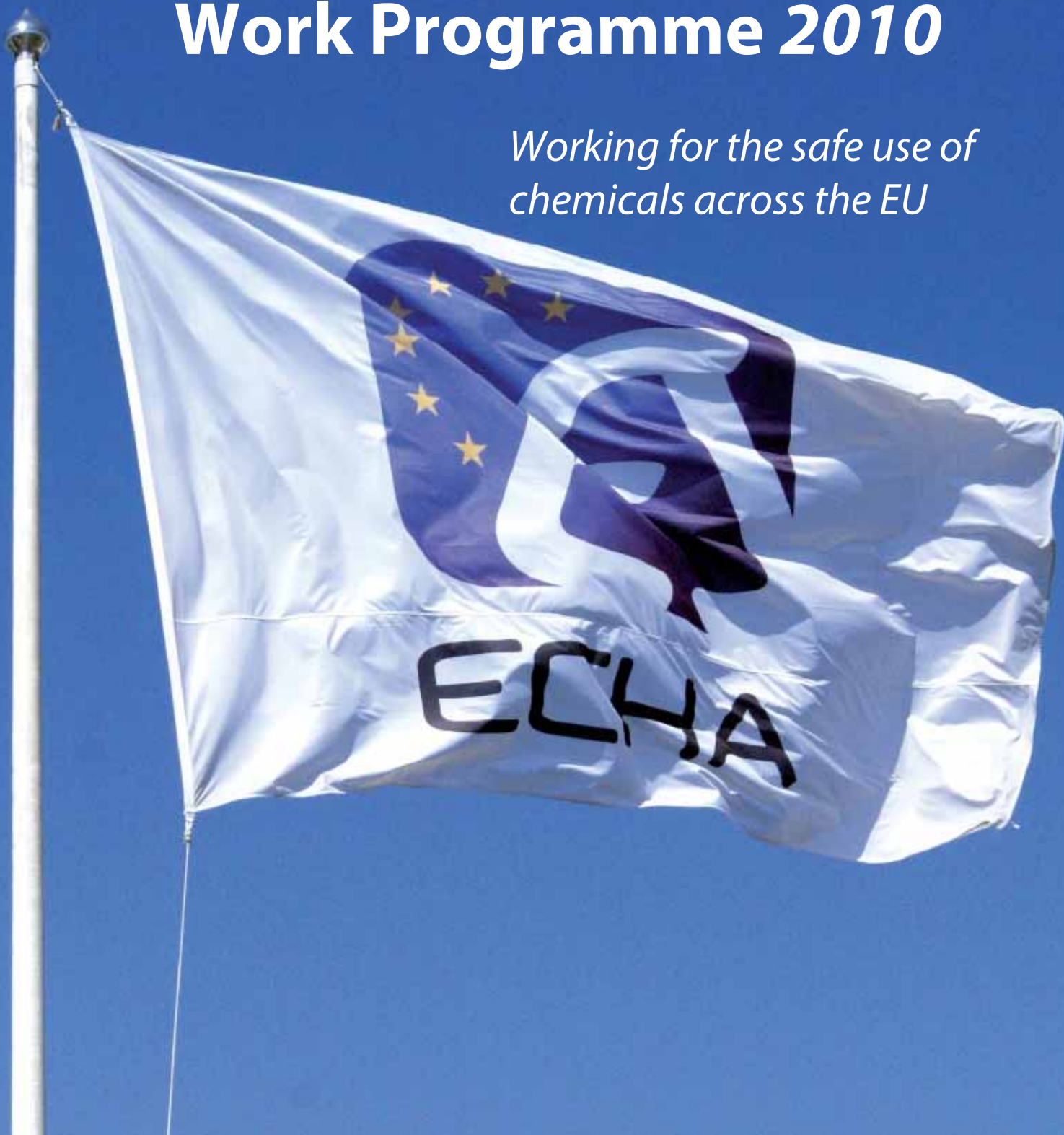


Work Programme 2010

*Working for the safe use of
chemicals across the EU*



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List of Acronyms

ACSHW	Advisory Committee on Safety and Health at Work
AD	Administrator
AST	Assistant
C & L	Classification and Labelling
CA	Contract Agent
CASPER	IT Characterisation Application for Selection, Prioritisation, Evaluation and Reporting
CHESAR	Chemical Safety Assessment and Reporting tool
CLP	Classification, Labelling and Packaging
COM	European Commission
EC	European Commission
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work
FAQ	Frequently Asked Questions
HR	Human Resources
IAS	Internal Audit Service of the European Commission
IQM	Integrated Quality Management
ISO	International Organization for Standardisation
IT	Information Technologies
IUCLID	International Uniform Chemical Information Database
JRC	Joint Research Centre of the European Commission
MB	Management Board
MSC	Member State Committee
MSCA	Member State Competent Authority
OECD	Organisation for Economic Cooperation and Development
PDB	Preliminary Draft Budget
PEG	Partner Expert Group
PPORD	Product and Process Oriented Research and Development
(Q)SAR	(Quantitative) Structure-Activity Relationships
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
REHCORN	REACH Helpdesk Correspondent Network
SEAC	Socio-Economic Analysis Committee
SIEF	Data Sharing & Substance Information Exchange Forum
SVHC	Substance of Very High Concern
UNECE SC GHS	Subcommittee of United Nations Economic Commission for Europe on the Globally Harmonised System for classification and labelling of chemical substances and mixtures
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 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 of 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, and the European Commission.

The purpose of the CLP Regulation is to ensure a high level of protection of human health and the environment, as well as the free movement of substances, mixtures and 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 Chemical Management (SAICM) adopted on 6 February 2006 in Dubai.

ECHA's Mission

ECHA's mission is to manage all REACH and CLP tasks entrusted to it by carrying out or coordinating the necessary activities, in order to ensure a consistent implementation at Community level and 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 decision-making process, using the best possible scientific, technical and regulatory capacities, and by working independently in an efficient, transparent and consistent manner.

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. ECHA will be a trustworthy, efficient and transparent regulatory authority and attract highly motivated and talented staff by applying the most modern administrative practices and staff policies. ECHA will be recognised as a reliable partner providing advice and assistance as needed.

Introduction

This Work Programme outlines the European Chemicals Agency's objectives for 2010, which will be its third full year of activity. The Multi-Annual Work Programme 2009-2012, adopted in September 2008 by the ECHA Management Board, provides the basis for this annual Work Programme. The structure of the Work Programme has been revised since 2009, and it is now divided across fifteen activities, each of which has a set of objectives and deliverables, as well as indicators, with which achievements can be followed up.

The planning in this Work Programme is founded upon the baseline figures presented in Annex 2, which are an update of the Commission estimates made when the REACH Regulation was prepared. It should be underlined that the baseline numbers are still subject to a high degree of uncertainty, meaning that a constant monitoring of the work volume is required, and potentially, a re-allocation of priorities and resources during the year. The biggest uncertainty concerns the volume of registration dossiers and C&L notifications that companies will submit, followed by the degree of efficiency of the REACH-IT system. As such, the Agency's planning for 2010 also contains contingency plans, which can be put in place should the baseline assumptions change remarkably.

The resource estimates are based on those of the Preliminary Draft Budget adopted by the ECHA Management Board in February 2009. However, the very tight budgetary situation eventually led to a much lower Commission request for ECHA. The final budget and the establishment plan for human resources will be adopted in December 2009 after the Budgetary Authority (Council and European Parliament) has authorised the final subsidy amount and the staff numbers for ECHA. The final budget will not only be based on the final amount of subsidy, but also on a re-estimate of the fee income over the entire year, corresponding to the updated volume of registration dossiers ECHA expects to receive during 2010. Should the total revenue or authorised staff figures differ significantly from the current estimates, the Work Programme will be adjusted accordingly in December 2009.

ECHA's challenges and priorities for 2010

After successfully completing the rush of pre-registrations in 2008, ECHA will face its second crucial deadline on 30 November 2010. By that date, industry has to submit registration dossiers for all high volume substances and for certain categories of substances of concern. Shortly afterwards, on 3 January 2011, ECHA faces its third deadline, as companies have by that date to submit notifications for their substances, irrespective of their volume of production or sale, in order to permit ECHA to set up a classification and labelling inventory.

It will be a challenge for the Agency to handle the steady increase of scientific dossiers concurrently submitted by authorities: restriction proposals, proposals for the identification of substances of very high concern, or proposals for harmonised classification and labelling. ECHA will also have to perform timely updates of the candidate list of substances of very high concern and prioritise those substances from the candidate list which it will recommend for inclusion on the authorisation list. The Agency will also process the first restriction proposals. In parallel, ECHA will have to build capacity for upcoming or accelerating operational tasks, namely the assessment of applications for authorisations and the science-based evaluation of the large volume of registration dossiers for chemical substances that will have been received by the 2010 deadline. Moreover, ECHA has to provide scientific advice, if requested, to the European institutions.

With regard to its biggest challenge linked to the first registration deadline, ECHA is facing uncertainty about the number of registration dossiers that will be received and will need to be processed. When setting up the REACH Regulation, the European Commission based its impact assessment on an estimated number of over 130 000 pre-registrations for a total of ca. 70 000 substances (ca. 30 000 chemical substances placed on the market and 40 000 intermediates)¹. At the first registration deadline in 2010, 25 000 registration dossiers were expected. However, last year, ECHA received more than 2 700 000 pre-registrations for some 150 000 substances, of which 250 000 pre-registrations for 50 000 substances flagged an intention to register by the first deadline. An internal analysis of the pre-registration data predicted that the number of registrations in 2010 would, in all likelihood, be close to the estimate of the Commission, but that it could also be up to three times that number. Consequently, this uncertainty is the main driver of ECHA's contingency planning.

In any case, it is already evident that most dossiers will arrive in two peaks, one in September - linked to the registration by lead registrants wishing to receive feedback from ECHA before other SIEF members register - and another, in November - linked to registration by other lead registrants and by other SIEF members. Even if the number of registrations is the 25 000 originally expected, there will be a high need for staff to support the submission and helpdesk functions during these peaks, and to support the staff verifying the technical completeness of dossiers from October 2010 until February 2011. This will drag some scientific and administrative resources away from other activities, affecting evaluation in the first instance - due to the strong interaction with registration -, and in the worst case scenario, nearly all other activities.

There is another exceptional workload in 2010, which will peak in December, linked to the deadline of 3 January 2011 for notifications of classification and labelling of dangerous chemical substances of any volume. ECHA has to establish and maintain a classification and labelling inventory in the form of a database, which will be generated from these industry notifications. Receiving these submissions will be a specific challenge, comparable to that related to pre-registrations in 2008, as the number of notifications is estimated to be equally high (for planning purposes a number of 2 million is used²). As similar uncertainties apply to the number of these notifications as to pre-registrations, ECHA must be prepared to process a much higher number than originally foreseen.

As a safeguard measure, the IT-systems supporting these operations will be scaled for and tested with a much higher load factor than the current estimates indicate; and ECHA is considering solutions to face the human resources challenge, should a higher number of registrations and notifications arrive. To this end, ECHA will establish a contract with a provider able to supply extra workforce in due time, to buffer unforeseen peaks in workload, and will train staff from other parts of ECHA to assist in supervising these personnel.

As a consequence of the revision of the EC biocides legislation, for which the co-decision procedure was initiated in 2009³, additional tasks will be expected of ECHA. ECHA has informed the Commission of the need to obtain financial and human resources from 2010 onwards, given the time needed for recruiting and training scientific experts and for adjusting the IT systems. The resources needed for these preparatory activities are not to be covered by the REACH and CLP fees. ECHA will thus strive to closely follow the legislative procedure and communicate its needs to the co-legislators and the Commission.

¹ No statistics were available for the intermediates.

² The estimate was 130 000.

³ (COM(2009)267) final.

As the scientific level of ECHA activities is linked to the capacity to recruit, train and keep highly qualified staff for scientific and technical tasks, specific effort is planned for the recruitment and training of 120 new staff members in 2010, mainly with a scientific background, and this will be enhanced by developing staff access to the best scientific know how and developing participation in the relevant international scientific communities.

Other challenges for 2010 include adapting the Agency's premises to its specific needs; securing the financial circuits; further developing management capacities and methods; and enhancing the functionality and performance of existing (scientific) IT systems.

In addition, in order to ensure the high quality and consistency of the decisions taken and opinions formed, ECHA has to further develop and refine procedures and work instructions that document its main processes, and train new staff. This is an ongoing activity, which, since the end of 2008, has developed into a corporate quality project, driven by the management, with the aim to conform to ISO 9001 standards in the coming years. In parallel, ECHA started to develop an Enterprise Content Management Programme in 2009 that will provide a solid base for managing documents, records and workflows, and will support the REACH-IT system. In 2010, these projects will continue to develop, in particular leading to an efficient, operational workflow management, and the publication of the main quality procedures applied by ECHA.

The question of security is another permanent challenge for ECHA, and has been addressed since the creation of the Agency. Information security has been considered as the main risk, and in 2008 an ISO 27001 project was launched, resulting in a three-year action plan based on a risk analysis being implemented from 2008 to 2010. In practice, the prioritised aspects of physical security have, for example, been the physical protection of the staff, visitors and premises, and control of access. Business continuity is also being tackled in a similar way. Nevertheless, there is a need to develop a comprehensive security policy and a risk management system based on an overall risk analysis for ECHA. A risk assessment exercise will be initiated by the end of 2009 and resulting further risk mitigation measures will be implemented from 2010 onwards, to safeguard security and the continuity of business in all circumstances.

***Programme 1:
Operational activities -
Implementation of the REACH Processes***



Activity 1: Registration, pre-registration and data-sharing

1. Main challenges in 2010

REACH is based on the principle that all manufacturers and importers of chemicals must identify and manage risks linked to the substances they manufacture and market. For substances produced or imported in quantities of 1 tonne or more per year per company, manufacturers and importers will need to demonstrate that they have appropriately done so by means of a registration dossier, which shall be submitted to the Agency. For substances above 10 tonnes per year, companies also have to complete a chemical safety report that includes exposure scenarios, leading to more precise estimates of risks and risk management measures.

ECHA checks registrations to ensure that they can be processed (the Business Rules Check) and that they are technically complete (Technical Completeness Check). Invoices are prepared, taking account of the company size, type of registration and claims for confidentiality. Additional work may also be needed to clarify substance identity. Companies intending to register new (non-phase-in) substances must also submit inquiries containing substance identity data which is checked by ECHA and, if the substance is already registered, ECHA has to put companies in contact to facilitate data sharing and to avoid unnecessary testing. Should the parties fail to reach agreement, ECHA will make the decisions.

In 2010 the expected number of registrations of existing (phase-in) substances and new (non-phase-in) substances is approximately 25 000, which is close to the original Commission estimate. ECHA also expects to receive approximately 1 500 inquiries prior to registration, 300 notifications for substances undergoing Product and Process Orientated Research and Development (PPORDs) and to make 500 data-sharing decisions. These baseline figures are also presented in Annex 2.

Nearly all registrations are triggered by the first registration deadline for phase-in substances, which is 30 November 2010. By that date, companies will have to submit registration dossiers for their high volume substances of 1 000 tonnes per year or more, and for certain categories of substances of concern. The main challenge for ECHA is to ensure that systems and staff are in place and capable of handling this large but uncertain number of registrations. While peaks had been anticipated in the original planning for REACH, feedback from potential registrants now indicates that these peaks are going to be much more pronounced than estimated. It is now assumed that most of the registrations are likely to arrive in two "peaks" (lead registrants submitting at the end of summer, and non lead registrants submitting close to the deadline) rather than gradually building up throughout the year.

Experience with pre-registration and with work over the past year suggests that the workload is going to be significantly higher than originally anticipated in the financial statement prepared for the REACH legislation. Contrary to the assumptions in the financial statement, a number of the work processes are not and will not be fully automated, so a significant level of manual processing will always be required for each registration. This impact is magnified by the fact that registrations will arrive in peaks as described above.

ECHA has sought to clarify with industry what the high number of pre-registrations means for the expected number of registrations in 2010. Evidently, the number of pre-registrants during the pre-registration phase in 2008 has slowed down the creation of substance information exchange fora (SIEFs) and is also making communication between SIEF participants more difficult than expected. Consequently, by mid-2009, industry has only

been able to provide limited information about the number of SIEFs and SIEF participants who intend to submit registrations by the 2010 deadline.

ECHA has performed an analysis of the pre-registration data, to determine a new estimate of the number of registrations for the first registration deadline. This analysis shows that the number of substances expected to be registered by 2010 - ca. 9 200 - is very close to the initial estimate made before the REACH processes started (8 730). Although substance and registration numbers are still subject to confirmation from industry, there is a much higher uncertainty in the number of registrations expected. Different alternative calculations have been undertaken, showing that the registrations could number from 25 000 up to 75 000. Without further comprehensive feedback from industry, the planning baseline for the 2010 Work Programme will remain at 25 000 registrations for 2010.

Currently, certain processes, in particular, clarifying substance identity, invoicing, the technical completeness check, drafting of regulatory decisions, the determination of confidentiality claims, and responding to helpdesk questions, require considerable manual work. Despite further progress with automation in 2009, the need to process a large volume of work manually will remain; of the processes listed, only invoicing is likely to be automated to a significant extent. Moreover, the resolution of IT-system failures requires human intervention; in addition the IT-system is still under development and although it will be thoroughly tested, it is unlikely to have been challenged by all the potential modes of failure before the complex submissions from lead registrants are received.

Considering the degree to which the submissions are expected to peak, and the significant amount of manual work that will still be required to process them then, even assuming that ECHA only receives the 25 000 registrations originally anticipated, the additional resources needed to cope with the expected workload, particularly towards the end of the registration period, will be more than foreseen in the original estimates made before ECHA was created, and significantly more during the six-month period around the deadline. This requires a much higher workforce than previously calculated and a substantial influx of short-term administrative support and the internal redeployment of staff will also be necessary for the peak period.

2. Objectives and Indicators

Objectives

1. All dossiers and data sharing disputes are processed, and PPORD notifications and confidentiality claims evaluated, 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.

Performance Indicators & Targets

Indicator	Target in 2010	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).	Not less than 90 %	Time recorded in REACH-IT monthly reporting
Number of appeals made by registrants and notifiers against decisions.	Not more than 10 % of decisions	Monitoring responses to decisions monthly

3. Main outputs

- Contingency plans, for increasing the capacity to process the expected number and distribution of dossiers, to be ready by early 2010.
- Increased numbers of staff trained within the Directorate of Registration & IT Tools and elsewhere in the Agency.
- Detailed and precise specifications developed for the enhancement of REACH-IT, so that the majority of procedures can be automated.
- Up-to-date manuals, guidance and other information for registrants.
- Dossiers processed, invoices sent and payments received, according to the appropriate deadlines.

4. Risks

ECHA will be strongly challenged by the number and timing of submissions of registration dossiers, putting the registration process at risk.

As indicated in the introduction, even if the 2010 Work Programme is still based on the initial estimate of 25 000 registrations by the 2010 deadline, there is a risk that the number of dossiers will be much larger. Consequently, while using the original figures as a baseline, ECHA is preparing contingency plans for handling 50 000 and 75 000 registration dossiers, for handling different degrees of performance of the IT system, for handling breakdowns of the REACH-IT and hardware systems, and for other circumstances disrupting business.

The contingency plans will include, in addition to re-allocating trained internal staff, the engagement of much larger volumes of additional temporary staff and experts to deliver the work required. Depending on the situation, ECHA will reprioritise its activities to support registration processing for a limited time, whilst ensuring compliance with its other core tasks - as derived from its founding legislations. Consequently, even if the number

of dossiers submitted is close to the original plan, ECHA intends to ensure that more current staff are trained in and will practise performing or supervising the processes of registration. Staff may then be reallocated to registration work at times of peak pressure.

With regard to the risks associated with the REACH-IT system, it is already foreseen that many of the functions initially missing from REACH-IT will have been successfully implemented in 2009 and early 2010: these include further automation of the workflows for dossier submission, inquiry, confidentiality, data sharing and data dissemination. If one or more of these functions were to fail, ECHA would have to carry out the processes manually, and consequently, would be significantly under-resourced. Therefore, staff will also be trained to execute certain tasks that will be automated by REACH-IT but may still fail. The failure of REACH-IT can also be more widespread and affect submission. To cover this risk a fall-back solution is foreseen under Activity 6.

Activity 2: Evaluation

1. Main challenges in 2010

The REACH Regulation distinguishes between dossier evaluation and substance evaluation. Dossier evaluation is further subdivided into the examination of testing proposals and the compliance check.

ECHA is obliged to examine all testing proposals submitted by the registrants or the downstream users, and to prepare a draft decision within the deadlines provided for in the REACH Regulation. 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. 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 registration dossiers and testing proposals submitted, ECHA will develop a multi-annual timetable for achieving the 5 % target for the compliance checks by December 2009.

It is planned to initiate about 400 new dossier evaluations (sum of compliance checks and examination of testing proposals) and to take a decision on about 70 dossiers, during the year 2010. These numbers also include about 50 dossiers for notified new substances where the Member State Competent Authorities did not finalise the decisions on further testing and, therefore, it is likely that for these substances, the available information will be incomplete. If the number of incoming testing proposals is considerably lower than anticipated in the original planning, ECHA may increase the number of compliance checks accordingly. However, the need to reallocate resources to support Technical Completeness Checks close to the first registration deadline will temporarily affect ECHA's capacity to process dossier evaluations in the last quarter of 2010.

The first community rolling action plan for substances subject to substance evaluation has to be submitted by 1 December 2011. According to the REACH legislation, the Agency should develop criteria for prioritising substances for substance evaluation in coordination with the Member States, and in 2010, ECHA will continue the preparatory work in dialogue with the Member States.

A number of other aspects related to evaluation under REACH also need to be further explored in order to ensure that the evaluation process, including interfaces with other REACH processes, can be made fully operational before the first registration deadline in 2010. These include, for example, the criteria for the selection of dossiers for dossier evaluation, on which aspects or elements of the registration dossiers the compliance check should be targeted, the interface between dossier evaluation and substance evaluation, and the link between evaluation and risk management measures.

In addition, further scientific and administrative capacity building is necessary to manage the peak workload in the years after 2010. The high production volume phase-in substances that will be registered by 1 December 2010 will contain the highest level of information per dossier, and ECHA expects that a considerable part of this information will not have been generated using recent standard and quality assured testing methodology. This will inevitably complicate the evaluation of the dossiers and raise complex and scientifically challenging questions. ECHA will therefore continue to recruit staff, reinforce internal scientific competences and networks with external experts, develop strategies for effective and efficient evaluations, implement a supporting IT evaluation tool, and train junior and senior staff.

For the evaluation process there is a need to continue organising training events and workshops and provide advice to Member States on their role in the evaluation processes. There is also a need to support industry in improving the quality of the registration dossiers.

2. Objectives and Indicators

Objectives

1. Scientifically sound draft decisions in compliance with the legal requirements are prepared.

Performance Indicators & Targets

Indicator	Target in 2010	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 around 400 dossiers (compliance checks and testing proposals).
- Agreement with Member State Competent Authorities on the targeting of the compliance checks. Targeting is a prerequisite for processing a high number of dossiers each year.
- Agreement with Member States on the criteria for prioritising substances for substance evaluation, in order to prepare for the submission of the first draft community rolling action plan for substance evaluation by 1 December 2011.
- Publication of the annual report on evaluation as required by the REACH Regulation.
- Capacity building for dossier evaluation, including recruitment of additional staff and on-the-job training of junior staff.
- Continuation of knowledge building for junior and senior scientific staff through specific training programmes and seminars on selected topics in the fields of toxicology, eco-toxicology and exposure assessment.

- Continuation of building up of ECHA scientific competences to address scientific questions arising from the evaluation process.
- Establishment of a network of external experts to provide up-to-date scientific expertise to the evaluation processes.

4. Risks

A first risk is linked to the quality of registration dossiers, which could delay the evaluation or may even render it impossible. While the experience with evaluating dossiers is still limited, the ECHA Secretariat has observed major shortcomings which hamper the rapid processing of the dossiers, e.g. in relation to ambiguous or unclear substance identity (both for the registered substance and read-across), missing or unclear justifications when applying the general rules for the adaptation of the standard testing regimes according to Annex XI (waiving statements), and incomplete (robust) study summaries. ECHA will invest in communication and awareness-raising to avoid such problems.

A second specific risk linked to the evaluation activities - which require a high level of expertise - is the possible difficulty in recruiting sufficient numbers of staff with the appropriate scientific backgrounds and levels of expertise in (regulatory) toxicology, ecotoxicology and exposure assessment; even if the economic crisis would seem to facilitate recruitment. As a mitigation measure, the Agency has to be prepared to use substantial resources to train junior scientific personnel.

A third risk is linked to the registration contingency plans, which, in some scenarios, may require the temporary redeployment of scientific and administrative staff to registration.

Activity 3: Authorisations and restrictions

1. Main challenges in 2010

1.1 Authorisation

In October 2008, ECHA published the first Candidate list of substances of very high concern (SVHC) and is committed to regularly updating it. However, further revisions of this list will depend upon the submission of Annex XV dossiers prepared by either the Member States or ECHA, on the request of the Commission. In collaboration with the Member State Competent Authorities and the Commission, ECHA has established fixed submission dates for new Annex XV dossiers of SVHCs. Given the public consultation requirements, it will take between four and five months for ECHA to establish which SVHCs meet the criteria to be placed on the candidate list. Provided that additional substances will be added to the candidate list that fulfil the priority setting criteria or that new information will have become available that would warrant prioritisation of the substances that ECHA has not yet prioritised, a new recommendation for SVHCs to be included in the list of substances subject to authorisation (Annex XIV, 'authorisation list') will be prepared and submitted to the Commission in 2010.

Based on the indications provided by Member States, ECHA estimates that it will process some 15 dossiers for the identification of SVHCs that were received in 2009, and around 30 new dossiers to be received in 2010.

On 1 June 2009, ECHA submitted its first recommendations for the authorisation list to the Commission, and it assumed that the respective Annex XIV will be adopted by the Commission in 2010, which implies that the applications to authorise the use of any of these substances would arrive in late 2011 or early 2012. Although it is possible for companies to apply in 2010, for planning purposes it is currently assumed that no such applications will be submitted in 2010. Nevertheless, ECHA will ensure that the procedures for handling authorisation applications will be further developed and finalised to handle early applications, should these arrive.

1.2 Restrictions

On 1 June 2009 title VIII (Restrictions) of REACH entered into force. In agreement with the Member State Competent Authorities and the Commission, ECHA has established fixed dates for submitting Annex XV dossiers for restrictions.

Based on the indications from Member States and the Commission, ECHA estimates that six Annex XV dossiers proposing restrictions will be processed in 2010. It is also anticipated that ECHA, on request by the Commission, will review the available evidence to re-examine the current restrictions on phthalates and on mercury in measuring instruments, in line with the review clauses related to existing restrictions for these substances in Annex XVII of REACH.

For both authorisation and restriction processes there is a need to 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. It will also be necessary to provide 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 possibilities to contribute effectively to these.

2. Objectives and Indicators

Objectives

i) Authorisation

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

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 2010	Means and frequency of verification
Percentage of SVHC dossiers treated within the legal timeframe.	100 %	Internal quarterly report
Percentage of restriction dossiers treated within the legal timeframe.	100 %	Internal quarterly 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 ⁴

⁴ All surveys planned in this Work Programme, with the exception of the staff surveys, will be prepared by ECHA for external target groups. The results will be analysed by ECHA.

3. Main outputs

- Two updates of the candidate lists published.
- Annex XV SVHC dossiers prepared, following the requests made by the Commission.
- Depending on the availability of new substances on the candidate list, the submission of a new recommendation for inclusion of an SVHC in the list of substances subject to authorisation (Annex XIV) will be prepared.
- Conformity reports on Annex XV restriction dossiers produced and submitted to the Committees for opinion formulation.
- Support provided to Commission for the review process of some of the existing restrictions.
- Annex XV restriction dossiers prepared on the demand of the Commission and submitted to the Committees for opinion formulation.
- 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 consultation.
- Support provided to industry.

4. Risks

A first risk is related to the timing and volume of incoming Annex XV dossiers (from Member States) or requests from the Commission to prepare them. The above objectives may not be achieved if the Member States do not submit the planned Annex XV dossiers for SVHC or restrictions. Similarly, the Commission may not ask ECHA to prepare SVHC or restriction dossiers according to the planning above. On the other hand, the number of dossiers or requests may be higher than planned.

In order to mitigate this risk, ECHA will continue to exchange information with the Member States and the Commission to have the best possible estimates on the timing and volume of incoming Annex XV dossiers (from Member States) or requests from the Commission to prepare them.

If there are fewer requests than planned, the resources could be used elsewhere in ECHA. If there are more requests, there will be a resource strain and the possible reallocation of resources in favour of this activity may be necessary.

A final risk is linked to the registration contingency plans, which may, in some scenarios require the temporary redeployment of scientific and administrative staff to registration.

Activity 4: Classification and labelling (C&L)

1. Main challenges in 2010

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

The main tasks under this activity for 2010 will be to manage the proposals for harmonisation of classification and labelling of substances. ECHA maintains the Commission's original estimate of approximately 90 proposals annually.

Furthermore, ECHA will have to establish and manage a C&L inventory based on C&L notifications from industry which constitutes a major challenge for the Agency. There is currently a high level of uncertainty related to the expected number of notifications as the C&L has to be notified - irrespective of the production volume - by the deadline of 3 January 2011. The original estimate was about 130 000, but in the light of current indications the number of notifications could be in the same order of magnitude as the pre-registrations. For planning purposes an estimate of 2 million is used.

ECHA will also provide support to MSCAs and guidance to industry. This includes further guidance on C&L on issues not dealt with in the current guidance, finalisation of the revision of the guidance on proposals for harmonised C&L as well as new practical guidance on preparing and submitting notifications to the C&L inventory.

In addition ECHA will run an awareness campaign to inform industry about the CLP Regulation; this will be launched at the end of 2009 and will focus on the obligation to notify C&L.

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. It is expected that the number of these requests will be close to zero in 2010.

2. Objectives and Indicators

Objectives

1. All proposals for harmonised C&L sent by the Member State Competent Authorities (MSCAs) and industry are processed within the legal timeframe and to a high degree of scientific quality.
2. An intermediary C&L inventory will be published in December 2010.

Performance Indicators & Targets

Indicator	Target in 2010	Means and frequency of verification
C&L Inventory is operational and published.	December 2010	Through project management
Proposals for Harmonised C&L processed within legal timeframe.	100 %	Internal quarterly report
Level of satisfaction of the MSCAs and RAC with the quality of the scientific, technical and administrative support provided.	High	Annual survey

3. Main outputs

- Support provided to the Member States through Guidance and the Helpdesk and to National Enforcement Activities through the Forum, in order to face the 2010-2011 peak linked to the inventory and the dual classification system that will be in place for the period 2010 to 2015.
- Technical advice on notification of C&L to the inventory provided to industry, with an adequate helpdesk support (peak in 2010 linked to the inventory).
- Public campaign for notification of C&L to the inventory successfully completed.
- Evaluation of requests for the use of alternative names (Art. 24).
- Processing of proposals for harmonised C&L received from MSCA and suppliers.
- First C&L inventory is published and operational.

4. Risks

The main risk on this activity is the high uncertainty about the number of notifications, which could even surpass the estimated 2 million, causing delays to or overloading the IT application for handling C&L notifications. To avoid potential problems, a back-up submission system will be developed in time.

There is also uncertainty about the exact number of proposals for harmonised C&L because of a backlog of proposals on 87 substances for which the classification was agreed at the technical level under the previous legislation but which were not yet introduced into the list of harmonised classifications, as well as due to proposals for classification of pesticidal and biocidal active substances. It will of course be known at an early stage whether the number will be higher due to the Register of Intentions. Should the number of proposals be considerably higher, it would have a clear impact on ECHA's ability to process them properly. Therefore, ECHA will plan contingency measures to deal with a possibly higher number of dossiers, e.g. through outsourcing or internal re-allocation of resources in the most optimistic scenario from other activities.

A final risk is linked to the registration contingency plans, which may, in some scenarios, require the temporary redeployment of scientific and administrative staff to registration.

Activity 5: Advice and assistance through guidance and helpdesk

1. Main challenges in 2010

Since taking up its functions in 2007, the ECHA Helpdesk has been an operational part of the Agency with well-established routines and processes. During 2010, it will carry forward its regular work on many challenges: it will continue to support the network of national helpdesks (REHCORN) and its tools (REACH Exchange Platform, RHEP) in order to achieve consistent replies at European level, and, when needed, to provide timely and consistent replies on industry obligations under REACH and CLP.

The provision of advice to industry and to authorities via guidance will be a priority for ECHA in 2010, in particular, the timely completion of guidance documents relevant to the first registration and C&L deadlines. Special emphasis will be put on those guidance documents that need to be published with a view to the deadlines, in order to allow industry to fulfil their obligations under REACH and CLP (e.g. the guidance on information requirements and chemical safety assessment).

Whilst the continuation of this work will in itself be demanding, the 2010 peak in ECHA's workload related to Registration and Classification and Labelling is likely to have a direct and major impact on guidance activities and on helpdesk activities.

1.1 Helpdesk

It is expected that the number of questions that industry (mainly lead registrants) and national helpdesks will address to the ECHA Helpdesk in 2010 will not only increase considerably but also that their content will cover a much wider scope than the questions received by ECHA during 2008-2009 (i.e. higher than the 15 000 questions received in 2008).

Furthermore, Helpdesk activities will be driven not only by regularly providing information on REACH and CLP obligations to industry in a timely and efficient manner but also by the occasional difficulties that potential registrants and companies notifying to the C&L inventory may experience during 2010.

The workload of ECHA's Helpdesk will also be determined by newly developed IT tools and new the functionalities of existing IT tools needed for the submission of data, and a subsequent number of queries. Lastly, the uncertainties regarding the expected number of registrations and C&L notifications and the timing of the actual peak in their submission will turn accurate planning into a challenging task.

Planned Helpdesk activities will consist of ECHA providing support and coordination to the network of national helpdesks on REACH and CLP, which will be fully operational in early 2010. The CLP helpdesk network will mirror the structure and procedures that currently already determine the REACH helpdesk network. This will increase the number of network participants from the current 38 to approximately 58. Moreover, the Secretariat support as well as ECHA's contribution to questions submitted by national helpdesks via the REACH Exchange Platform (RHEP) to both the REACH and the CLP helpdesk network will need to be increased in line with the expected increase of their activities in view of the first registration and CLP notification deadlines.

Following through the campaign "The clock is ticking – form your SIEF now", initiated in 2009, the ECHA Helpdesk will continue to focus its activities in 2010 on lead registrants preparing for joint submissions by 30 November 2010. To this end, ECHA has elaborated a special helpdesk service for lead registrants. The campaign addressing potential registrants facing the 2010 registration deadline will itself generate further work for the ECHA Helpdesk as well as for the national REACH helpdesks, as the latter are the first

point of contact for companies having their seat in a given country. The efficiency of these services also relies on the ability of the Commission to respond rapidly enough to the questions that affect the legal interpretation of REACH.

1.2 Guidance

The overall guidance and awareness-raising actions on the obligations to classify, label, package and notify in line with the CLP rules will constitute a high priority for ECHA. This will include providing practical information (guidance, explanatory information, FAQs, training activities, etc.) and support tools that will assist industry in all aspects when dealing with the notification. The project has tight time constraints and the information, tools and guidance need to be made available to stakeholders well ahead of the notification deadline. The activity on guidance will scale down in the final months before the two crucial deadlines to permit support to the helpdesk in the peak period.

While updating or developing guidance, ECHA will follow its framework for guidance governance, designed to efficiently implement cooperation procedures within ECHA, as well as to implement the consultation procedure with all parties involving Partner Expert Groups (PEGs), ECHA's Committees, as well as MSCAs in order to ensure the broadest possible acceptance of guidance. Closer the registration deadline, any necessary last minute changes to the guidance will be communicated to the stakeholders through other means (e.g. news alerts and FAQ via the website).

1.3 REACH training

REACH training events will continue to be organised in 2010 with a focus on the first half of the year. The objective is to provide support via training to selected audiences, charged with implementing the legislation, such as MSCAs, third countries and others, in order to achieve common implementation standards for the REACH and CLP regulations.

2. Objectives and Indicators

Objectives

1. The industry receives timely and efficient support from the Helpdesk, and through high quality guidance documents, for submission of their registration dossiers and CLP notifications.
2. Support is provided to the implementation of REACH in the Member States by the training of trainers.

Performance Indicators & Targets

Indicators	Target in 2010	Means and frequency of verification
Percentage of Helpdesk questions answered within the established timeframe (on average 15 days for questions other than those on the user management on REACH IT).	Not less than 75%	Business Object report / monthly
Number of FAQ updates agreed with REACH and CLP helpdesk correspondents and published on the web.	At least 3	Annual report
Percentage of feedback replies provided by ECHA to questions submitted to RHEP and CLP helpdesk exchange platform 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

- Timely and consistent replies and support provided to industry on their obligations under the REACH and CLP Regulations, IT tools and ECHA-related processes.
- Helpdesk requests for technical advice on the registration and C&L notification processes answered.
- Special support to registrants and notifying companies for the C&L inventory in particular during the peak time of joint submissions and before the first registration and C&L notification deadlines.
- Fully operational CLP helpdesk network established.
- Two REHCORN and CLP helpdesk correspondents meetings (back to back) organised.
- FAQs on REACH and CLP-related matters updated and published, following identification, discussion and agreement by the helpdesk network.
- FAQs on REACH IT and update of FAQs on IUCLID 5 updated and published.

Guidance

- Guidance documents, (initiated in 2009) published in 2010:
 - Guidance on Registration (Quarter 1)
 - Guidance on information requirements and chemical safety assessment/chemical safety report (Quarter 1 and Quarter 2)
 - Guidance on substances in articles (Quarter 1)
 - Guidance on Annex VI of the CLP Regulation (Quarter 1)
 - Guidance on risk communication (Quarter 4)
 - Guidance on authorisation (following its hand-over from the European Commission).
- The most important guidance documents or summaries thereof (e.g. “guidance in a nutshell”) will be made available in all official EU languages.
- Accessibility of the guidance improved via a revamp of ECHA’s website and provision of documents such as fact sheets and explanatory notes.
- Stakeholder relations intensified through direct contacts, participation in meetings, and the organisation of workshops.

REACH training

- Further development of REACH training for trainers for Member States and targeted third countries.
- Two workshops/training sessions particularly targeted at REACH and CLP national helpdesks organised.

4. Risks

For the Helpdesk, the main risk in 2010 is linked to the registration. ECHA’s workload estimates are based on the initial number of registrations and on previous experience in 2008-2009. Developments could turn out very differently in 2010, as more SIEFs may be active and more complex questions may be raised than anticipated. A much higher than expected number, or more complex questions over the second half of 2010, could lead to an increase in the response time provided by ECHA. This could result in registrants and C&L notifying companies remaining uncertain of how to overcome unexpected difficulties with the submission of their dossiers by the deadline.

Peaks in registration activity will directly affect the workload of the Helpdesk. In line with the registration contingency plans, ECHA will be prepared to hire interim staff, and reprioritise its registration-based activities to support the Helpdesk for a limited time. ECHA intends to ensure that more of its staff is trained and versed in the principles and processes of the Helpdesk. Staff may then be reallocated to Helpdesk work at times of peak pressure.

Furthermore, update or development of guidance documents, and their publication on the web, requires continuous close cooperation between many different players in ECHA Secretariat, ECHA scientific committees and the European Commission, as well as smooth cooperation with external partners and stakeholders such as MSCAs and PEGs. Against this complex background, delays in some guidance activities planned for 2010 may need to be accommodated in order to facilitate cooperation and common understanding among all parties.

A last risk is linked to the registration contingency plans, which may require the temporary redeployment of scientific and administrative staff from the guidance activity to registration.

Activity 6: IT support to operations

1. Main challenges in 2010

The main IT tools used in support of REACH operations are REACH-IT and IUCLID 5. ECHA is also developing a number of additional specialised applications such as the Chemical Safety Assessment and Reporting Tool (CHESAR) and decision support systems for priority setting and reporting (CASPER), and to support the evaluation process (Odyssey).

REACH-IT is an online system that manages the communication between industry, ECHA, Member States and the Commission as well as ECHA's internal workflows in relation to the REACH processes. It also aims at supporting the public in consulting databases and communicating online. REACH-IT is therefore essential for the successful implementation of the REACH legislation.

The main challenge to the Agency in 2010 will be the processing of a very large number of registrations and C&L notifications. Successful processing depends upon a fully functional REACH-IT system. Ensuring that REACH-IT is fully functional in time to meet the demands that will be placed upon it is the critical IT support challenge of 2010. Consequently, the activities in 2010 will be focused on two main areas:

- the successful further adaptation of the existing system for the first registration deadline of 30 November 2010 and the subsequent C&L notification deadline; and
- the addition of functions to replace manual, resource intensive "work-around" solutions put in place in 2008 when ECHA started operations.

REACH-IT is not only concerned with registration or with use within the Agency. Subject to the main priority areas above, ECHA intends to improve dissemination of information on chemical substances by making access to and searching within the website easier. Workflows supporting the evaluation and the classification and labelling processes will be finalised. In addition, a specialised application (RIPE) will be developed to support the enforcement authorities in the Member States. Finally, ECHA intends to support outside users by providing translations of key help information within REACH-IT and parts of the supporting guidance.

IUCLID 5 is viewed as the international standard tool for the storage and exchange of data on the intrinsic and hazardous properties of chemicals. Registration dossiers have to be submitted to the Agency in the IUCLID 5 format in accordance with the REACH legislation. In 2010, ECHA will continue to maintain and support IUCLID, developing new functions in response to user requirements, in close contact with the OECD and its OECD IUCLID User Group Expert Panel. These will include implementing new OECD harmonised templates for reporting results of studies assessing the properties and effects of chemicals and allowing the results of chemical safety assessments to be recorded directly in the database.

CHESAR is intended to help prepare exposure scenarios and chemical safety reports that are required for some of the registrations and to provide practical tools for calculating the risks of chemical emissions. After completion of the first version at the end of 2009, additional functions will be added in 2010 in time for the registration deadline, which will include substance profiling (to help select the appropriate assessment approach), qualitative assessment methodology, interfaces with other external exposure assessment tools, and additional administration enhancements.

CASPER allows the information needed for evidence-based priority setting required in a number of REACH processes to be collected, analysed and presented. The development will initially aim at assisting in the screening and the prioritisation of registration dossiers for evaluation to manage the peak workload in the years after 2010.

The evaluation tool Odyssey supports the ECHA Secretariat in dossier evaluation by guiding the evaluator to the most relevant issues of the registered substance dossier, and to the corresponding information in the guidance documents; by supporting the drawing of conclusions; and by recording the outcome of the evaluation. The tool will be further developed by adding more functions and by improving existing features based on practical experience.

RIPE (REACH Information Portal for Enforcement) allows inspectors in Member States to access necessary information from REACH-IT, such as selected information from registration dossiers, so that they can enforce REACH more effectively. The first release of the application is planned for the end of 2010 to coincide with the first registration deadline for phase-in substances.

The Agency will also work on IT tools (including the (Q)SAR toolbox and other screening and predictive systems) to help make better use of alternative computational approaches to animal testing. The Agency will work with the current Project Coordination Group, which provides scientific and technical input and assesses and accepts the project deliverables. The group consists of members from ECHA, the OECD and the Joint Research Centre of the European Commission (JRC).

2. Objectives and Indicators

Objectives

ECHA is able to receive and process all registration dossiers for phase-in substances and all C&L notifications, subject the first registration deadlines in 2010 and early 2011, with the assistance of a well functioning, upgraded REACH-IT tool and databases, and registrants are supported by specialised IT-tools (IUCLID 5 and CHESAR).

Performance Indicators & Targets

Indicator	Target in 2010	Means and frequency of verification
Percentage of software modules for the different IT tools completed according to schedule.	Not less than 80%	Project planning: Monthly activity reporting

3. Main outputs

REACH-IT

- Before June 2010, a re-engineered REACH-IT, scaled and tested with a much higher load factor to process the high number of dossiers expected to arrive for registration and C&L notification.
- A completed workflow for processing the C&L notifications received from industry, from online submission to dissemination of the C&L inventory on the ECHA website. Key workflows for evaluation will be operational in time for 2011.
- An improved ECHA website making information on the properties of chemical substances available to the public.

IUCLID 5

- Stakeholder driven upgrades including introduction of new OECD harmonised templates for reporting study results and improved interfaces between IUCLID 5 and other IT systems, in particular REACH-IT and CHESAR , facilitating electronic data exchange across IT systems in industry and regulatory bodies.

CHESAR

- A new version with more functions, interfaces to more exposure assessment tools and the possibility to import structured information from the CHESAR Tool into IUCLID 5 will be delivered well before the registration deadline.

CASPER

- The first release of the tool is delivered to users for automatically identifying and prioritising the registration dossiers that are suitable candidates for compliance checking in order to facilitate the evaluation process.

RIPE

- The first release of the application, planned for the end of 2010, will cover functionalities to access and search the selected submission data as well as prepare standard reports.

4. Risks

REACH-IT is at the front line when the Agency is facing a high degree of uncertainty concerning the expected number of dossiers arriving for registration and C&L notifications. In addition, as these dossiers are expected to be submitted shortly before the deadline, the performance and the usability of the system could be put at risk. Therefore, an alternative IT system for submissions will be put in place to respond to any eventual disruption of critical functions and services.

CHESAR and RIPE are developed within a very tight schedule. Therefore, in the development of the tools, meeting the delivery dates will be given priority over the broadness of functionalities.

A third risk is linked to the registration contingency plans, which may require, as far as possible, the temporary redeployment of scientific and administrative staff to registration.

Activity 7: Scientific and practical advice for the further development of legislation

1. Main challenges in 2010

According to its mission ECHA shall 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 role also covers, beyond what is described under other operational activities, certain horizontal and general scientific issues, as well as the scientific and technical support ECHA will give to the Commission and other institutions in the development or revision of chemicals legislation.

The main areas in which ECHA is working under this activity cover the safety of nanomaterials, the development of test methods (including alternative methods and non-animal approaches, such as QSAR, categories and read-across), and the preparatory work in relation to the forthcoming Biocides Regulation⁵. So far, ECHA has had very limited resources to invest in these areas but will continue to build up its capacities and planning in 2010 with a view to becoming more a prominent actor in the coming years. This activity partly depends on the requests received from the Commission or other EU institutions, and therefore, the implementation of these tasks also partly relies on additional appropriate support from the Commission.

2. Objectives and Indicators

Objectives

ECHA has improved its capacity to provide scientific and technical advice on the safety of nanomaterials and development of alternative testing methods and has provided scientific and technical advice to the Commission (and if appropriate to the other co-legislating institutions) on the proposed Biocides Regulation.

Performance Indicators & Targets

Indicator	Target in 2010	Means and frequency of verification
Level of satisfaction with the quality of the scientific, technical and administrative support provided to Commission.	High	Annual survey

3. Main outputs

- Advice in the field of nanomaterials, with a view to supporting the development of new methods and guidance for examining and assessing their safety.
- Improved scientific and technical capacity to deal with nanomaterials in REACH processes.
- Improved scientific and technical capacity to contribute to the development of test methods and non-animal methods and approaches.
- Support to the co-decision procedure on the Biocides Regulation (subject to appropriate resources being made available by the Commission).

⁵ Proposal for a regulation of the European Parliament and the Council concerning the placing on the market and use of biocidal products (COM(2009)267 final)

- Practical Work Plan and start of its implementation ensuring the appropriate preparation of ECHA's role and tasks under the Biocides Regulation (subject to appropriate resources being made available by the Commission).
- Continued support for the amending of Annexes to REACH Regulation and, if relevant, the CLP Regulation.

4. Risks

It is difficult to estimate precisely the resources needed to carry out the above tasks and fulfilling the aforementioned objectives. ECHA must ensure the fulfilment of its objectives related to core REACH and CLP processes described under other activities. Therefore, in its resource planning ECHA can only reserve a limited amount of expert resources for these tasks. In addition, the high workload anticipated for core REACH processes may lead to negative priorities under this activity. ECHA cannot predict with any certainty the number and complexity of the future requests from the Commission.

It should also be noted that this activity may be affected by ECHA's contingency plans for registrations.

***Programme 2:
ECHA's bodies and supporting activities***



Activity 8: Committees and Forum

1. Main challenges in 2010

The Committees (the Member State Committee, the Risk Assessment Committee and the Committee for Socio-economic Analysis) are an integral part of ECHA and play an essential role in carrying out its tasks, in particular for issuing science-based opinions in their field of competence. With the exception of the MSC, the members of which are appointed directly by the Member States, the members of the Committees are experts appointed by ECHA's Management Board on the basis of proposals from the Member States.

The overall workload and the number of meetings of the Committees are highly dependent on the number of dossiers and draft evaluation decisions submitted to the Committees, and in particular, on the complexity of the restriction cases. The objectives and targets mentioned below are based on the baseline figures described in Annex 2.

The expected number of different types of dossiers submitted by MSCAs or ECHA, (6 restriction dossiers, 30 Annex XV dossiers for identification of SVHCs, 90 proposals for harmonised classification and labelling), and some 70 draft evaluation decisions being submitted to the Member State Committee, would result in around 20 Committee/Forum plenary meetings being needed in 2010, even though written procedures will be used to the extent possible. In addition, the Forum is expected to run at least five working groups that will need support.

It is clear that the Committees are to face an increased workload in 2010 as the number of dossiers submitted by the MSCA, and the number of evaluation decisions, is constantly increasing. The quality and timeliness of the opinions adopted by the Committees will become a point of attention and therefore an appropriate quality assurance system has to be established.

The Forum for Exchange of Information on Enforcement is, as are the Committees, a formal body of ECHA, consisting of members appointed directly by the Member States. The 2010 deadline for registrations and the early 2011 deadline for C&L notifications for inventory will mean that the importance of and expectations laid on the Forum's coordinated enforcement activities by the stakeholders, Member States and the Commission will grow. ECHA is committed to increasing its support to effective enforcement activities through establishing specific IT-applications for enforcers, providing reinforced secretarial support to the Forum and its Working Groups, organising training for trainers of inspectors, and through developing and publishing project manuals and best practice guidelines for enforcement activities.

2. Objectives and Indicators for 2010

Objectives

1. The work of the Committees will be supported efficiently and effectively so that they 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-makingin a transparent manner while ensuring the necessary confidentiality.
2. The work of the Forum will be supported efficiently and effectively so that it has been able to strengthen and harmonise further the enforcement of the REACH

and CLP Regulations in the Member States in a transparent manner while ensuring the necessary confidentiality.

Performance Indicators & Targets

Indicators	Target in 2010	Means and frequency of verification
Percentage of opinions / agreements delivered in time.	Not less than 90 %	Annual internal report
Percentage of unanimous MSC agreements.	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 European 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 the Forum activities.	High	Annual survey

3. Main outputs

Outputs:

General

- Implementation of cooperation procedures with relevant scientific bodies and EU agencies.
- Written contracts with rapporteurs and experts serving the working groups handled.
- Renewal of appointment or replacement of the RAC and Forum members having served for three full years (by December 2010).

Member State Committee

- Agreements on draft decisions based on dossier evaluations (testing proposals and compliance checks) for all draft decisions commented on by the MSCAs.
- Agreements on identification of Substances of Very High Concern.
- Opinions on further priority substances recommended to be included in Annex XIV (for authorisation).

Committee for Risk Assessment

- Opinions on classification and labelling dossiers (according to both Dangerous Substances Directive and CLP criteria).
- Opinions on first restrictions dossiers (if any conforming dossiers are submitted by MSCAs by the end of Quarter 1 of 2010).

Committee for Socio-economic Analysis

- First draft opinion(s) on restriction dossier(s) prepared (and adopted) (if any conforming dossiers are submitted by MSCAs in 2009).

Forum for Exchange of Information on Enforcement

- Practical results in coordinated enforcement projects as proposed by the Forum (e.g. registration, restrictions etc) and development of guidance for REACH enforcers based on the experience from the first coordinated project.
- Advice on enforceability of proposals for restrictions.

4. Risks

Should the number of dossiers be significantly higher than estimated, more written procedures will need to be used; meeting the deadlines and ensuring high quality will be highly challenging, will require a very high commitment from members, strong MSCA support to individual members, and an increase in the Secretariat resources. In order to be ready to prepare for such a situation, ECHA will liaise closely with Member State Competent Authorities to plan for the future workload.

The ability of the rapporteurs of the Committees to deliver high quality work depends on the scientific and technical support given by the MSCAs and the ECHA Secretariat. The rapporteurs for the first dossiers will be a valuable source of feedback on the level and quality of support necessary by them and ECHA should therefore actively seek their views and communicate possible concerns to the MSCAs early on.

The ability of the Forum members to agree on joint activities and commit resources depends on the Member States' resources. This responsibility pertains solely to the Member States but ECHA should continue promoting harmonised enforcement and supporting the joint Forum activities to the extent possible.

It should also be noted that these activities may also be affected by ECHA's contingency plans for registrations.

Activity 9: Board of Appeal

1. Main challenges in 2010

The Board of Appeal (BoA) decides on appeals brought against certain individual decisions of the European Chemicals Agency. It is a new body created by REACH to provide legal redress to the parties involved. An important challenge for the BoA at this early stage is to build up stakeholder confidence and raise understanding about the new appeal system created by REACH. Another key challenge for the BoA is to pave the way for its decisional practice within the novel legal framework of REACH. It is expected that the BoA will often be confronted with the task of deciding on new and complex issues concerning the substantive aspects of appeal cases brought before it, for which very limited and only remotely relevant case law exists.

The BoA's workload will depend on several factors: the quality and number of decisions adopted by ECHA, the percentage of decisions adversely affecting one of the interested parties, and particularly the willingness of stakeholders to appeal against those decisions. Precise estimates regarding the number and types of appeals are extremely difficult to project.

It is anticipated that most cases in 2010 will result from the preparatory activities carried out by industry between the beginning of the year and the first registration deadline (30 November 2010) for phase-in substances, especially with respect to decisions related to data-sharing.

Based on the ECHA 2010 baseline figures for decisions the BoA is required to have the ability to engage sufficient resources to deal with a base load of 100 cases and to have a well-prepared contingency planning for a higher number of appeals in place, including the calling upon alternates and additional members and reliance on adequate reserve lists of suitable candidates for support staff or experts who can be recruited or mobilised as soon as the need arises.

2. Objectives and Indicators

Objectives

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

Performance Indicators & Targets

Indicators	Target in 2010	Means and frequency of verification
Percentage of cases concluded within 12 months of their introduction.	90 %	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).
- Effective communication with the parties in relation to appeal proceedings and with stakeholders.
- An effective and user-friendly database of decisional practice and relevant case-law established on ECHA's website.
- Access to online information and adequate guidance on the appeal procedure in order to minimise delays or rejections caused by procedural errors provided to potential appellants.
- Capacity building plan will be implemented.

4. Risks

The above planning for the Board of Appeal is achievable only if the number of appeals is not considerably higher than the estimate given above as the base load within the range. Should the number of appeals be considerably higher than this baseline, the requested resources are to be revised upwards. In order to mitigate the risk, the Registry will ensure – when needed and as far as is feasible – that external interim support can be obtained. Conversely, should the number of appeals be substantially lower than the baseline for the foreseeable future, a number of new posts can be redeployed to the operational activity of the Agency.

In addition, an uneven distribution of appeals over the year might lead to a situation where the BoA will not be in a position to examine all appeals within a reasonable time frame. Such a situation could cause a backlog in the processing of appeals and consequently lower stakeholder confidence in the work of the BoA. In order to mitigate that risk, accurate case time management will be adopted, and if needed, the setting up of additional capacity will be appropriately considered in due time before the actual peak occurs.

Activity 10: Communications

1. Main challenges in 2010

ECHA's 2010 communications plan seeks to establish coherent internal and external communications strategies and processes that will serve as a robust basis for the workload that is expected in 2010. The main challenge will be to support the achievement of ECHA's business objectives by ensuring that all aspects of the way in which ECHA communicates both internally and externally are the best they can be. ECHA has numerous and heterogeneous external audiences and all communications must be tailored to meet their needs. A further challenge will be to manage ECHA's developing reputation by consolidating its brand, reviewing all our contacts with the outside world to ensure that we deliver an effective service, and by ensuring that crisis communications plans are in place. An accurate and balanced presence in the media needs to be ensured. ECHA needs to understand its key stakeholders' views and to know how best to communicate with them. Therefore, an early warning and media monitoring system will be put in place.

In a rapidly growing Agency it is important to develop effective internal communication to ensure that all staff in ECHA have the information that they need to do their jobs well, that they feel part of a common corporate endeavour, and are ready to be redeployed in case of emergency.

2. Objectives and Indicators

Objectives

1. ECHA's external audiences are communicated with effectively, and ECHA benefits from an accurate and balanced media presence.
2. All material (whether online or offline) that is produced for large numbers of small and medium sized enterprises or the general public will be translated into 21 official EU languages.
3. With the help of effective internal communication, ECHA staff is well informed, have a sense of belonging, and feel part of a common corporate endeavour.

Performance Indicators & Targets

Indicators	Target in 2010	Means and frequency of verification
Level of website customer satisfaction.	Very Good	Annual user surveys, quarterly web statistics
Level of staff satisfaction with internal communications.	Good	Annual staff survey
Level of satisfaction expressed in customer surveys of publications readerships – newsletter, internal newsletter.	Good	Annual customer surveys
Level of stakeholder satisfaction with their involvement.	Very good	Survey on Stakeholder Days
Publication of translations of guidance documents relevant to large numbers of small and medium sized enterprises (within an average period of three months after the original document, without validation).	100%	Internal quarterly report

3. Main outputs

- ECHA internet and intranet sites rebuilt.
- External communications activities enhanced, with a new External Communications Strategy and Stakeholder Engagement Strategy.
- Risk and Crisis Communications Strategies prepared and executed.
- ECHA's Press Office and proactive media management policy in place.
- Study into the communication of hazards and safe use of chemicals with the public across Europe begun.
- Translation of material published on the website and in hard copy in 21 Community languages, in particular when the target audience is small enterprises and the general public.

4. Risks

The primary risk in the communications field is of damage to ECHA's reputation. That could be as a result of the sheer volume of work and any slowing down in response times to journalists and stakeholders that might result. New Press Officers are being recruited in 2009/2010 to try to reduce the likelihood of that.

There is also a risk of downtime when the migration of content from the old website and intranet to the new versions takes place; planning is underway to reduce the likelihood of this occurring.

Some of these activities can also be affected by the contingency plans that may need to be put in place to support the registration activities.

Activity 11: Relations with EU institutions and international cooperation

1. Main challenges in 2010

1.1 EU institutions and other bodies

In 2010 ECHA will continue its active cooperation with the European Parliament and the Commission by, *inter alia*, informing the institutions regularly of its activities and seeking counsel from the Commission on legal interpretation issues, in particular. Cooperation with other European agencies and scientific committees will continue and where necessary, Memoranda of Understanding may be established to provide a more formal framework for ECHA's cooperation and coordination with them. The Rules of Procedure for cooperation with EFSA and the Advisory Committee for Health and Safety at Work to be adopted by the Management Board in accordance with Article 110 of the REACH Regulation by the end of 2009 will lay down the basis for intensive cooperation between ECHA and these two bodies.

ECHA will discuss, and potentially develop, a co-operative work programme on (Q)SARs ((Quantitative) Structure-Activity Relationships) with JRC, building upon their existing experience with QSAR tools.

Cooperation with Member States will continue as an essential aspect of the Agency's day-to-day work. The meetings of the Competent Authorities of the REACH and C&L Regulations (CARACAL) will provide the main platform for consulting MSCAs, but *ad hoc* workshops and training sessions may additionally be organised when necessary.

1.2 International cooperation

ECHA will continue its international activities in accordance with a detailed work plan developed jointly with the Commission and agreed by the Management Board in 2009. As in the previous year, this work plan will identify the fields in which ECHA will provide technical-scientific support to the European Commission in multilateral bodies working on the management of chemicals and will be determined by the annual calendar of such bodies.

The main focus will continue to be on cooperating with the OECD on issues relevant to REACH implementation.

In 2010 ECHA will continue to be involved in two OECD projects on the request of the European Commission. The first is the Global Portal to Information on Chemical Substances (eChemPortal), an internet gateway, which aims at improving the availability of hazard-related data on chemicals found in the environment, homes and workplaces, and in products used daily. To promote worldwide accessibility to data and to achieve synergies with ECHA's own dissemination obligations, the Agency is co-managing the project with the OECD. ECHA will also play an important role in hosting the portal after completion of its development, which is scheduled for the second half of the year.

Another important OECD project addresses (Q)SARs. These are methods for estimating properties of a chemical from its molecular structure and may provide information on hazards of chemicals, while reducing time, monetary cost and animal testing ECHA is co-managing the development of the (Q)SAR Application Toolbox with the OECD for practical applications of (Q)SARs in regulatory contexts.

In addition, ECHA will continue to chair the OECD IUCLID User Group Expert Panel which was originally established in 1999, with the aim of enhancing the software and collecting user requirements. In accordance with the REACH Regulation, ECHA coordinates the further development of IUCLID with the OECD.

ECHA will also continue, in 2010, to help increase the preparedness of EU candidate countries, and potential candidates and partner countries of the European Neighbourhood

Policy (ENP), to implement REACH. To that end, ECHA will be participating in programmes arranged mainly by the European Commission Technical Assistance and Information Exchange (TAIEX) office, as well as activities funded from the EC's Instrument for Pre-Accession (IPA). The latter programme aims to carry out activities to ensure that candidate countries and potential candidates can participate effectively in the activities of the Agency.

Finally, ECHA will also provide scientific and technical support to the Commission on the multilateral international activities such as the Stockholm Convention on Persistent Organic Pollutants and the technical work of the UNECE SC GHS.

2. Objectives and Indicators

Objectives

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

Performance Indicators & Targets

Indicators	Target in 2010	Means and frequency of verification
Occurrence of conflicts of opinions with Scientific Committees of other Community bodies.	Only in well justified cases	Internal evaluation report
Level of satisfaction of the Commission with the support given by ECHA on international activities.	High	Annual survey
Joint IT projects (eChem portal and IUCLID 5) with the OECD completed successfully.	New release of eChem portal has been delivered to ECHA and a new release of IUCLID 5 published by the end of 2010	Annual report

3. Main outputs

- Implementation of the practical technical cooperation with EFSA, EMEA and ACSHW and EU-OSHA⁶ and scientific committees of other Community bodies.
- Scientific and technical support to the Commission's work on the Stockholm Convention on Persistent Organic Pollutants and the UNECE SC GHS.
- Actions to support candidate countries for EU accession and, as appropriate, potential candidates as well as ENP (European Neighbourhood Policy) partners to prepare for REACH implementation and participation in ECHA.
- Contacts with third countries and their respective authorities as appropriate.
- Scientific and technical cooperation with the OECD (continuation):
 - The eChemPortal project delivered to ECHA by the end of 2010.
 - The (Q)SAR Toolbox project progressing according to plan and to a high-scientific level; the second version of the Toolbox released by the end of 2010.
 - IUCLID 5 has incorporated all user requirements prioritised by the OECD IUCLID User Group Expert Panel in its meeting of September 2008.
 - Task force on hazard assessment.
 - Task force on exposure assessment.
 - Harmonised Templates projects.
 - Working party on nano-materials.
 - Task force on Harmonized classification and labelling.

4. Risks

The likelihood of potential differences of opinions with scientific committees of other Community bodies is very difficult to estimate. The nature of relevant cases can vary and affect the workload for ECHA accordingly.

Concerning international cooperation, the workload will depend very much on the requests made by the Commission. As only a limited amount of resources can be allocated to international activities, requests for cooperation from third countries will be carefully examined, whereby prioritisation of different tasks is essential. Should the Commission ask ECHA to provide additional support for international cooperation, additional resources would need to be allocated by the Commission to these activities and ECHA may have to outsource some of that support.

This activity may also be affected by the contingency plans that could be triggered to safeguard the registration activity, particularly in the last quarter of 2010.

⁶ European Food Safety Authority, European Medicines Agency, Advisory Committee on Safety and Health at Work and European Agency for Safety and Health at Work.

***Programme 3:
Management, organisation and resources***



Activity 12: Management

1. Main challenges in 2010

While the Executive Director of ECHA is responsible for the day-to-day administration of the Agency and the management of its resources, ECHA's highest decision making body is the 35-member Management Board, which adopts the Agency's multi-annual and annual work programmes, budget, annual report and internal 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 ECHA RAC and SEAC Committees. The Secretariat of the Management Board in ECHA, provided by the Executive Office, will continue to ensure the smooth functioning of the Management Board meetings as well as the legality of its meeting procedures and decisions.

The Executive Office will continue to support the Executive Director in the management and the horizontal coordination of the Agency's operations. It will provide organisational support for the Directorates, lead the quality and security policies, organise document management and process initial requests for access to document. It will also support the Executive Director's contacts with the European institutions and other European bodies, and will develop further links with the scientific community and academia.

The 2010 registration deadline will reflect on the number of decisions to be taken by the Agency. ECHA's legal advisors will need to give constant support to REACH operations to ensure that decisions are taken in accordance with legal requirements; and also defend the Agency in case of possible appeals. The Legal Affairs, established as a separate unit in 2009, also supports the Executive Director in taking decisions in review procedures, e.g. regarding confirmatory requests for access to documents or requests to accept confidentiality claims.

ECHA will continue the establishment and implementation of the integrated quality management system (IQMS), based on the internationally recognised standard for quality management systems (ISO 9001:2008), and its underlying process approach. Considering the complex nature of ECHA's processes, the work to put in place the necessary procedures, work instructions and other quality documents will continue for some years beyond 2010, in accordance with the mapping done in 2009.

Further to a risk assessment workshop at the end of 2009, a corporate risk management system will be developed and an action plan for risk management will be implemented in 2010. Security issues, both regarding information security as well as physical security, remain priorities in 2010, with emphasis placed on establishing business continuity management. Ensuring secure communication channels with Committee Members, Member State Competent Authorities, as well as with external experts, will receive special attention. ECHA's internal auditor will conduct audits as well as advise the Executive Director on control systems.

Management information systems will be further developed, including those relating to planning and reporting, and document management.

2. Objectives and Indicators

Objectives

1. The Agency fulfils all its statutory obligations with regard to the Management Board and the EU institutions.
2. The Agency continues the development of a structured quality and internal control system, having reviewed its risks and has a comprehensive security system as well as a solid information management system in place.

Performance Indicators & Targets

Indicators	Target in 2010	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 risk mitigation plan.	Not less than 90%	Annual internal report
Percentage of quality procedures released to the public.	Not less than 70%	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 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

- Management Board meetings organised professionally.
- Regulatory documents for planning and reporting provided and adopted according to the agreed schedule.
- Quality Management System documentation developed, with the main operational procedures published together with the compulsory part of the quality manual.
- Corporate risk management system published internally to support the implementation of a multi-annual, full scale risk management system, including a business continuity project.
- Internal Audit Capability annual work plan for 2010 implemented, including an update of the IAS risk assessment following the start of new operations (authorisations, restrictions), and the follow-up of 2009 audits.
- Provision of strong legal support to ensure that ECHA's decisions are legally correct, also during peak periods; provision of effective defence in case of appeals.
- Development of a corporate management information system featuring planning and monitoring as well as secure filing and electronic archiving.
- Development of EU inter-institutional relations, for a better link with, *inter alia*, the EU Commission, the European Parliament and other Agencies.
- Coordination of requests for access to documents in accordance with Community legislation.

4. Risks

The Agency has been operational for rather a short time, during which the security management has been intensively developed. The security management is being set up at the same time as the processes of the Agency are being established. Considering the speed with which the Agency has been set up and the limited resources, there is a risk that the risk management done in the Agency fails to address all the risks facing the security systems. This could pose a risk of a failure relating to the information assets, which would have a high impact on ECHA's reputation and could lead to liability claims, in particular as the source will be difficult to identify once all eligible external bodies obtain access to the data of the Agency. The Agency is aware of this and gives a clear priority to mitigating actions in this respect.

Some of these activities may also be affected by the registration contingency plan.

Activity 13: Finance, Procurement and Accounting

1. Main challenges in 2010

The Agency's main challenge in the financial domain in 2010 will be efficient cash management. Of particular concern will be the adequacy of the cash inflow to cover the Agency's legal obligations throughout the year. Originally, no Community subsidy was foreseen for the Agency from 2010 onwards in the current financial programming period (2007-2013) as the deadline for the first fee-generating registration wave was foreseen to be 30 June 2010. However, with the postponement of this deadline until 30 November 2010 by the co-legislator, the bulk of fee revenue from the first registration wave is expected to be received only at the very end of 2010 and in the following year. ECHA cannot rely on sufficient early submissions of registrations and corresponding fee income throughout the year, as the experience gained so far from the pre-registration phase shows that it is very likely that registrants will wait until the deadline before submitting their dossiers. The anticipated continuing weakness of the general economic situation reinforces this assumption.

The Agency's planning has been based on the assumption that the budgetary authority will grant a reimbursable temporary subsidy, which is high enough for ECHA to execute its essential tasks under REACH, and that it is willing to review the situation during the year to increase that amount if the cash-shortfall is higher than predicted.

The Agency will also be faced with the operative challenge of being able to swiftly process the expected high volumes of and peaks in the financial transactions in 2010. The number of fee invoice transactions and the amount of fee revenue to be cashed during the year is expected to grow dramatically and depends fully on the number of registrations and their distribution over the year. According to the baseline figures presented in Annex 2, there should be around 25 000 invoices to be sent to registrants by the end February 2011. However, as already discussed in the preceding chapters, this figure could perhaps change radically. In any case, as the Community subsidy requested was not foreseen in the financial perspectives, the Agency has to ensure that a sufficient volume of invoices is cashed at year-end to permit the repayment of the subsidy to the Commission in the course of 2010 in line with the provisions set out in the Agency's Financial Regulation (Art. 16).

In addition, it is expected that the Agency will have some 800 commitments and over 3000 outgoing payment transactions as a result of its operational activities.

2. Objectives and Indicators

Objectives

1. The Agency has sound and as efficient as possible financial management.
2. Invoices are efficiently generated and cashed in order to reduce the need for subsidy during the entire year.

Performance Indicators & Targets

Indicators	Target in 2010	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%	BO report on ABAC/ annual
Payment rate.	Not less than 70%	BO report on ABAC/ annual
Cashed fee income.	106,8 million euros	REACH report / annual
Number of complaints against ECHA procurement procedures.	0	Annual internal report
Surplus necessary for the reimbursement of the Community subsidy.	100 % of the value of subsidy	2010 accounts

3. Main outputs

- Rigorous budget and liquidity management.
- Efficient accounting work-flows and procedures in view of the invoicing peak related to the first registration deadline.
- Mechanism for managing and investing the Agency's cash reserves implemented.
- System for procurement and contract management developed.
- Analytical (activities) accounting system in development.
- Follow up and execution of the budget improved to reach commitment rate of 98%.

4. Risks

The work plan of the Finance, Procurement and Accounting activity is realistic if the baseline figures of Annex 2 are valid. If the number of registrations or any other volume indicators are drastically higher than estimated, the resources could be insufficient and appropriate framework contracts need to be employed to have access to short term assistance in a swift and flexible way.

There is a risk that the budgetary authority will ultimately not grant the temporary Community subsidy up to the level foreseen. In this case there is also a risk of having to scale down the operational activities. Close monitoring of the liquidity situation, effective cash-flow planning and cooperation with the Commission services will be undertaken to mitigate the risk.

As regards the repayment of the Community subsidy, there is a risk that due to a number of circumstances (e.g. quality of the submitted REACH dossiers, the bulk of the

registration dossiers only arriving close to the deadline) the amount of the budgetary outturn account is insufficient to repay the Community subsidy of 2010 in 2011, and thus that part of the reimbursable temporary subsidy becomes a net subsidy to ECHA. To reduce this likelihood the invoicing procedures will be streamlined and tuned for large volumes. A contingency plan will be ready to (re)deploy staff resources when this would be needed, while close contact with stakeholders will be maintained as to obtain early indications on timing and volumes of registrations.

Activity 14: Human resources and infrastructure

1. Main challenges in 2010

The main challenges for Human Resources in 2010 is continuing the extremely high rate of selection and recruitment (102 Temporary Agents and 18 Contract Agents) with the additional challenge of organising written tests as part of the selection procedure. New staff will be provided with relocation support and the high volume of new staff will also receive induction and initial training at the start-up-phase of their employment.

The growing number of existing staff will continue to receive a high level of training based on the Learning and Development Strategy 2009-2012 and Training Guidelines. The implementation of performance management for a growing volume of staff (job descriptions, objectives, probation reporting, performance appraisal, promotions) is challenging and resource intensive both for HR as well as for other units.

The HR administration capacity and payroll will be scaled up to cope with the growing number of staff, in particular via the implementation of a new HR information system and related workflows.

Specific and contingency measures could be required in case the number of submissions and registrations exceeds the estimates, or if more manual intervention is needed in the REACH processes, as compared to the initial plans. This could mean the need for the recruitment, training and management of a considerable number of temporary staff. If this occurs, it will also result in a substantial increase in logistics and IT support to host and accommodate these additional and temporary staff.

A new Corporate Services Unit will be created at the beginning of 2010. The new unit will take over the responsibilities of the Facility Team as well as some technical tasks from the Executive Office, such as mail registration and physical archiving. The new unit has, as one of its main responsibilities, the operation of the conference centre and other common facilities of the Agency, as well as the continuous challenge of providing office space and internal services for an estimated 580 persons at the end of 2010 (statutory staff, Seconded National Experts, trainees, interims, consultants). The high volume of ECHA's staff and assets, in particular its information assets, also requires the highest level of security and safety. The new conference centre and its support staff will continue to deliver high quality conference services.

The principal challenge for the Human Resources and the new Corporate Services units will be to deliver a significantly higher volume of services without a corresponding increase in its staff numbers. This will have to be achieved via improved information systems (e-HR) and workflows, more efficient procedures, further decentralisation of HR administration tasks (e.g. time and absence management) to line units and outsourcing.

2. Objectives and Indicators

Objectives

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 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 2010	Means and frequency of verification
Percentage of establishment plan posts filled at the end of the year.	Not less than 95%	Annual internal report
Percentage of selection procedures for the new posts for the year completed.	100%	Annual internal report
Turnover of the Temporary Agents.	Not more than 5 %	Annual internal report
Level of satisfaction of the Committee, Forum and MB members with the functioning of the conference centre.	High satisfaction	Annual survey
Average number of training days per staff member.	10	Annual internal report

3. Main outputs

Human resources

- An estimated 50 selection procedures to be organised with written tests with an estimated 1000 candidates, and 120 recruitments, without counting short-term staff needs to meet the peak workload at the end of 2010.
- 30 % increase in the number of staff in payroll, with a corresponding increase in the workload in the area of HR finance, administration and performance management, without counting short-term staff needs to meet the peak workload at the end of 2010.
- Continued relocation support and induction training at the same level as in 2009.
- High volume of training (av. 10 days per staff member) provided for a growing number of staff (+30 %).
- Management of an important increase of short-term staff (interim and contract agents) to meet the peak workload at the end of 2010.
- First steps towards competence-based HR management.

Infrastructure

- Further renovation and other activities linked to the space needs of c. 580 persons by the end of 2010.
- Space found for short-term staff linked to the peak workload at the end of 2010, and further office space in building taken over.
- Written manuals for technical systems in place.
- Health and safety activities for staff developed.
- Maintaining physical archives and creation of a documentation centre and library.

4. Risks

Human Resources

A main risk factor to human resources and staff recruitment is the uncertainty in the financial situation in 2010, and the eventuality that the recruitment pace has to be postponed until the very end of the year due to budgetary constraints. This would have a major negative impact since it would jeopardize the operational capacities of ECHA at the moment when it would be most needed to meet the deadlines at the end of 2010.

Due to the peak activities in 2010 requiring internal reallocation of staff and the possible reduction of the resources leading to insufficient recruitment, health problems linked to stress and excessive workloads may be expected. Flexible work programming and objective setting, together with motivational management and HR practices and active policies to promote a balanced work-life, could prevent these risks, but the problems could also be alleviated by recourse to external contractors.

Finally, part of the HR activities may also be affected by the contingency plans for registration.

Infrastructure

Contingency planning with the possibility of scaling up infrastructure capacities, within short time frames, is needed in order to be able to cope with the possible temporary need for 100 short-term staff from external contractors to help face higher volumes of work than anticipated.

Activity 15: Informatics and communication technology

1. Main challenges in 2010

The main IT challenge for 2010 relates to the readiness for legal deadlines and the expected large volumes of registration dossiers and C&L notification submissions by November/December. The readiness preparations will require continuous and large scale performance testing, the tuning of REACH-IT applications as well as the assurance that the system is scalable and that reserve capacity and back-up solutions are aligned.

In 2010, also several strategic products resulting from projects started in 2009 will also become operational (e.g. CHESAR, CASPER, Odyssey, Global Portal, etc.) and will be supported by the IT team. The Agency-wide Customer Relation Management system, the information system for the administration of human resources (e-HR) and the adoption of a centralized Enterprise Content Management system are high on the agenda for further development and implementation.

Extension of the technical infrastructure for accommodating the planned growth of staff, and the increased demand on technical resources, will continue to be a key challenge and strain the support services - such as the first line helpdesk and back office support. Other back office developments are foreseen for the implementation of an Agency-wide Identity Management System and for the registration of the Agency as an official Certification Authority for proper Public Key Infrastructure implementation.

As a part of the overall business continuity management of the Agency, Security and IT Business Continuity measures will continue to receive due attention and include the activation of fully featured disaster recovery facilities, the further strengthening of security for IT systems and the fine tuning of the intrusion detection system.

IT governance and project management will be further strengthened with additional staff being recruited, and will focus on the refinement of Agency Architectural Guidelines, project management support and quality assurance aspects, such as the preparation of procedures and guidelines as well as the formalisation of Service Level Agreements.

2. Objectives and Indicators

Objectives

The staff, stakeholders and external clients are provided with continuous IT services including operational back-up systems.

Performance Indicators & Targets

Indicators	Target in 2010	Means and frequency of verification
Availability of operational systems for external customers (uptime).	99 %	Data centre statistics
IT business continuity & disaster recovery plan operational in August 2010.	100%	Annual disaster recovery, business continuity tests and management reporting
Level of user satisfaction with internal IT services.	High	Annual customer survey and <i>ad hoc</i> feedback

3. Main outputs

- Equipment for 120 incoming statutory staff and for staff on short-term contracts.
- Back-office, storage and backup and restore systems upgraded to cater for staff growth.
- Core systems and applications, in particular REACH-IT, hosted, maintained and operated during peak loads.
- Second generation REACH-IT infrastructure and flexible scalability implementation installed.
- IT business continuity, and disaster recovery plans for core systems documented and tested.
- Architectural guidelines implemented, as defined in 2009.
- IT support for ECHA applications, including REACH-IT and dissemination and other web developments like Global Portal, provided.
- Fully featured data-warehousing environment created for the purpose of REACH-IT Dissemination, Enforcement, Global Portal and support to internal business processes.

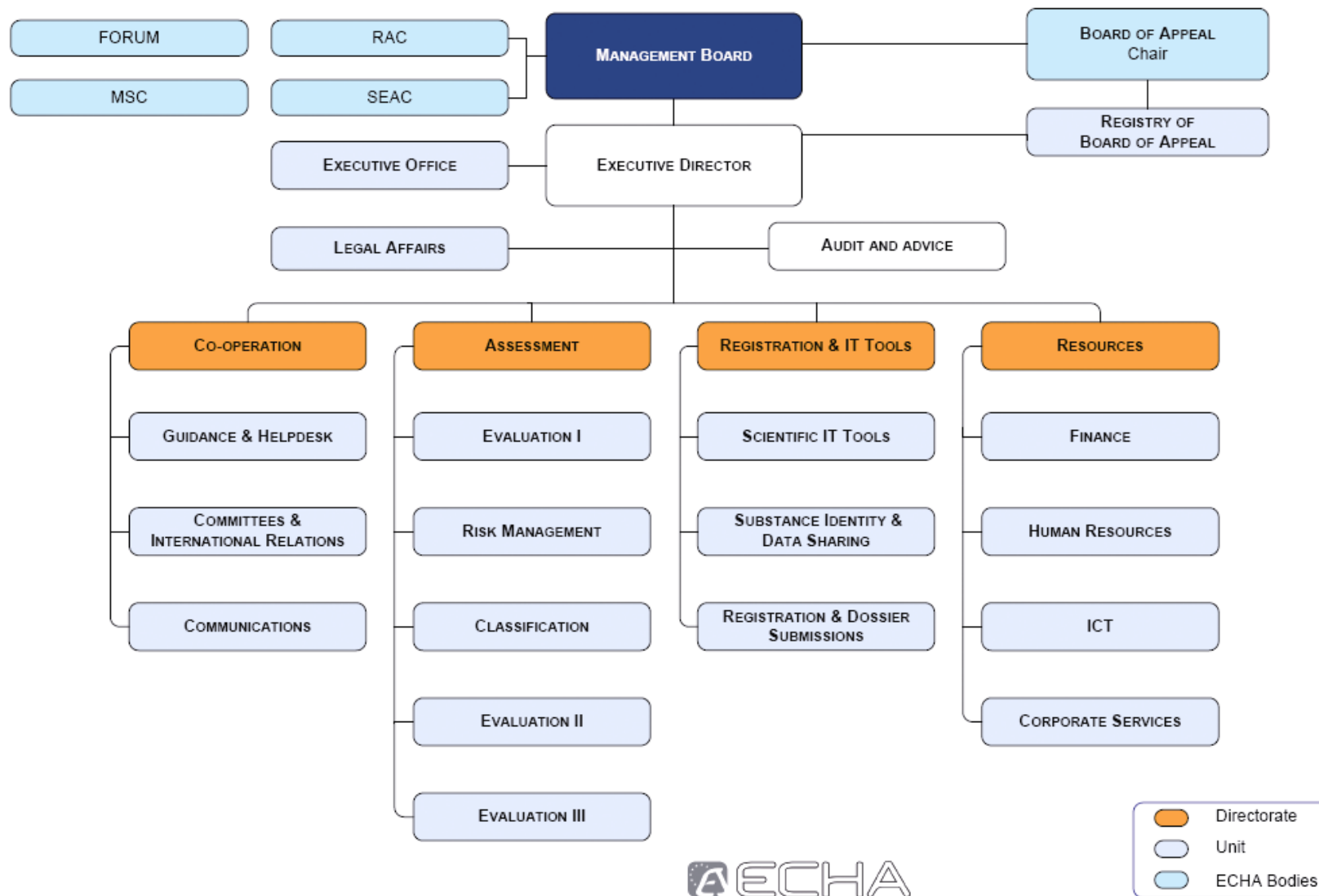
4. Risks

A much higher than expected number of registration dossiers and C&L notifications submitted shortly before the deadline would put the performance and usability of the systems at risk. Intensive performance testing, the assurance of flexible scalability, the access to reserve resources and contingency plans could mitigate this risk to a large extent.

Security aspects will receive continued attention through close monitoring and proactive measures. A third risk is linked to the registration contingency plans, which may require, as far as possible, the temporary redeployment of scientific and administrative staff to registration.

Annex 1: ECHA Organisation

ECHA ORGANISATION 2010



Annex 2: Activity levels used for the Work Programme

Baseline figures for 2010

These figures will be revised before the end of 2009 if necessary, depending on the evidence gathered during the year

ECHA main activities drivers	Estimation for 2010 (9/2009)
Dossiers arriving in 2010	
Substances	9 200
Registration dossiers (including intermediates)	25 000 ⁷
PPORD notifications	300
Inquiries	1500
Restriction proposals (Annex XV)	6
Proposals harmonised classification and labelling (Annex XV)	90
Proposals for identification as SVHC (Annex XV)	30
C&L notifications	2 million
ECHA decisions in 2010	
Decisions on dossier evaluation	70
Decisions on data sharing	500
Decisions on completeness check	500
Appeals submitted in 2010	100
Others	
Questions to be answered/harmonised answers (REACH Advice, REACH-IT, IUCLID 5, others)	15 000
New staff vacancies to be filled	120

⁷ This number will be reviewed based on information from SIEFs and chemical associations.

ANNEX 3: Estimated resources for 2010

- Amounts differ from the respective budget lines as operational mission costs and training to external parties have been allocated across different activities.
- Activity 11 (Relations with EU institutions and international cooperation) also contains amounts of BL3801 for multi-annual contracts and of BL3901 for the ear-marked IPA project.

Activities (Title III of the Budget)	Human Resources			Final budget
	AD	AST	CA	
The numbering below refers to the WP 2010, not to the numbering in the budget				
<i>Operational activities – Implementation of the REACH Processes</i>				
General coordination, management and support				
Activity 1: Registration, pre-registration and data-sharing	40	12	8	731.600
Activity 2: Evaluation	62	9	1	608.419
Activity 3: Authorisations and restrictions	20	4	1	1.517.519
Activity 4: Classification and labelling, SVHC	14	3	2	177.519
Activity 5: Advice and assistance through guidance and helpdesk	31	13	4	1.150.465
Activity 6: IT support to operations	25	5		10.598.925
Activity 7: Scientific and practical advice to the further development of legislation	3	0		4.380
<i>ECHA's bodies and supporting activities</i>				
Activity 8: Secretariat, Committees and Forum	17	8	2	2.990.158
Activity 9: Board of Appeal	12	5	3	652.100
Activity 10: Communication	10	8	7	5.695.309
Activity 11: Relations with EU institutions and international cooperation	8	4	0	896.321
<i>Management, organisation and resources</i>				
Activity 12: Management	21	14	3	1.329.500
Total	263	85	31	26.352.215
Activities 13-15: Title II (Infrastructure and operating expenditure)	25	53	21	12.915.200
Title I (staff expenditure)				47.214.285
Total	288	138	52	86.481.700
In Establishment plan:	426			

ANNEX 4: Procurement plan

WP Activity	Sub-activity (where applicable)	Unit	Task or project	Proposed budget in EUR	Tentative procurement channel	Foreseen date for launching procurement	Foreseen date for contract signature
2.0: Evaluation	Scientific support	B1	Service requests targeting specific questions coordinated by the scientific platforms and in support of Dossier Evaluation tasks	250 000,00	FWC 2008/02 or negotiated procedure	Q1-Q2	Q2
2.0: Evaluation	Training	B4	Training for junior and senior staff	420 000,00	FWC 2008/02	Q1	Q1
3.0: Authorisations and restrictions	3.1 Authorisation	B2	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	1 100 000,00	FWC 2008/02	Q1-Q2	Q2-Q3
3.0: Authorisations and restrictions	3.2 Restrictions	B2	Services to support development of restriction proposals (PFOS/PFOA, phthalates)	300 000,00	FWC 2008/02	Q1 (depends on request by COM)	Q2
3.0: Authorisations and restrictions		B2	Miscellaneous	100 000,00	low-value procedures	Q1-Q2	Q2-Q3

WP Activity	Sub-activity (where applicable)	Unit	Task or project	Proposed budget in EUR	Tentative procurement channel	Foreseen date for launching procurement	Foreseen date for contract signature
4.0: Classification and labelling	Guidance updates	B3	Services to support ECHA to complete CLH dossiers provided by MSCA and other services	160 000,00	FWC 2008/02	Q1 or Q2 (depends on discussion with MSCAs and COM)	Q2-Q3
5.0: Advice and assistance through guidance and helpdesk		A1	Contracts (CLP & substances in articles, upgrade of the navigator regarding the CSA/CSR guidance, evaluation of Exposure Scenarios)	350 000,00	FWC 2008/02	Q3	Q4
5.0: Advice and assistance through guidance and helpdesk		A1	Miscellaneous	755 500,00	FWC/low-value procedures	Q3	Q4
6.0: IT support to operations	Consultants	R3	<u>Tentative sample of profiles:</u> Application Administrators (2) Data Warehouse Administrator DBA for Oracle-RAC DBA for Oracle Application Security Tester (5 days/month) Specialist Consultants (e.g. Documentum, BMC) (2) Weblogic Administrators (2) Other profiles (3)	2 000 000,00	FWC2009/39 for IT projects and FWC 2009/40 for IT consultants	Q1-Q4	Q2-Q4

WP Activity	Sub-activity (where applicable)	Unit	Task or project	Proposed budget in EUR	Tentative procurement channel	Foreseen date for launching procurement	Foreseen date for contract signature
6.0: IT support to operations	IUCLID 5	C1	Development of IUCLID 5.x	700 000,00	FWC 2008/02 or FWC 2009/39	Q2	Q3
6.0: IT support to operations	REACH-IT next generation	C1	Implementation of redesigned REACH-IT NG system	4 000 000,00	FWC 2009/39	Q2	Q3
6.0: IT support to operations	REACH-IT derivatives	C1	Consultancy (SW testing for different parts of REACH-IT, Dissemination, workflows, creation of plug-ins as ad-hoc solutions to support REACH-IT development)	1 200 000,00	FWC 2009/40	Q1-Q4	Q2-Q4
6.0: IT support to operations	Chesar/ CSA Tool	C1	Recruitment of programmers	700 000,00	FWC 2009/40	Q1	Q1-Q2
6.0: IT support to operations	Odyssey	C1	Recruitment of programming and webmaster services for Odyssey development and maintenance. Jointly with Unit B4.	500 000,00	FWC 2009/40	Q1	Q2
6.0: IT support to operations	CASPER: Evaluation & data sharing support	C2	Recruitment of 2 programmers and renewal of 1 part-time Oracle expert consultant	440 000,00	FWC 2009/40 FWC DIGIT	Q1	Q1
6.0: IT support to operations	ECM / Documentum implementation projects	C1	Consulting for ECM projects	4 000 000,00	FWC 2009/40, Hansel, DIGIT FWC	Q1	Q1
6.0: IT support to operations	Application hosting	R1	Outsourced hosting for Secondary Business Plan, Global portal, all other applications	5 000 000,00	Negotiated procedure	Q1-Q2	Q2
6.0: IT support to operations	HW, SW and Licences	R3	Miscellaneous purchase of HW and SW	3 000 000,00	FWC DIGIT/ HANSEL	Q1-Q3	Q2-Q4

WP Activity	Sub-activity (where applicable)	Unit	Task or project	Proposed budget in EUR	Tentative procurement channel	Foreseen date for launching procurement	Foreseen date for contract signature
8.0: Committees and Forum	Forum for Exchange of Information on Enforcement (Forum)	C1	RIPE - REACH Information portal for enforcement) - REACH IT part	480 000,00	FWC 2009/40	Q1	Q1-Q2
8.0: Committees and Forum	Forum for Exchange of Information on Enforcement (Forum)	R3	RIPE - hardware (tokens for enforcement users)	250 000,00	FWC DIGIT	Q2	Q3
10.0: Communication	Digital communications	A3	Website development (customer insight activities, further development)	850 000,00	FWC 2009/39	Q3	Q4
10.0: Communication	Communication related-activities	A3	Framework Contract to cover different tasks related to communication activities of the Agency (2-4 years)	<i>Expected 2000000 per year</i>	Open procedure	Q1	Q3
10.0: Communication		A3	Miscellaneous	1 600 000,00	FWC/low-value procedures	Q1	Q3
11.0: Relations with EU institutions and international cooperation		A2/ C1	Miscellaneous + IUCLID	400 000,00	FWC/low-value procedures	Q1-Q2	Q2-Q3
Tentative estimated value				28 555 500,00			

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