registration deadline of 2010. Feedback from users will be the primary source for identifying needs for improvement – both in the tools and in their documentation.

2. Objectives and Indicators

Objectives

1. ECHA receives and successfully processes all registration dossiers and C&L notifications with the assistance of a well functioning, upgraded REACH-IT.
2. Specialised IT tools (IUCLID5, C&L submission tools and Chesar) and targeted user manuals and workshops have efficiently supported registrants in preparing their dossiers and meeting their legal obligations.
3. An advanced screening tool (Casper) and an efficient decision-support system (Odyssey) are efficiently supporting ECHA in its goal of conducting compliance checks on 5% of dossiers per tonnage band.

Performance Indicators & Targets

Indicator	Target in 2011	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 of the IT tools (IUCLID, REACH-IT, Chesar and RIPE).	High	Annual survey

3. Main outputs

- REACH-IT
  - Redesigned application architecture.
  - Integration of REACH-IT and the Document Management system.
  - Enhancements in workflows to handle inquiry, assessment of confidentiality requests, data sharing and data dissemination.

- Development of new functionalities related to the implementation of the CLP Regulation: request for an alternative name and submission of proposal for Annex VI entry by Industry.

- Dissemination website
  - Non-confidential information on substances disseminated in a timely and reliable manner, with support of an enhanced IT system.
  - Integration with eChemPortal (Global Portal).
  - Enhanced search functionality.

- IUCLID 5
  - New OECD harmonised templates and/or new functionality (depending on prioritisation from the OECD IUCLID Expert Panel) implemented.

- RIPE
  - The first version of RIPE is rolled out to Member State enforcement authorities in early 2011.
  - Further development of RIPE is initiated, to achieve a comprehensive electronic information system.

- Document Management system
  - SVHC, testing proposal examination and compliance check rolled out to users.
  - Implementation of a selection of other processes started. Some candidate processes are: classification and labelling harmonisation, and authorisation.

- Chesar
  - Provision to industry of a reliable tool with supporting documentation to perform safety assessment.
  - Integration with selected exposure estimation systems.

- Casper
  - Provision of robust data-warehousing (e.g. screening, priority setting) and reporting services on registration data.
  - Integration of a selection of other systems.

- Odyssey
  - Increasing efficiency in dossier evaluation, specifically for less-experienced staff members.
  - Traceable decision-making process.

- General
  - Implementation of technology framework for the integration of applications.
  - IT processes in place (incident, problem, change, release, and configuration).
  - Maintenance plans and processes in place for applications in production covering ICT infrastructure, application support, and further development.

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

1. Main challenges in 2011

Benefitting from the vast information at its disposal after the first registration deadline, ECHA will considerably increase its knowledge on chemicals so as to be able to respond better to scientific and technical questions raised by the policy institutions of the EU.

Based on reporting obligations in the REACH Regulation, ECHA will draw up the first five-year report[6] for the Commission on the operation of the REACH Regulation and, in this context, will also make suggestions for improving the workability of the Regulation. In addition, and at the request of the Commission, ECHA will conduct a feasibility and needs assessment with regard to enhancing SME accessibility to communication with the Agency, including via REACH-IT, in different languages. Moreover, ECHA will draw up the first three-year report[7] for the Commission on the status of implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of REACH Regulation, with a view to promoting the use of alternative methods by the registrants for the second registration deadline.

ECHA's active cooperation with the European Parliament and the Commission will continue in 2011 by, *inter alia*, informing the institutions regularly of its activities. Cooperation with other European agencies and scientific committees will continue 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.

Cooperation with Member States will continue as an essential aspect of the Agency's day-to-day work. The meetings of the Competent Authorities for REACH and CLP (CARACAL) will provide the main platform for informing and consulting MSCAs.

ECHA will continue its contribution to the OECD test guideline programme and considerably increase its support to the international development of alternative test methods.

ECHA will significantly advance its understanding of the hazard, exposure and risks of nanomaterials by following carefully all developments and outcomes from the EU and international organisations, so that it can produce revised guidance in regard to nanomaterials in time before the 2013 registration deadline. ECHA will also compile a report for the European Commission by 30 June containing information on nanomaterial types and uses that have been registered, to contribute to the report that the Commission will prepare for the European Parliament. Furthermore, ECHA will increase its scientific capacity to deal with other substances or aspects of high interest, such as endocrine disruptors or mixture toxicity.

The Commission is planning to propose the recast of the PIC Regulation, which foresees the transfer of tasks currently performed by the Joint Research Centre of the Commission to ECHA. This could impose new tasks on ECHA as of 2013. In order to be ready for the new tasks, ECHA will have to start the relevant preparations already in 2011 subject to the availability of additional resources made available by the Commission.

[6] REACH Regulation Art. 117.2.
[7] REACH Regulation Art. 117.3.

The Commission has proposed a new Biocidal Products Regulation[8], which foresees that ECHA will be given additional administrative, technical and scientific tasks from 2013 onwards. ECHA will follow the progress of the legislative process regarding the proposed Regulation, continue to plan for the assumption of responsibilities for biocides activities from 2013 onwards, and initiate the first activities to support the implementation of the future legislation subject to the receipt of an EU subsidy and/or the necessary staff. The preparations could include initiation of guidance development, identification of the necessary IT development, and development of workflows.

2. Objectives and Indicators

Objectives

1. ECHA has improved its capacity to provide scientific and technical advice on the safety of chemicals; nanomaterials and testing methods.
2. ECHA delivers timely, high quality reports that help the Commission in assessing and improving the workability of the REACH Regulation and in promoting the availability of non-animal testing methods (Art 117).

Performance Indicators & Targets

Indicator	Target in 2011	Means and frequency of verification
Level of satisfaction with the quality of the scientific, technical and administrative support provided to the Commission.	High	Annual survey
Timely delivery of the REACH Art. 117 reports.	1 June 2011	Internal report

3. Main outputs

- Five year report on the operation of the REACH regulation (Art. 117.2).
- Three year report on the status of implementation and use of non-animal test methods and testing strategies (Art 117.3).
- Scientific opinions in response to questions of the European Commission or European Parliament.
- Scientific and technical input to the European Commission, Council and Parliament to support the co-decision procedure on biocides and the Commission's preparation of implementing rules, including a future Biocides Fee Regulation.
- Key internal preparations for future biocides and PIC tasks launched (including e.g. a detailed roadmap for the preparatory phase, design of workflows started, and plan for necessary guidance documents).
- Report compiled for the Commission by 30 June containing information on registered nanomaterials.

[8] COM(2009)267 12.6.2009.

2. ECHA's bodies and cross-cutting activities

Activity 8: Committees and Forum

1. Main challenges in 2011

Member State Committee (MSC)

The main challenge for the MSC is to manage an increasing workload when all the REACH processes requiring MSC involvement are running in parallel. In 2011, a high number of draft decisions arising from dossier evaluation (testing proposals and compliance checks) are expected as a result of the first REACH registration deadline in 2010 – leading to the examination of all testing proposals and a number of compliance checks of the registered phase-in substances. All Member States' proposals for amending ECHA's draft decisions will be addressed in the MSC to reach a unanimous agreement. In seeking agreement on testing proposal draft decisions, the Committee will consider options for avoiding unnecessary animal tests. Unanimous agreement on compliance check draft decisions aims to ensure that the relevant data gaps for different hazard end points are fulfilled and that Chemical Safety Reports cover all provisions of Annex I of the REACH Regulation.

In 2011, the substance evaluation process will start with an MSC opinion on the Community Rolling Action Plan establishing the list of substances subject to further examination of risks by appointed Member States.

Concerning the identification of SVHCs, the workload is also expected to increase in view of the Commission announcement to have a target of 135 substances addressed for identification as SVHCs by the end of 2012. A more extensive candidate list is expected to serve information needs regarding the PBT/vPvB properties of substances, as well as SVHC content in articles.

Furthermore, the MSC will prepare its opinion on ECHA's third recommendation for Annex XIV (the authorisation list). After registration dossiers have been submitted in 2010, the preparation of the recommendation and of the opinion will be supported by data provided by companies. The MSC opinion on ECHA's draft recommendation for Annex XIV is of importance to the final decision of the Commission, as a favourable opinion signals the support of the majority of Member States.

It is also possible that the MSC will receive requests for *ad hoc* opinions, in particular for the assessment of the PBT/vPvB properties of substances outside the REACH Regulation.

Risk Assessment Committee (RAC)

In 2011, the main challenge for the RAC is associated with the significant growth in its workload due to a growing number of proposals for harmonised classification and labelling, restrictions, and the first applications for authorisation, which the Committee will need to process simultaneously. In addition, the Committee may be requested to provide several *ad hoc* opinions for the EU institutions to support their legislative activities.

The increase in the RAC workload will occur in parallel with the first main change of the Committee composition, as the mandate of most members will end in early 2011. In ECHA's overall interest in ensuring the continuity of the Committee's work, rapid integration of the new members is needed. If the mandates of the members acting as

(co)rapporteurs are not renewed, *ad hoc* solutions will be required. As the Committee will already be involved in all processes and will require the full availability of expertise, there is an additional challenge in ensuring that RAC members receive adequate support from MSCAs and that the workload is properly shared among members.

Socio-Economic Analysis Committee

The Committee will decide on its opinion on the first four restriction proposals submitted in 2010, and will address further proposals on restrictions. With the submission of the first applications for authorisation, the workload of the Committee will increase rapidly. In addition, the Committee may be requested to handle requests for *ad hoc* opinions from EU institutions. Renewal of memberships or the nomination of new members will take place, as the mandate for most of the Committee members will end in early 2011.

Forum for Exchange of Information on Enforcement

The Forum is concentrating on harmonising approaches to enforcement through an integrative application of the REACH and the CLP legislations. This is expected to be achieved by implementing co-ordinated projects, setting common enforcement strategies, agreeing methods for dealing with non-compliance, and setting minimum criteria for inspections. The Forum will formulate practical conclusions and recommendations for the inspectors enforcing REACH and CLP, on the basis of experience collected through the coordinated enforcement projects dealing with the enforcement of "no data – no market" provisions as well as with the obligations on formulators of mixtures.

All in all, the effective enforcement of registration and C&L notifications requires more support from the ECHA Secretariat to the Forum. An important example of such support is RIPE, an IT tool providing inspectors with access to specific data from REACH-IT – the first version of which will be rolled-out by ECHA in 2011.

Joint inspections and study visits should start as a new type of coordinated Forum activity. These will give members of participating administrations the opportunity to study, share and spread knowledge and good practice. The Forum will intensify activities related to the enforcement of the CLP Regulation and prepare training for trainers. Cooperation could also be established with other services, especially customs services. Moreover, the Forum and ECHA will finalise the clarification of links between ECHA, Member States authorities and national enforcement authorities. Lastly, the Forum is involved in the restriction procedure where the Forum will give advice on enforceability. The workload will increase in view of the receipt of proposals for restrictions, submitted by the Member States or the ECHA Secretariat on request of the Commission. In addition, the Forum may be requested to provide *ad hoc* advice on restrictions to support the legislative activities of the institutions. Moreover, the cooperation and sharing of information with Committees and the ECHA Secretariat, regarding decisions on substances, is expected to increase.

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 through the coordination of activities of mutual interest.

Performance Indicators & Targets

Indicators	Target in 2011	Means and frequency of verification
Percentage of opinions/agreements delivered within the legal timeframe.	100%	Annual internal report
Percentage of unanimous MSC agreements.[9]	Not less than 80%	Annual internal report
Percentage of Committee opinions adopted by consensus.	Not less than 70%	Annual internal report
Degree of Committee opinions taken on board in the final decision of the Commission.	High	Annual internal report
Feedback from the Member States enforcement authorities and ECHA stakeholders on the added value of the Forum activities.	Positive	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	Annual 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	Annual survey
Occurrence of conflicts of opinions with Scientific Committees of other EU bodies.	Only in well justified cases	Internal evaluation report

[9] Concerns Evaluation and Authorisation processes, whereas the indicator under Activity 2 concerns only Evaluation.

3. Main outputs

- 40-60 RAC opinions on dossiers on harmonised classification and labelling.
- 4 RAC and SEAC opinions on restriction proposals.
- MSC opinion on the priority setting of candidate substances for authorisation.
- First MSC opinion on the Community Rolling Action Plan.
- Updated MSC Manual of Decisions.
- Unanimous agreements (or opinions) of the MSC on 40 proposals for identification of substances of very high concern and on 50 draft decisions on testing proposals and compliance checks.
- Agreement on common approaches to enforcement (reflected in Forum conclusions, best practice documents and other reports), carrying forward enforcement projects (REACH-EN-FORCE), with a short-term focus on the obligations of formulators of mixtures, training of enforcers on CLP, drawing lessons learned by information exchange and communication with the aim to support harmonised enforcement of chemicals legislation.
- 1-2 training events for national trainers of inspectors.
- 2-6 reports on advice of enforceability of proposed restrictions.
- 19 plenary meetings of the Committees and the Forum, 20-30 Working Group meetings.

Activity 9: Board of Appeal

1. Main challenges in 2011

The Board of Appeal was set up to provide 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.

In 2011, the Board will most likely face its first wave of appeals, especially regarding data sharing and evaluation. In fact, over the course of 2011, a gradual shift to more evaluation-related appeal cases is anticipated. This will be taken into account in the Board's proactive knowledge management activities.

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 2011	Means and frequency of verification
Percentage of cases concluded within target time[10] 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 (dependent on the number of appeals lodged).
- A robust body of case law related to the specific legal issues resulting from the REACH Regulation.
- Effective communication with the (potential) parties in relation to appeal proceedings (dependent upon the number and type of inquiries received).

[10] 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).

Activity 10: Communications

1. Main challenges in 2011

There are four key challenges in 2011.

Firstly, external communications: the website is ECHA's primary means of communicating with stakeholders. The present website needs improvement to enable it to be an effective tool for communication with all users – from members of the public to scientists. ECHA plans to rebuild it entirely in 2011, based upon the branding and customer insight work done in 2010. Through the new website, ECHA will, in 2011, need to reach out to the general public with information received through the processes for REACH registration and for Classification and Labelling notification. This will require a user-friendly database and inventory, and also require campaigns to raise awareness of the new material. ECHA also intends to provide information, ideally together with Member States, on the rights of citizens, on how to access new information available on chemicals, and on the means to make use of this information.

Providing material, including press releases and reference documents, in many languages will continue to be a major challenge. The practice of focusing on translating for small and medium sized enterprises and the general public will continue, as will the aspiration of trying to meet demand whilst securing value for money for the public purse. A particular challenge will be to validate the quality of translations – the combination of scientific language requiring expert review, the large volume of material, and 22 languages makes ECHA's translation work extremely demanding.

Of strategic importance for REACH and CLP is the completion of an EU-wide study with the general public on their perception of the safe use of chemicals.

Lastly, ensuring effective internal communication throughout an Agency which has grown so quickly is a crucial challenge. In 2011, ECHA will additionally be implementing, throughout the Agency, the recommendations of a review of ECHA's corporate identity which was undertaken in 2010.

2. Objectives and Indicators

<u>Objectives</u>

1. ECHA's external audiences are communicated with effectively, and ECHA benefits from an accurate and balanced media presence.
2. Stakeholders are involved in ECHA's work and are satisfied that their views are heard and taken into account.
3. All material (whether online or offline) that is produced for small and medium sized enterprises or the general public will be published in 22 official EU languages.
4. ECHA staff are well informed, have a sense of belonging, and feel part of a common corporate endeavour.

Performance Indicators & Targets

Indicators	Target in 2011	Means and frequency of verification
Level of website customer satisfaction.	High	Annual user surveys, 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 surveys
Publication of translations of new documents relevant for small and medium sized enterprises or the general public (within an average period of three months after the original document, without validation).	100%	Internal quarterly report

3. Main outputs

- Communications campaigns (e.g. on authorisation requirements and procedures as well as SIEF formation for 2013 deadline), including activities targeting industry and the general public, carried out.
- ECHA's website re-built and re-launched to be more user-friendly, with information aimed at SMEs and the general public in 22 official EU languages.
- All material (whether online or offline) that is produced for SMEs or the general public published in 22 official EU languages.
- Weekly internal e-newsletters (ECHAexchange) produced, quarterly internal newsletter (ECHO) printed, daily updates of internal information screens and intranet (ECHAnet) provided.
- A study of the public's perception on the safe use of chemicals (Article 34 of the CLP Regulation) completed.
- *Ad hoc* Press Releases and weekly e-news bulletins produced, two press briefings organised.
- Two Stakeholder Days and *ad hoc* Stakeholder workshops held.

Activity 11: International cooperation

1. Main challenges in 2011

The large amount of data from registration dossiers that ECHA will disseminate to the general public in 2011, and its own public profile, is expected to increase the interest of third countries and international organisations in the work of ECHA. This may lead to further requests for bilateral cooperation arrangements between third country regulatory agencies and ECHA, similar to that which exists between ECHA and the Canadian authorities from the Federal Department of Environment and the Federal Department of Health. Provided that such bilateral cooperation is useful for REACH and CLP implementation, ECHA will negotiate, within the mandate given by Article 77(2)l, cooperation arrangements of a scientific, technical and operational nature with such third country bodies. ECHA will undertake different activities implementing the signed memoranda.

Furthermore, ECHA will intensify its capacity-building activities benefiting EU candidate countries, in particular with country(ies) having received a firm EU accession date in 2012. ECHA will continue its involvement in spreading knowledge on REACH in countries outside the EU.

In 2011, ECHA will continue to participate in a number of different OECD activities, which are of relevance to the implementation of REACH. (Q)SAR methods allow estimation of the properties of a chemical from its structure and therefore reduce the time, cost and animal testing required in the context of identifying hazards of chemical substances. In 2011, ECHA will actively participate as a co-manager in the development of the OECD (Q)SAR Application Toolbox. The focus will be to develop functionalities for version three which will be rolled out in 2012, and in providing training and training material for version 2.0.
In 2011, ECHA will take over the hosting of eChemPortal (Global Portal to Information on Chemical Substances) phase 2. As a member of the eChem Portal Steering Group, ECHA will actively participate in the review and prioritisation of new user requirements to promote the usability of the portal.

Other OECD related activities in which ECHA will be involved include contributing to the work of the Task force on Hazard Assessment, the Task Force on Exposure Assessment, the Harmonised Templates Project, the work on the health and environmental aspects of nanomaterials and the Test Guidelines Program. In addition, ECHA will also create contacts with new OECD member countries to facilitate their understanding of REACH and CLP.

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.
3. Awareness of the eChem portal and (Q)SAR Application Toolbox has been raised.
4. (Q)SAR Application Toolbox development progresses in accordance with the plan and budget.

Performance Indicators & Targets

Indicators	Target in 2011	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 eChem portal from previous year.	20%	Internal annual report
Level of implementation of the annually planned modules of (Q)SAR 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 2011.
- Bilateral cooperation arrangements with interested third country regulatory agencies.
- Scientific and technical cooperation with the OECD (continuation):
  - The eChemPortal phase 2 is hosted by ECHA.
  - Participation in the OECD steering group of the eChemPortal (review and prioritisation of new user requirements for potential further development).
  - (Q)SAR Application Toolbox: software modules for third version developed (e.g. advanced interactive help functionality, speciation modules on hydrolysis, ionisation and tautomers, endpoint-specific knowledge-base expert systems, new structural alerts), and training material provided on version 2.0.
  - Task force on hazard assessment.
  - Task force on exposure assessment.
  - Working party on manufactured nano-materials.
  - Working Group of the National Co-ordinators for the Test guidelines. Programme.
- Capacity- building activities targeted at EU candidate countries under the IPA project.
- Efficient handling of speaking and visit requests from third countries.

3. Management, organisation and resources

Activity 12: Management

1. Main challenges in 2011

ECHA's highest decision making body is the 35-member[11] Management Board. It is assisted by a Secretariat provided by the Executive Director. As the Agency will have reached a steady cruising speed in 2011, the Management Board will concentrate in its core functions i.e. 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, dissemination 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 and therefore, ECHA will reinforce its cooperation with the MSCAs to improve coordination among them.

From March 2011, ECHA will chair the Troika of the European Agencies Network for 12 months.

ECHA's organisational structure has remained largely unchanged since the entry into operation in 2008. Since then the Agency has grown rapidly and its emphasis is shifting from preparatory activities towards multiple science-based decision and opinion making. A more horizontal new organisation of the Agency will be implemented by the start of 2011, when three new Directorates will be created. It will be an important management challenge to ensure that this takes place smoothly, in particular by adapting management processes to the larger organisation and ensuring 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 risk management. At the same time, ECHA will also implement its new corporate identity.

After the first registration deadline in 2010, ECHA will be entrusted with a large amount of information from the entire EU chemicals industry. Part of this information is by nature highly confidential (in particular, due to the fact that the data contains confidential business information). Therefore, ensuring security – both information and physical security – will be a priority. A security management and reporting system will be developed. Implementation of ISO27001 will continue and an external assessment of the security management system will be conducted. Moreover, ECHA will continue to organise the meetings of the Security Officers' Network, in order to support the secure implementation of access to REACH-IT for Member State Competent Authorities, Mandated National Institutions, and the Commission.

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

Furthermore, ECHA will continue the implementation of an Enterprise Content Management system (ECM) based on ECHA's process approach. This will ensure that all processes leading to a decision and/or opinion are standardised, documented, auditable and transparent and the documentation related to them is handled securely, efficiently and in compliance with all applicable legislation. ECHA information and knowledge management policies will be further implemented.

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 notification of all processing operations as listed in the inventory established in 2010 will continue in 2011. Consequently, the Data Protection Officer will, where necessary, send the notifications to the European Data Protection Supervisor for prior verification.

The implementation of the Integrated Quality Management System will continue. The Agency will establish IT-assisted tools and methods integrated into the Agency's infrastructure to facilitate the administration of Quality Management elements. Internal Quality System audits will be performed to check the IQMS against standard requirements and assess its maturity. The first steps in ECHA's preparation for the implementation of the Eco-Management and Audit Scheme (EMAS) will be initiated.

Considering the increase in the number of ECHA's decisions, major efforts are needed to guarantee legally sound decisions and effective defence in case of appeals or proceedings before the European Court of Justice: in 2011, the challenge will be to handle peaks in workload and ensure consistency of legal positions.

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 proper planning of activities, allocation of resources, assessment and management of risks, safety of staff and security of assets and information and provides a quality assurance for outputs.

Performance Indicators & Targets

Indicators	Target in 2011	Means and frequency of verification
Percentage of statutory documents submitted to the Management Board within legal deadlines.	100%	Quarterly internal report
Level of implementation of the annual risk mitigation plan.	100%	Annual internal report
Percentage of quality procedures released to the public according to plan.	Not less than 90%	Quality Manager's annual report

Number of “critical” findings by the auditors relating to the internal control system in place.	0	Internal auditors annual report
Percentage of important audit recommendations implemented within the deadline.	100%	Internal auditors 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 organised.
- Inter-Agency network meetings organised.
- Electronic and physical archives system developed and implemented.
- Information security management audit and/or internal audit of the quality system.
- ECHA Business Continuity Management documentation to cover the main processes.
- Strong legal support to ECHA’s decisions and their effective defence.

Activity 13: Finance, Procurement and Accounting

1. Main challenges in 2011

The Agency's primary focus in the financial field in 2011 will be on efficient liquidity management and rigorous budget discipline. The Agency is expected in 2011 to be fully self-financing through fees and charges, which ought to cover all of the Agency's legal obligations during the year. No European Union subsidy is foreseen for the REACH and CLP activities of the Agency during the current financial programming period ending in 2013. In addition, ECHA will have to repay the EU subsidy received in 2010 to the Commission, based on the result of its budgetary outturn account for 2010.

Early 2011, the Agency will have some tasks left from the high volumes of financial transactions in the aftermath of the first REACH registration deadline. In addition to the incoming fee payments, it is expected that the Agency will have some 800 financial commitments and close to 4000 outgoing payment transactions as a result of its operational activities. ECHA will carry out *ex post* checks on companies who have claimed to have an SME status in order to verify the correctness of the claims. Any company found to have made an erroneous claim will be charged the full fee corresponding to its correct size as well as an administrative charge.

In view of preparing for the implementation of other regulations, a mechanism has to be set up to separate the financial management of activities under the REACH and CLP Regulations and other possible regulations under which ECHA may be given tasks. This is envisaged to be done through further development of activity based cost-accounting which assigns the revenue and cost of each activity resource to the activity.

Sizeable investments will continue on IT support to operational activities and on IT security. Whereas framework contracts are largely in place for the identification of potential contractors, the re-opening of competitions between relevant contractors will require considerable efforts in procurement activity. (A draft plan is presented in Annex 4).

2. Objectives and Indicators

Objectives

1. The Agency has sound and efficient financial management.
2. Fee invoices are efficiently generated and cashed and cash reserves securely and effectively managed.

Performance Indicators & Targets

Indicators	Target in 2011	Means and frequency of verification
Number of reservations in the annual report of the European Court of Auditors.	0	ECA reports/ annual
Commitment rate.	Not less than 98%	Monthly financial report / annual
Payment rate.	Not less than 75%	Monthly financial

		report / annual
Carry over rate (of committed funds).	< 25%	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.
- Efficient accounting work-flows and procedures in view of managing the invoicing aftermath from the first REACH registration deadline.
- Mechanism for managing and investing the Agency's cash reserves in operation.
- Further monitoring of SME status.
- Analytical (activities) accounting system developed further.
- Repayment to the Commission of the EU subsidy received in 2010.
- Follow up and execution of the budget improved to a commitment rate of 98%.
- 2010 accounts.

Activity 14: Human resources and corporate services

1. Main challenges in 2011

Human resources

Having successfully accomplished the initial start-up phase, the Agency will focus in 2011 on consolidating the human capital and on organisational development. The human resources team will steer its emphasis from the massive recruitment exercises of the years 2008-2010 towards staff retention, with reinforced attention to learning and development, innovative strategies in organisational development, and dedicated care for the wellbeing of the staff.

An in-depth stocktaking of the effects of this registration wave on the long term human resource needs will be required and conducted in 2011. The outcome might trigger changes to resource planning, have an effect on the balance of expertise and competencies in the Agency, require adaptation to learning and development plans, raise the need for extended mobility of the workforce, or demand other measures in the human resources field.

Specific focus will be given to the development of an HR IT system in 2011, as part of the development of a corporate management system. This will require the focused attention of the HR staff on developing the system requirements, on supporting the implementation, on managing the change process, and on providing adequate support and training.

Corporate services

A corporate services unit was established in 2010, with responsibilities to manage the infrastructure and physical security of the Agency Secretariat, to support and organise travel and meetings, and to provide administrative services with regard to mail registration, supplies, library and archiving and inventory management. The unit's organisation and services will be further consolidated in 2011.

Two specific challenges emerge for 2011: specific focus will be given, via a dedicated project, to the digitization of the archives inherited from the pre-cursor legislation to REACH. Relevant documents will be scanned and the data integrated in the REACH database.

A reorganisation, including the creation of three new Directorates, is foreseen to take place in 2011. This will require the office space available to be redistributed to take these new Directorates, and the tasks entrusted to them, into account. The allocation of office space will be carried out efficiently in order to minimise necessary relocations and avoid disturbing staff during peak periods of work.

2. Objectives and Indicators

<u>Objectives</u>

1. The Agency has a sufficient number of skilled staff in order to secure the implementation of the work plan and offers them a well functioning working 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 2011	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.	100%	Annual internal report
Turnover of the Temporary Agents.	< 5%	Annual internal report
Average number of training 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, overall some 550 persons.
- An estimated 10 selection procedures to be launched.
- An estimated 50 recruitments to be completed.
- An average of 10 training days per staff member.
- Performance appraisal and reclassification exercise for over 400 statutory staff.
- Advice and assistance to staff and management on HR matters, in particular individual rights and wellbeing.
- Staff survey results and follow up plans.
- Active development of the people and performance management processes and methods.

Corporate services

- Completion of the equipping of the 600 workstations in ECHA's premises.
- Space allocation plans 2011 and change management during the reorganisation.
- 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 facilities inventory.

Activity 15: Information and Communication Technology

1. Main challenges in 2011

By the end of 2011, ECHA is expected to benefit from a fully featured ICT business continuity plan and efficient ICT disaster recovery capabilities. This will include having a well established external data centre delivering full redundancy for the entire ECHA ICT infrastructure and supporting co-location of hardware investments. ECHA started outsourcing its data centre operation to an external contractor during 2010. Existing systems will be gradually moved to a new environment, based upon a detailed transition plan. Preparing systems and documentation, overseeing the transition, and testing the transferred system will be a considerable exercise during 2011.

In the first half of 2011, ECHA will have set up and deployed secure network connectivity with Member State Competent Authorities via encrypted lines. Specifically encrypted connectivity will be provided to Member State Enforcement Authorities, employing secure two-factor authentication.

The Enterprise Architecture function will further focus on consolidation to improve the overall robustness of the ECHA information systems landscape while improving its future manageability and further growth.

Continued support to the roll out of the centralised content and knowledge management system will be provided in 2011, especially focused on maximising the automation of established business processes and the level of integration of various information repositories. Formal identity management procedures will be adapted into an Identity Management System.

Towards the end of 2011, the process of reviewing and incremental renewal of the technical and communication hardware infrastructure will be initiated.

Within available capacity, specialised technical and architectural support will also be offered to new and emerging business needs (e.g. ERP).

The efficiency and reach of well-established services such as the Project Portfolio Office or the ICT Helpdesk will be maintained and further expanded during the course of 2011.

2. Objectives and Indicators

<u>Objectives</u>

1. To operate the technical ICT infrastructure of the Agency at a high service level and maximise continuity, efficiency and security for all supported business operations.
2. To assure a consistent and common corporate architectural approach as well as to foster best practice in governance and management of IT projects, and to ensure professional, competent and timely responses to any of the planned or recurring business activities.

Performance Indicators & Targets

Indicators	Target in 2011	Means and frequency of verification
Availability of operational systems for external customers (uptime).	99%	Data centre statistics
Level of user satisfaction with internal IT services.	High	Annual customer survey and *ad hoc* feedback
Level of implementation of fully featured ICT business continuity and plan.	100%	Annual internal report

3. Main outputs

- External Data Centre (supporting co-location) suitable for business and disaster recovery.
- Documented, up-to-date and tested fully featured ICT business continuity and disaster recovery plan in place and implemented.
- Efficient ICT Helpdesk.
- Effective support to IT project management and governance.
- Support and maintenance of administrative IT applications.
- Secured and stable network connectivity.
- Monitoring and maintenance of core business applications.
- Continued high-quality technical support and guidance on ICT aspects.
- Services provided according to documented requirements and SLAs.

4. Risks

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

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 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, ECHA's most serious risk continues to relate to planning its human resources, both quantitatively and qualitatively.

Scrutiny of the processes in order to improve their efficiency will continue to mitigate the risk relating to the workload. As 2011 will be particularly important for dossier evaluations, and in view of the risk relating to the estimated dossier processing times, ECHA will target these processes in particular, in its plans to improve efficiency.

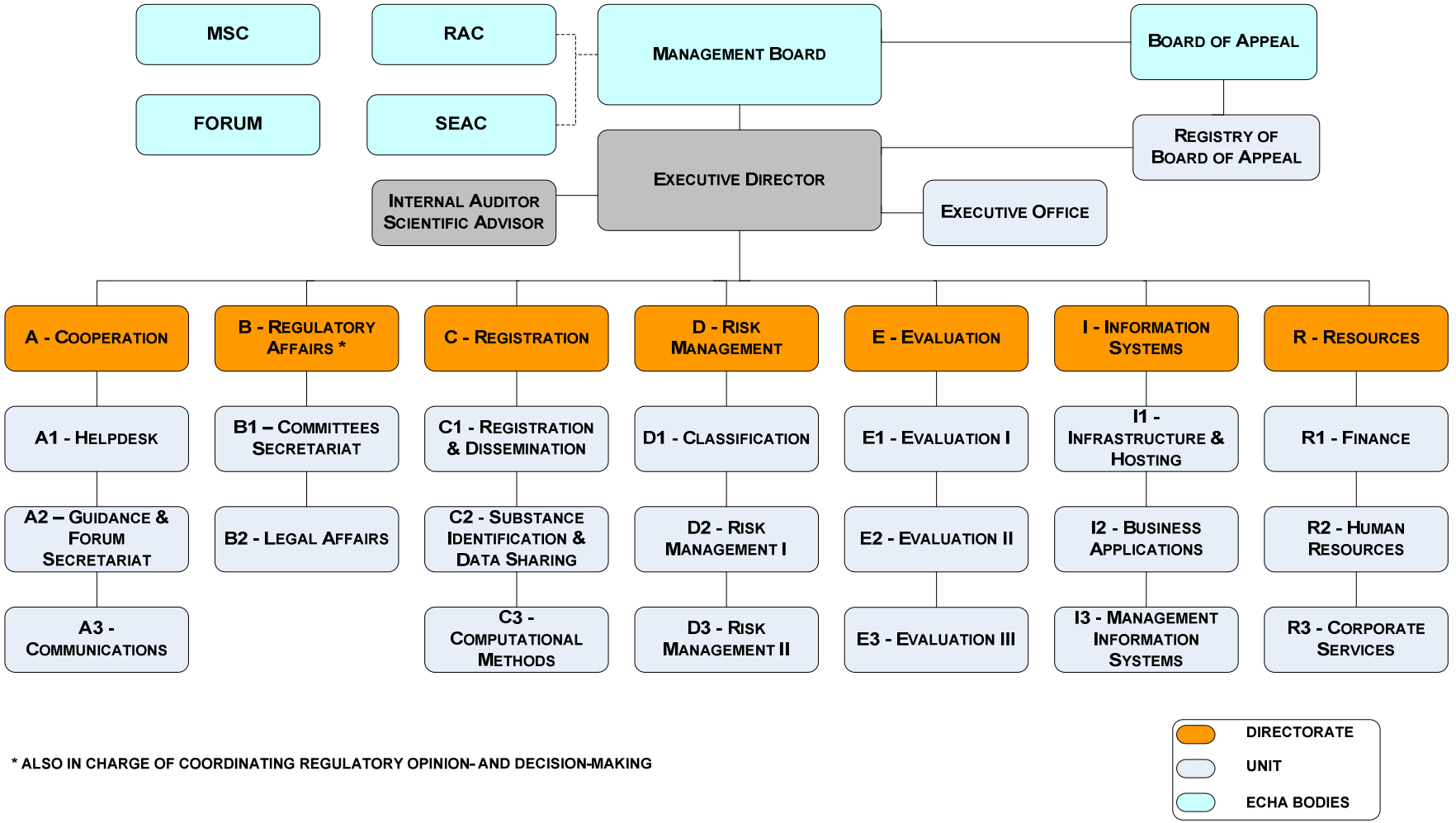
A longer term risk identified relates to the resources available to the Agency after 2013. It is estimated that ECHA will need an EU subsidy after 2013 and its needs should be taken into account in the financial perspectives to be negotiated for the EU for 2014-2020.

ECHA's activities rely heavily on efficient IT systems for processing 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, an Enterprise Architecture project has been initiated in 2010. In 2011, ECHA should have a long term IT development plan in place, including a resource plan that takes into account the gradual outsourcing of most of the data centre activities.

An additional human resource risk that ECHA has identified relates to the retention of staff 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 2011 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 highly qualified and trained staff in the future.

These risks as well as the responses and actions to be taken to mitigate them will be duly monitored and followed up during the year.

ANNEX 1: ECHA Organisation 2011



* ALSO IN CHARGE OF COORDINATING REGULATORY OPINION- AND DECISION-MAKING

ANNEX 2: Baseline assumptions

Baseline figures for 2011

Main drivers of ECHA activities	Estimate for 2011 [12]
Dossiers arriving in 2011	
Registration dossiers (including updates)	4500
Confidentiality requests	250
Access to data older than 12 years	120
Requests from third parties	150
PPORD notifications	200
Inquiries	1800
Number of notifications under Article 7(4)	40
Number of reports and notifications under Article 38	45 000
Restriction proposals (Annex XV)	10
Proposals for harmonised classification and labelling (Annex VI of CLP Regulation)	90
Proposals for identification as SVHC (Annex XV)	40
SVHC dossier developed by ECHA	5
Authorisation applications	15
Alternative name requests	20
ECHA decisions in 2011	
Decisions on dossier evaluation - no. of dossier evaluations initiated - no. of completed evaluations - no. of dossier evaluation decisions	 500 350 280
Decisions on data sharing	75
Decisions on completeness check (negative, i.e. rejections)	10
Decisions on releasing information requested by third parties	150
Decisions on confidentiality requests (negative)	20
Decisions on requests for alternative names	20
Appeals submitted in 2011	40

[12] These figures don't include the carry over deriving from the 2010 deadline and processed in 2011.

Others	
Questions to be answered/harmonised answers (REACH Advice, REACH-IT, IUCLID 5, others)	7 000
SME checks conducted	250
Management Board meetings	4
MSC meetings	6
RAC meetings	6
SEAC meetings	4
Forum meetings	2
New TA posts to be filled	30

ANNEX 3: Resource allocation in 2011

Activities (Title III of the Budget)	Human Resources WP 2010			Final Budget 2010 (after 2nd amendment)	Human Resources 2011			Budget 2011
The numbering below refers to the WP 2011, not to the numbering in the budget	**AD**	**AST**	**CA**		**AD**	**AST**	**CA**	
Operational activities – Implementation of the REACH Processes								
Activity 1: Registration, data-sharing and dissemination	40	12	8	932 879	34	11	7	1 151 289,00
Activity 2: Evaluation	62	9	1	95 001	81	13	2	440 198,00
Activity 3: Authorisation and restrictions	20	4	1	226 300	32	7	2	1 496 675,00
Activity 4: Classification and labelling	14	3	2	50 150	13	3	2	230 258,00
Activity 5: Advice and assistance through guidance and helpdesk	31	13	4	387 683	26	11	5	967 469,00
Activity 6: IT support to operations	25	5		10 044 009	28	8	0	12 793 811,00
Activity 7: Scientific and technical advice to EU institutions and bodies	3	0		0	5	0	1	308 623,00
ECHA's bodies and supporting activities								
Activity 8: Committees and Forum	17	8	2	1 645 700	21	8	3	1 868 183,00
Activity 9: Board of Appeal	12	5	3	73 200	9	6	5	362 801,00
Activity 10: Communications	10	8	7	5 026 000	10	9	8	7 739 753,00
Activity 11: International cooperation	8	4	0	556 560	4	0	0	777 845,00
Management, organisation and resources								
Activity 12: Management	21	14	3	1 550 302	24	14	3	1 603 095,00
Total	**263**	**85**	**31**	**20 587 784**	287	90	38	**29 740 000,00**
Activities 13-15: Organisation and resources (Title II: Infrastructure)	25	53	21	11 481 281	24	55	28	15 587 000,00
Title I (staff expenditure)				43 412 635				54 473 000,00
Total	**288**	**138**	**52**	**75 481 700**	**311**	**145**	**64**	**99 800 000,00**
In Establishment plan:	**426**				**456**			
New activity: PIC								p.m.
New activity: Biocides								p.m.

ANNEX 4: Procurement Plan

WP Activity	Sub-activity (where applicable)	Unit	Subject of the Contract	Estimated budget in EUR	Tentative procurement channel	Foreseen date for launching procurement	For s
1.0: Registration, pre-registration and data-sharing	Scientific support	C3	Consultancies on data-mining from submissions, prioritisation of factors and methods, read-across analysis; data integration for SID & QSAR activities (data analysis) and implementation of data integration (1st phase) + CSA programme	775 000	FWC 2008/02 or new FWC	Q1-Q3	
2.0: Evaluation	Scientific support	E2/E3	Workshops on environmental and human health issues; service requests targeting specific questions coordinated by the scientific platforms and in support of Dossier Evaluation tasks; upgrade of dossiers; Support to report development by professional scientific author	240 000	FWC 2008/02 or new FWC and negotiated procedures	Q1-Q4	
3.0: Authorisations and restrictions	3.1 Authorisation	D2/D3	Services to support development of Annex XV dossiers for SVHCs; to collect data for priority setting for authorisation, SEA Methodology development/increase knowledge base, RMM Methodology/increase knowledge base; workshops and awareness raising activities on authorisation	1 005 000	FWC 2008/02 or new FWC and negotiated procedures	Q1-Q3	

3.0: Authorisations and restrictions	3.2 Restrictions	D2/D3	Services to support development of restriction proposals	250 000	FWC 2008/02 or new FWC	Q1-Q4	
3.0: Authorisations and restrictions	3.3 Handling of Authorisation applications	D2/D3	Workshops and awareness raising activities on authorisation	125 000	FWC 2008/02 or new FWC and negotiated procedures	Q1-Q2	
4.0: Classification and labelling	4.2 C&L notifications	D1	Pre-analysis of C&L inventory	70 000	FWC 2008/02 or new FWC	Q1-Q4	
4.0: Classification and labelling	4.1 Handling of proposal for CLH	D1	Services to support RAC rapporteurs and the MSCA preparation of CLH dossiers for pesticides	60 000	FWC 2008/02 or new FWC	Q2	
5.0: Advice and assistance through guidance and helpdesk	5.3 Guidance	A2	CLP - Safety Data Sheets & exposure scenarios for mixtures (formulators, DPD+); Substances in Articles: strategies for SVHCs in articles, recommendations for authorities	220 000	FWC 2008/02 or new FWC and negotiated procedures	Q1-Q2	
6.0: IT support to operations	IT Consultancies	I	IT consultants to support operational projects (REACH-IT, IUCLID, ECM, Chesar, Casper, Odyssey and RIPE)	6 205 000	FWC 2009/39 and FWC 2009/40	Q1-Q4	
6.0: IT support to operations	IT security	I	Refurbishment of DC1 and DC 2	200 000	Negotiated procedures	Q1-Q2	
6.0: IT support to operations	IT applications hosting	I	Outsourced hosting for Secondary Business Plan, Global portal, all other applications	20 000 000	Restricted procedure	Q1	
6.0: IT support to operations	ICT Equipment	I	Miscellaneous purchase of HW and SW & telecommunication	791 500	FWC DIGIT/ HANSEL	Q1-Q4	
6.0: IT support to operations	Inquiry	C2	Scientific software (ACD, ChemFolder, NMR Predictor suite) licenses, upgrade and maintenance	60 000	Negotiated procedures	Q1	

6.0: IT support to operations	QSAR/Predictions	C3	Scientific software (ACD, Lhasa, Topkat, Sparc) licenses, upgrade and maintenance	340 000	Negotiated procedures	Q1-Q4	
10.0: Communication	10.2 Digital communications	A3	Website and Intranet development	900 000	FWC 2010/124	Q1	
10.0: Communication	10.2 Digital communications	A3	Audiovisual services	150 000	FWC 2010/64	Q1	
10.0: Communication	10.3 Internal Communication	A3	External audit, all staff off-site conference	75 000	Negotiated procedures	Q1	
10.0: Communication	10.4 External Communication	A3	Corporate identity, surveys, campaigns, promotional material, printing and publishing tool	736 300	FWC 2010/66, FWC 2010/20 and Hansel	Q1-Q2	
10.0: Communication	10.5 Media management	A3	Media monitoring project	250 000	FWC 2010/20	Q1	
10.0: Communication	10.6 Stakeholders' engagement	A3	Stakeholders' Days and Stakeholders survey	120 000	Hansel and negotiated procedure	Q1	
11.0: Relations with EU institutions and international cooperation	11.1 Coordination of International Relations	I	Further development and maintenance of IUCLID	200 000	FWC 2009/39	Q1	
12.0: Management	12.5 Quality Management	EO	Production of quality management system documentation:	660 000	FWC 2010/93	Q2	
12.0: Management	12.6 Security Management	EO	Consultancy and web certification courses on security	110 000	FWC 2010/93	Q3	
12.0: Management	12.12 Planning, monitoring and reporting	EO	Consultancy ((including the specification for a PM system)	66 000	FWC 2010/93	Q3	
12.0: Management	12.5, 12.7 and 12.12	EO	ICT equipment (Software and maintenance)	208 000	FWC DIGIT	Q1-Q3	

12.0: Management	12.7. Information Management	EO	Developing contact management (COMA) in ECHA	60 000	FWC 2009/40	Q1	
14.0: Human resources and infrastructure	14.0	B2	Expert support on IPR issues	100 000	Joint procurement with JRC	Q1	
14.0: Human resources and infrastructure	14.0	B2	Legal services	386 000	Negotiated procedure or CEI	Q1	
15.0: Informatics and communication technology	Consultancies	I	IT consultants for recurring services	1 500 000	FWC 2009/39 and FWC 2009/40	Q1-Q4	
15.0: Informatics and communication technology	ICT Equipment	I	Miscellaneous purchase of HW and SW & telecommunication equipment	2 250 000,00	FWC DIGIT/ HANSEL	Q1-Q4	