Helsinki, 25 September 2008
Doc: **MB/57/2008 final**

WORK PROGRAMME OF THE EUROPEAN CHEMICALS AGENCY FOR 2009

(**Document adopted by the Management Board)**

ECHA WORK PROGRAMME 2009

Table of contents

Foreword by the Executive Director

In 2008, it was of crucial importance that ECHA could effectively ensure that companies would be able to fulfil their legal obligations from 1 June and begin on time with submitting their pre-registrations, inquiries, registrations and PPORD notifications. This was achieved thanks to the extraordinary commitment of the staff who worked particularly hard in the months around the entry into operation. On 3 June, ECHA was formally inaugurated with the participation of Commission President Barroso, Vice-President Verheugen, European Parliament Vice-President Onesta, and the Finnish Prime Minister Vanhanen. By the end of October ECHA will have issued its first candidate list of substances of very high concern eligible for authorisation and before the end of the year it will have published the complete list of pre-registered substances.

In 2009, the first full year of operation, ECHA will still be in a period of rapid growth and transition. Even though the core REACH process, the registration of chemical substances, has successfully started in 2008, the work linked to the first registration deadline in 2010 needs intensive preparations. Evaluation, and in particular compliance check, will become the core activity of ECHA in 2009, which is reflected by the addition of two units in the Assessment Directorate. New operational tasks, such as restrictions that will enter into force in 2009 will also need to be organised. Moreover, with the adoption of the new Regulation on Classification, Labelling and Packaging, the legislator has allocated new tasks to ECHA and discussions have started on entrusting the Agency with other duties in the context of biocides. Consequently, ECHA remains a highly dynamic organisation, facing numerous technical, organisational and scientific challenges combined with a degree of uncertainty about the way in which the different activities will evolve.

The most important challenge for ECHA in 2009 will be for the Committees and the operational departments to develop routines in dealing with the work that began in 2008. Opinions on individual dossiers, based on a science-based assessment of the information and delivered in accordance with the deadlines, need to be developed. The work will be facilitated by the newly constructed ECHA conference centre which will be ready by the start of 2009 and will also host the meetings of Agency bodies.

I would like to emphasise that all ECHA activities depend on the harmonious functioning of a number of networks with the national competent authorities, the European institutions and stakeholder organisations. The cooperation started in the preceding years will need to be further strengthened and made more effective for making REACH work in daily life for industry and consumers as well as for the relevant authorities. ECHA will place a special focus on reinforcing these partnerships and on training activities with Member States.

Finally, in 2009 the Agency will further develop the process of management by objectives and will increase efficiency in resource-allocation. It will also strive to optimise transparency and guarantee the flexibility that is needed for mastering the diversity of tasks and the uncertainties linked to its workload and revenues.

Geert Dancet
Executive Director

1 Main Achievements in 2008 and work in progress

The major challenge for ECHA in the first half of 2008 was to get ready for entry into operation of the REACH Regulation[1] on 1 June. ECHA achieved this goal and companies were able to fulfil their legal obligations. ECHA also completed the relevant guidance documents in time before entry into operation.

Not all the planned functionalities of REACH-IT were ready by 1 June. ECHA staff absorbed these technical deficiencies by using manual work-arounds; whilst work to complete REACH-IT continued. Stakeholders were regularly updated on the status of temporary IT-tools. By the end of October 2008, it is foreseen that the temporary IT-solutions will be replaced by REACH-IT and all the data from the temporary databases will be migrated to REACH-IT. The delays in REACH-IT in particular and the manual work-arounds have led to the necessity to re-prioritise ECHA's tasks and set a number of activities listed in the Work Programme 2008 as negative priorities and postpone these activities to 2009.
To encourage companies to pre-register, ECHA – in collaboration with the European Commission – launched a pre-registration awareness campaign on 14 April in Brussels. At the request of the down-stream user industry at that time, ECHA has agreed to present a first list of pre-registered substances in advance of its first stakeholder day on 10 October.

The Management Board held five meetings in 2008 and helped to steer ECHA and its management through the first year of financial independence. The ECHA Committees and the Forum held their first meetings and established their working procedures, thus meeting the strict timeframes set by the REACH Regulation, while meeting the high level of expectation for the scientific and technical quality of their work. Following a first call for expressions of interest, stakeholder associations have been selected for observing ECHA's work in these Agency bodies and other networks.
ECHA launched the first public consultations on 30 June on the first list of substances proposed by Member States to be identified as substances of very high concern. Based on the comments received, in October 2008 the Member States' Committee will be asked to agree on the first substances to be included on the candidate list of substances for authorisation.

Training of the Member States´ competent authorities has progressed according to plan. ECHA has also started to provide training material on its website, in particular on REACH-IT for industry. In addition to the website, the Agency published brochures, guidance fact sheets and other printed information material, and embarked on the request of the Commission to participate in information meetings on REACH in third countries.
More than 100 additional staff were recruited and selection procedures were initiated for establishing new reserve lists for the coming years. Significantly, it is expected that the setting up of ECHA's in-house conference facilities will be concluded on target before the end of the year. In parallel, several construction projects were started after September 2008, when the owner had left the premises, to enable ECHA to efficiently occupy the entire building in which it is located.

[1] Regulation (EC) No 1907/2006

2 Challenges and priorities for 2009

2.1 Challenges and objectives

The Agency has four central challenges for the year 2009, namely to establish its reputation for adopting timely opinions and decisions based on sound scientific opinions on chemical substances, to prepare the ground for the first registration deadline and authorisation procedures, to make progress in building its evaluation capacities and take further steps towards establishing itself as the authoritative source of information on chemical substances.

The effectiveness of the working procedures will be tested as ECHA continues to grow and also as it enters into new areas of REACH operations. This means that the operational staff, the scientific Committees and the administrative and legal staff need to cooperate and function in a timely and efficient manner.

On the operational side, the Agency will recommend the first substances for authorisation, and updates will be made to the first candidate list of substances of very high concern. Whilst only a limited number of dossiers have been submitted to ECHA for the first candidate list, ECHA expects the Member State and the Commission to put forward a much larger number of substances in 2009. Furthermore, the first opinions on proposed harmonised classification and labelling will be issued and ECHA will have to prepare for the tasks assigned to it under the newly-agreed CLP Regulation[2].

From 1 June the REACH procedure for restrictions on the use of chemical substances will be in force. This will mean a considerable increase in the workload of the relevant Committees, the Committee for Risk Assessment (RAC) and the Socio-Economic Analysis Committee (SEAC), which have to prepare for adopting their first opinions on new restrictions in 2010.

With regard to preparing for the first registration deadline in 2010 and the authorisation process, ECHA needs to substantially augment its trained scientific staff and consolidate its working procedures and IT tools. In particular, ECHA will launch a new chemical safety assessment IT-tool that will assist companies in demonstrating the safe use of chemicals and producing the chemical safety report to be attached to registrations. . It also needs to facilitate, where appropriate and if resources allow, the data sharing process between potential registrants that takes place before registration, and this will be likely to require significant additional capacity to advise registrants, e.g. on substance identification.

These core challenges, which involve all ECHA staff, are broken down into many different objectives for all work areas of the Agency, and these are developed in the chapters below. To meet these challenges, ECHA will need to maintain and consolidate its close contact and

[2] The Regulation on classification, labelling and packaging of substances and mixtures, is expected to be adopted by the European Parliament and the Council and to be published by the end of 2008. It will implement in the EU the international criteria agreed by the United Nations Economic and Social Council (UN ECOSOC) for the classification and labelling of hazardous substances and mixtures, called the Globally Harmonised System of Classification and Labelling of Chemicals (GHS).

effective collaboration with the European institutions, in particular the European Commission and the European Parliament, as well as other European Agencies and the Member States competent authorities (MSCAs) and with stakeholders. The Agency will also continue to build up strong relationships with other European or (inter)national agencies active in the field of chemicals and their risk assessment.

By the end of 2008 most of the experienced seconded Commission officials will have left the Agency, and over 100 new staff members will need to be recruited in 2009. The new management will therefore place an emphasis on recruiting and training new staff to ensure that there is sufficient operational capacity for managing the increasing workload generated by the approaching first registration deadline in 2010.

On the budgetary side, ECHA will have to follow the development of fee income closely in order to be prepared for the eventuality that the factual revenues differ significantly from the Commission's estimates and from the budgetary authority's assumption that ECHA does not require any subsidies in the years 2010-2013.

Finally, the Agency will have to further strengthen its interface with the public at large. To this end it will enhance its public websites and promote the active participation of citizens in public consultations, e.g. on the selection of substances subject to authorisation and substitution. Efforts will continue to make complicated information easily accessible and to provide the best possible advice and assistance to all stakeholders. ECHA will also start to make available an increasing amount of information on chemical substances. In this context it will be a major challenge to establish the Agency as a trustworthy source for unbiased information.

ECHA will have succeeded in its mission and challenges for 2009 when it meets its deadlines and continues to be perceived by the public, European institutions, authorities and stakeholders as an efficient, transparent, trustworthy and equitable organisation.

2.2 Priorities

Beside consolidating its structures and working routines, ECHA will need to prioritise its resources in 2009 for a number of cross-cutting actions that will determine the success of its activities in its second full year of activity in order to meet the challenges to:

1. Ensure efficient decision-making of the Agency, in particular with regard to testing proposals, compliance checks and the first recommendations to the Commission of substances of very high concern for inclusion in the authorisation list (Annex XIV of the REACH Regulation);

2. Establish and maintain the final list of substances that have been pre-registered after the initial deadline and the list of substances notified by downstream users, and facilitate, where appropriate, efficient data sharing before the first registration deadline in 2010;

3. Continue to consolidate procedures and IT support tools, especially REACH-IT and the new CSR tool, to ensure efficient execution of all operations of the Agency, its bodies and the MSCA;

4. Issue further updates of guidance, addressing restrictions, authorisation and the new classification and labelling legislation as well as major issues on registration raised by the network of national helpdesks, the Agency, the Commission, Member States Competent Authorities and other parties;

5. For harmonised classification and labelling of substances, introduce efficient working procedures for managing the first proposals for classification and labelling and restrictions, while ensuring transparency and high scientific quality of this work;

6. Intensify, in cooperation with Member States and the European Commission, the relationship with ECHA's EU and non-EU partners in chemical risk assessment;

7. Enhance ECHA's interface and dialogue with the general public, particularly *via* the Agency's website, including the section disseminating detailed information on chemicals, and also through cooperation with the Member States;

8. Recruit and train staff needed to execute the operational tasks to be undertaken in 2009 and to prepare for the first registration deadline in 2010 and further develop training programmes on REACH for Member State experts and trainers from third countries.

9. Monitor closely the fee revenues and expenditure so as to achieve a high proportion of budget consumption and identify any potential shortfall of revenue in advance, taking into account the new estimates to be calculated according to the pre-registrations received by 1 December 2008.

2.3 Risk Management

The Agency will maintain a comprehensive risk management in order to ensure that it meets its challenges and objectives, despite the unavoidable uncertainties, such as the estimated numbers of dossiers submitted. ECHA must have the capacity to react with flexible work allocation throughout the Agency, combined with recruitment of temporary support staff, to deal with unscheduled workload peaks and unforeseen demands. On the one hand; his also includes that the helpdesk is proactively adapting on the permanently changing user requirements and effectively coordinates the in-house expertise available. On the other hand, ECHA will, when necessary, re-prioritise its tasks and may set a number of activities planned for 2009 on negative priority to ensure an effective functioning of the core REACH processes. A key element for an overall risk management is the development and implementation of the Agency's future management and reporting tools in accordance with the Agency's quality policy. These tools have to include aspects of risk identification, assessment, documentation, coverage and follow-up, which will disseminate a risk management culture from the early stage of Agency operations and recruitment.

With regard to the above-mentioned priorities, ECHA foresees a series of special risk management measures in order to safeguard success:

1. If needed, a large volume of *ad hoc* scientific support could be purchased externally, based on framework contracts concluded in 2008. Through close cooperation with MSCAs the fraction of decisions that have to be considered by the MSC can also be minimised, and at the same time the quality of Annex XV dossiers prepared by Member States be enhanced.

2. While ECHA is not supporting the operations of the SIEFs as such, ECHA will be prepared to respond to a high volume of requests coming from and relating to SIEFs, most likely in relation to substance identification. Reinforcing this area of competence will therefore receive special attention.

3. If constraints arise with the IT systems, ECHA will ask the contractors to focus on remedies and, if possible, perform tasks manually or using *ad hoc* work-arounds.

4. ECHA will make all efforts to stimulate feed-back from the various communities using the guidance, if necessary by actively approaching the national helpdesks, the MSCAs and industry helpdesks and experts to obtain information on their experience. If needed, ECHA will revert to external experts to draft updates, e.g. through concluded framework contracts.

5. Committee Members will be supported by ECHA resources to help them in delivering timely and scientifically-sound draft opinions to enable the Committees to adopt high-quality opinions within their legal deadlines.

6. Measures will be taken to enable external expertise and workforce to be brought in whenever necessary, by a range of means, including *ad-hoc* task forces as well as consultancy contracts.

7. Appropriate back-up capacities will be made available to prevent any major breakdowns in the ICT Infrastructure and in particular the website's communication modules.

8. ECHA will estimate the total fee revenues and closely monitor the development in its first year of full operation. Any budgetary constraints will be addressed with modifications to the ongoing budget and/or the identification of changed priorities.

9. Although the major selection procedures for scientific and IT officers will be completed in 2009, resulting in reserve lists that will yield the largest share of the new recruits needed, it is also foreseen that new calls for additional staff reserves are possible. Moreover, it is envisaged that some of the training capacities now planned to take place in-house could be outsourced.

3 Management

3.1 The ECHA Management Board

In 2009 the Management Board will have reached full cruising speed. It will continue to play its role in the budgetary cycle of the European Community and in programming and reporting the Agency's activities.

Individual action points in this area will cover, in particular:

- Approval of the draft budget and the estimate for revenue and expenditure for 2010.
- Adoption of the general report for 2008.
- Analysis and assessment of the Authorising Officer's annual report on the financial year 2008.
- Issuance of an opinion on the Agency's final accounts for 2008.
- Adoption of the Agency's Work Programme 2010.
- First update of the Multi-Annual Work Programme.
- Adoption of specific implementing rules for the Staff Regulation.
- Fine-tuning, where appropriate, of the Agency's internal rules and procedures.
- Adoption of the Agency's final budget for 2010.

3.2 Managing ECHA

It is the responsibility of the management to guide the Agency through its first full year of operation, and prepare it for the additional tasks that enter into operation and the increasing workload in the years to come. Building on the good progress that has been made so far, one of the main objectives for the ECHA Management will be to consolidate and improve the working routines and structures developed since 2007. This includes the cooperation with the MSCAs in the various REACH processes, where a smooth information flow and cooperation is essential for success, as well as ensuring that the Agency presents a consistent view to its stakeholders. On all matters relating to administration, budget and finance, staffing, audit and accounting, ECHA will introduce efficient reporting tools and closely cooperate with the European Parliament and the Council (the European Communities Budgetary Authority), as well as with the Commission and the Court of Auditors.

This overall challenge for the Agency will require in particular the following priority actions that are explained subsequently:

- Consolidate, improve and develop the operational structure, procedures, and the management of the Agency, including integration of new managers and cooperation with the MSCAs;

- Recruit new highly-qualified staff and train these staff members in preparation for the first phase-in registration deadline in 2010, making use of relevant MSCA staff for this training;

- Consolidate the internal control systems to ensure an efficient resource management that is consistent with the adopted rules, while producing the required high level of quality output;

- Finalise or improve ECHA's Standard Operating Procedures (SOPs) of the Agency, including testing and adjusting them where necessary.

The Agency has recruited new middle and senior management staff in 2008, replacing the experienced seconded Commission officials that have executed management functions since 2007. While efforts were made to ensure a smooth hand-over, it remains a challenge for these new managers to quickly pick up where the seconded Commission officials left off and to guarantee full functionality of the Agency. Special attention will be given to building the relations between the new management and stakeholders.

In addition to the initial training of new staff, a continuous training programme will be developed for the Agency's staff to ensure that it maintains and enhances its expertise towards the high level needed for the successful operation of ECHA. As the operations of the MSCAs are of equally high importance for the overall implementation of REACH, the Agency's management will cooperate with the management of the MSCAs in designing new training programmes for their scientific staff. ECHA will also invest in maintaining and developing the professional management skills of its middle and senior managers. External trainers will be hired wherever necessary.

Decisions of the Agency must be taken fully in line with the requirements fixed in the REACH Regulation and based on sound and well documented science. Quality control of the administrative processes as well as of the science behind decisions must be fully implemented, well in advance of the 2010 deadline that will trigger a steep workload increase with tight deadlines. To consolidate the necessary IT-support (in particular the envisaged workflow management system) will be a major challenge.

In 2009, ECHA will further develop its document management system. This includes providing staff with the most effective access to internal and external information needed to perform their professional tasks, and ensuring access to information in line with legal requirements.

Within the monitoring function of the quality system, the management will systematically review the SOPs and streamline them wherever necessary.
Based on key performance indicators, the management will start in 2009 to systematically define and measure the progress towards achieving ECHA's objectives and the progress on indicators and regularly inform the Management Board.

4 Operations

4.1 (Pre-)registration and inquiries

With the publication of the list of pre-registered substances, ECHA has fulfilled its main role in pre-registration under REACH. The publication of the list marks the change in focus of ECHA's work to data sharing and facilitating contacts between potential registrants and with down stream users. The focus for 2009 will therefore be routinely to:

- publish the names of the substances notified by downstream-users;
- assist potential registrants to resolve disputes regarding the data sharing activities.

Until the public dissemination site is available, ECHA will need to invest more efforts in data sharing. ECHA will continue its proactive assistance to industry organisations which develop tools for efficient SIEF implementation.

The experiences gained through the manual implementation of the inquiry procedures prior to registration in the last seven months of 2008, including a continuous monitoring of its implementation, will lead to a routine application of the inquiry procedure in 2009. Efforts will be made to provide feedback to industry in order to improve the quality of inquiry dossiers.

In 2009, ECHA expects to receive several hundred inquiries, with peaks before the summer and before Christmas.

Indicators: Relevant performance indicators are the time needed to process inquiries with scientifically sound outcomes and the good quality of the list of pre-registered substances finalised and published by 31 December 2008.

It is expected that in 2009 the functionality of REACH–IT for handling data submissions will be completed, replacing all manual working routines used in 2008.

The experiences gained through manual processing of submitted dossiers, covering both registration and notifications of PPORD exemption requests, in the last seven months of 2008, including the continuous monitoring of this work, will lead to a more routine implementation of the tasks during 2009.

In 2009 the registrations and notifications covering updating of registrations and notifications from down stream users will start. As for registration and PPORD notifications in 2008, the implementation of these new procedures will be carefully monitored and the underlying processes streamlined if need be, with the aim of establishing a routine workflow by the end of 2009.

In 2009, ECHA expects to receive a relatively low number of registration dossiers and several hundred PPORD exemption notifications.

It is also expected that the notification process for the classification and labelling inventory can become functional in 2009, although the peak workload is first expected towards the end of 2010.

Indicators: Relevant performance indicators are the time needed to process registration dossiers, completeness checks, to allocate registration numbers and to make decisions on confidentiality claims within the capacity available.

4.2 Evaluation

The work on evaluation in 2009 (and 2010) should be seen as preparation in advance of the peak workload from 2011 to 2013 resulting from the registration deadline for high volume chemicals of 1 December 2010. The high volume substances include some of the most complex and scientifically-difficult substances for industry to develop registration dossiers for and for ECHA to evaluate. It is therefore key for ECHA, in particular for the Secretariat and the Member State Committee, that these early years are used to develop and test the high scientific and regulatory capacity to meet this challenge.

The focus of the work for the Secretariat will therefore be to build the capacity, by developing evaluation strategies, training new staff, expanding the competence base of staff and testing the approaches on registration dossiers and other dossiers (in particular, through active participation in the relevant OECD programmes). The Secretariat will need to work closely with the Member State Committee to develop capacity-building activities, to ensure that the work of the Secretariat on evaluation will meet consensus within the MSCA and in the Member State Committee.

In 2008, ECHA's evaluation activities had to be set at lower priority as a consequence of the additional workload arising from the reduced scope of REACH-IT in 2008. As the target of achieving full preparedness for the expected work peak from December 2010 remains, the efforts in 2009 in this area have to be reinforced to catch up on the ground lost in 2008.

In the light of the experiences made in 2008, the number of registration dossiers submitted and the corresponding testing proposals are expected to be very low. ECHA is obliged to examine all testing proposals. In addition, ECHA has to carry out a compliance check on at least 5% of the submitted registrations. Priority will therefore be given to capacity building on evaluation.

In 2009, the ECHA Secretariat will develop its first draft evaluation decisions, concerning both testing proposals and compliance check, with the first testing proposal draft decisions expected at the beginning of 2009.

In order to support to Member States in substance evaluation, ECHA may propose to carry out some early substance evaluations in 2009 and 2010 on non-phase-in substances in order to test the Agency and Committee procedures,

Indicators: A relevant performance indicator is if scientifically sound draft evaluation decisions are prepared within the required deadlines and unanimously agreed by the Member State Committee.

4.3 Classification and Labelling, Substances of very high concern (SVHC)

A key priority in 2009 will be the publication of ECHA's first proposal for a list of substances of very high concern (SVHC) recommended to the Commission for authorisation. A considerable challenge facing the Agency in doing this work will be to collect and evaluate information enabling a science-based priority setting, to make a transparent proposal which finds support from the Member States and to create a list which will enable an efficient and manageable implementation of the steps to follow. At the same time, ECHA has to meet the deadline of 1 June 2009 for submitting the first recommendations to the Commission.

Given the limited number of substances on the first candidate list of SVHC, ECHA's first recommendations for Annex XIV inclusion will likewise contain a limited number of substances. ECHA will make it a priority to update the candidate list in 2009 and to find agreement in the Member State Committee. As the inclusion of a substance into the list will put obligations on producers and importers of articles, this will in turn increase the work of ECHA in advising in this area. The focus is expected in this aspect to be on substance identification.

The processing of proposals for harmonised classification and labelling through the Committee for Risk Assessment (RAC) will be refined in 2009. A high number of dossier throughput is anticipated. It is however expected that additional efforts will be needed in 2009 to train Member States in developing Annex XV dossiers. Following the entry into force of the newly agreed CLP Regulation, suppliers of chemicals may also submit dossiers proposing harmonised classification and labelling against fee payment.

It is also expected that a revision of the Guidance for preparing Annex XV dossiers will be needed, based on the experience gained in 2008 and the beginning of 2009.

Indicators: *Relevant performance indicators are the high scientific and technical quality of support provided by the Secretariat and the chairpersons to the Committees, the percentage of suggested solutions to differences of views which are upheld by the Committees and the average time required to process the dossiers.*

4.4 Restrictions and Authorisation

The application of the restrictions process will start on 1 June 2009. This "new" process under REACH will be very challenging to implement. In contrast to the "old" system under the Existing Substances Regulation and the Limitations Directive, the discussions on the risk assessment, restrictions proposal and the socio-economic analysis occur in parallel rather than sequentially, and very strict deadlines are set, whereas formerly there were no deadlines.

The main challenges will therefore be to manage the process and to make sure that the deadlines are met, ensure the scientific and technical quality and make sure that the content of the Agency opinions - if supportive - are sufficient to enable the Commission to take decisions.

ECHA will be prepared for the eventuality that some Member States may experience difficulties in developing Annex XV restrictions dossiers in a way that the outcome would enable a fruitful scientific discussion and conclusion within the strict deadlines. In this case it will be a challenge to ensure that such dossiers are rejected early on in the process, whilst providing Member States with the support necessary to develop high quality dossiers.

Regarding the authorisation process, ECHA will significantly advance the preparatory activities for the implementation of the evaluation of authorisation requests.

The RAC and the Committee for Socio-economic Analysis (SEAC) are required to deliver high quality opinions within the deadlines set by the REACH Regulation[3]. The ECHA Secretariat therefore has to provide support to the extent possible and requested by the Committees. Significant resources are foreseen for this.

Indicators: *Relevant performance indicators are the high scientific and technical quality of support provided by the Secretariat and the chairpersons to the Committees, the percentage of suggested solutions to differences of views that are upheld by the Committees and the average time required processing the dossiers.*

[3] ECHA is preparing opinions for the Commission. The Commission decides on restrictions and authorisations with the assistance of committees of Member State representatives in a process known as comitolgy

4.5 Communication

The maintenance and further development and integration of the Agency's website will remain a crucial communication activity in 2009. The objective is to ensure that the public as well as the various stakeholders recognise the ECHA website as a single point of access to REACH- and Agency-related information, including training material for free downloads. ECHA will be perceived by the key opinion makers as a trustworthy source of factual information on chemicals.

With the same intention, ECHA will continue to translate key documents. This will be supported by a translation management and quality control system that needs to be further developed and streamlined in order to optimise the cooperation with the European Translation Centre CDT. Also, cooperation with the Member States for the review of translations will be aimed at. In order to facilitate the communication on REACH, ECHA will develop a multilingual REACH terminology which would be used by ECHA, stakeholders and authorities.

Making all stakeholders and the general public aware of REACH remains an overarching objective, and the Agency's press/media service will be further developed in 2009. In addition to regular press/media activities (press conferences, interviews, articles) and speaking engagements, journalist and multiplier group visits to ECHA from the Member States and third countries will be organised.

Various documents, including the 2008 Annual Report, updated brochures and REACH related material, will be published electronically, fully implementing the corporate identity of ECHA. A limited number of copies may be produced in print form. The "REACH communicators'' network, working groups of REHCORN, that was set-up in 2008 and brings together the communication managers of the MSCAs and ECHA, will be used to co-ordinate ECHA's publication and translation activities with those of the MSCAs for optimal complementarities. In addition, the Agency will cooperate with the Central Translation Service of the Communities (CdT) to improve further the quality of translations.

Two stakeholder conferences/events will be organised in the course of the year in Helsinki. The first one preceding the Helsinki Chemical Forum in May 2009 to which ECHA will intensively contribute. The purpose of these events is to provide an opportunity for interested parties to be informed and have a dialogue about the activities of the Agency.

Stakeholder involvement in Agency activities, e.g. by means of observers, remains an important element. As it is impossible to allow interested individuals to participate in the Agency's work, a decision was taken in 2008 to establish a stakeholder organisation registry of ECHA. This allows stakeholder organisations that meet the published criteria to be considered for sending observers to Agency bodies. This registry will be maintained and kept open in 2009, allowing interested and eligible stakeholder organisations to subscribe to it at any time.

In parallel to the work of the Risk Communication Network, and in line with its Communication strategy established in 2008, the Agency will start taking steps to establish its own issue management capabilities and prepare pro-active communication activities on all matters relating to the safety of chemicals. An important tool for this will be the designated dissemination section on the ECHA website. In 2009, priority will be put on issues relating to classification and labelling and substances of very high concern.

To enhance common understanding and to provide up-to-date information on the implementation of REACH, ECHA will continue to provide REACH training sessions for trainers, primarily from of the Member States. At the same time, ECHA will further develop its REACH training programmes on REACH for ECHA staff and for Member State experts and trainers from third countries needing to keep up with the latest technical and scientific developments in the field, including REACH-IT.

Beside the external communication activities, ECHA is providing information to staff, in particular through the further development of the intranet.

Indicators: Relevant performance indicators are the number of visitors on the Agency's website, the volume and quality of documents and their translations made available by the Agency, the number of and participation to events organised by ECHA or to which ECHA contributed and feedback received from participants in these events and from media in general.

4.6 Advice and Assistance

Guidance

Guidance describes commonly-agreed ways on how to fulfil the obligations of the REACH Regulation for both industry and MSCAs to facilitate implementation of the scheme. Guidance serves as an accurate reference framework helping companies and industry associations to develop tailor-made sector- or company-specific solutions to fulfil the REACH requirements.

The work in 2009 will focus on finalising and implementing the procedure for systematic harvesting of feedback from guidance users initiated in the year before. Necessary guidance updates will be identified and produced, cross-guidance harmonisation tackled, and new guidance developed as needed. This work will be triggered by feedback from the different guidance-user communities, including industry, national helpdesks, Commission, Member States Competent Authorities, ECHA or MSCA staff, and the Committees. There will be a priority for those guidance updates needed to ensure consistency between regulatory decisions in operations and the content of the published guidance. The same principle applies to the development of additional guidance elements needed to carry out ECHA operations with regard to submitted registration dossiers. Also, new guidance or updates required as a consequence of changes in the legal text (e.g. Annex XI or Annex V) or new legislation (the

CLP Regulation) as well as updating the relevant guidance with regard to waste and recovered substances are a priority. The latter CLP Guidance will be combined with development of Guidance on Safety Data Sheets.

The Guidance on Information Requirements and Chemical Safety Assessment is likely to require a step-wise updating and development process during 2009. This may include, for example, the incorporation of methods and tools under development by industry, research organisations, MSCA and ECHA, as well as adaptation of the guidance in the light of the questions received by the national and ECHA helpdesks. The work on updating the Guidance on Requirements for Substances in Articles will make significant progress in 2009. New guidance is also planned on risk communication, aiming to improve the communication of information on risks and safe use of chemicals and with a view to coordinating Member States in these activities.

For the guidance updates and new guidance development, the guidance update procedure adopted in 2008 by the Management Board will be systematically applied, including, where required, the establishment and involvement of Partner Expert Groups. To ensure the procedure functions as planned, ECHA will monitor it closely and install a formal review process for learning from the experience gained with a view to permanently improving it.

ECHA will also concentrate on improved integration of the different elements of guidance offered *via* its website, on further incorporating the user perspective into the guidance provided, and making it more accessible - including the provision of translated short summaries on guidance (e.g. fact sheets and other explanatory documents). This includes the restructuring of the website with a view to provide more efficient access to the guidance.

Internally, efforts will also be made to enhance the coordination of the work on maintenance and update of guidance with the ECHA operations.

Indicators: Relevant performance indicators are the progress made towards a timely endorsement and publication of new guidance documents (e.g. risk communication) and towards updated guidance documents (e.g. revised registration guidance, revised CSR&CSA guidance). Guidance user feedback will serve as indicator for the quality of guidance.

Advice (Helpdesk)

The ECHA helpdesk will continue to provide advice within adequate response times to registrants and others, including on the use of REACH-IT and IUCLID 5 for submitting data to ECHA. To ensure consistent responses, and also with a view to communication to the general public and the press, efforts will be intensified to keep a complete overview of the external information requests arriving at ECHA *via* various channels. Consolidating the necessary encoding and despatching capacities is a challenge in itself. For questions related to REACH requirements, the ECHA helpdesk will focus on those directly linked to submissions, but will also provide information to companies located outside the Community as they have an interest in facilitating the marketing of their products in the EU. The current structures will

be further improved by refining existing tools and training the helpdesk staff. Regular three-monthly reports will be produced for the management to show the patterns of customer queries and the level of service provided. Feedback on shortcomings of existing guidance, including gaps as identified by the helpdesk customers, will be collected and provided to the units in ECHA responsible for the concerned item, be it guidance, REACH-IT or IUCLID 5.

ECHA will continue to run the network for the national REACH-helpdesks (REACH-Help-Net and its working groups, e.g. on REACH communication), and enhance cooperation in order to make optimal use of the resources. While the work on harmonised answers will become the highest priority, cooperation and efficiency will be enhanced with regard to pro-active information efforts aimed at raising awareness, with special emphasis on the upcoming 2010 deadline. Finally, the network will provide systematic feed-back on frequently asked questions that will be answered *via* FAQ documents on the Agency's web site once they are agreed.

Towards these objectives, the REACH-Help-Net will hold at least two meetings and additional workshops and training sessions of the REACH-Helpdesk-Correspondents' Network (REHCORN) in 2009, where progress towards its objectives will be assessed and work plans established and updated. Training specifically targeted to helpdesk officers will be organised by ECHA, whenever possible back-to-back with the REHCORN meetings. In 2009, the helpdesk will continue to play an active role in exchanging good practice on helpdesk organisation and service providing. Emphasis will be put on keeping the expertise of the helpdesk team at the level needed to adequately respond to the increasingly complex and difficult questions, while ensuring the necessary short response time.

Indicators: Relevant performance indicators are the proportion of enquiries resolved within adequate response time, the number of harmonised answers on REHCORN level, and user feedback.

Advice to the Community institutions

ECHA will on a case by case basis provide relevant scientific and practical advice to the *Community institutions, in particular* to the Commission. A first priority will be advice on nanomaterials and the way their specificities need to be addressed in registration dossiers. Furthermore, following a request by the Commission, discussions have started in 2008 regarding the potential future role of ECHA under the foreseen revision of the Biocides Directive. ECHA will have to stay closely involved in the further process and provide detailed analyses regarding the resource implications of different options for it's potential role.

Indicators: Relevant *performance indicators are the number and quality of contributions provided as well as their take-up in Commission papers and, if appropriate, legislative proposals to amend REACH, CLP and relevant implementing legislation.*

4.7 Preparing Agency opinions and decisions - Committees and Forum

The year 2009 will see an increase in the number of dossiers requiring treatment by the Committee for Risk Assessment (RAC) and the Member State Committee (MSC), putting the working procedures developed by the Committees in 2008 to the test. Moreover, the Committee for Socio-economic Analysis (SEAC) will start its operations when the first restriction proposals are received after 1 June 2009. The three Committees will each convene four to six times during 2009. The MSC especially might require more meetings, and all Committees will be prepared to increase the number of meetings. In addition, there may be several working groups that would work inter-seasonally.

For the RAC the start of the application of the restrictions Title in June 2009 will mean a heavily-increased workload, and therefore six meetings have been scheduled. A number of Annex XV dossiers for restrictions are foreseen to be formally submitted by the end of the year. The RAC will also continue dealing with the new Annex XV dossiers for harmonised Classification and Labelling (C&L) and finalising its opinions on the dossiers submitted in 2008. A significant number of finalised dossiers are estimated in 2009.

Alongside the restriction procedures, work will also commence on the dossiers in the SEAC. The SEAC has to agree on methodological issues in order to efficiently start the handling of the Annex XV dossiers on restrictions in the second semester 2009. However, as the public consultation period is set to six months by the REACH Regulation, no opinions of the SEAC are yet foreseen to be adopted in 2009. All in all, four meetings of the SEAC are scheduled for 2009.

The MSC will address the Agency's draft decisions on testing proposals, to which amendments are proposed by Member States, and will seek agreement between Member States on the procedures falling within its remit. It is estimated that the amount of testing proposals will be very low in 2009, and that the majority of the draft decisions will need to be addressed by the MSC. The MSC will also continue addressing proposals for substances of very high concern (SVHC) and give its opinion on further priority substances recommended to be included in Annex XIV (the list of substances subject to authorisation). The number of meetings will be five to six, and the MSC will have to utilise extensively the written procedure in order to cope with the stringent time limits.

The uncertainty about the actual number of Annex XV dossiers for harmonised C&L, restrictions and proposals for SVHC, as well as in the number of non-phase-in registrations and subsequent testing proposals, is posing a significant risk for the Committee work. Therefore the planning of meetings needs to be sufficiently flexible. For this reason additional meetings will be tentatively scheduled, and the resources established to manage these.

The Forum for Exchange of Information on Enforcement will meet three times in 2009, addressing issues as foreseen in its work plan and updating its rolling work plan in light of the enforcement priorities identified by the Forum members. In this initial phase the Forum is focusing its activities on the clarification of the tasks of REACH enforcement officers and

elaboration of best practices. The involvement of the Forum in a number of "coordinated projects", e.g. on enforcing the "no data, no market" rule with regard to (pre)registration will be of particular importance. It will also react on questions regarding enforceability posed by the RAC or the SEAC on restrictions and in the context of guidance. Its work will be supported by a number of working groups. ECHA will support the Forum activities as far as budgetary constraints allow, e.g. by co-financing joint activities or small studies deemed necessary by the Forum for its work, and seen to be essential for enhancing the coordination and overall quality of the REACH enforcement activities. ECHA will also contribute to the establishment of an effective and secure exchange of information between ECHA and the enforcement authorities.

All Committees and the Forum will continue consolidating their cooperation procedures with the other ECHA bodies and their relations with relevant scientific bodies and EU Agencies. The necessary rules of procedure and/or memoranda of understanding are planned to be established by the end of 2009.

Indicators: Relevant performance indicators are the quality of the scientific and technical opinions and deliberations, the degree to which deadlines are met, the percentage of consensus reached in the Member State Committee, and the satisfaction of the participating parties.

4.8 IT tools supporting the operations

REACH-IT

The work on REACH-IT in 2009 is dependent on the deliverables of REACH-IT in 2008 and decisions made regarding the contractual arrangements at the end of 2008.

It is however expected that, in addition to the publication of the list of pre-registered substances by 1 January 2009, all the industry functionalities of REACH-IT and the dissemination site will be finalised in 2009. It is also expected that the first ECHA workflows will be finalised, providing a basis for the encoding of all the necessary workflows to be finalised in 2010.

The close cooperation with the REACH-IT stakeholders will be continued. For instance, this will include several meetings with the REACH-IT stakeholders and the Security Officers Network as well as interaction with industry.

IUCLID 5

The year 2009 should see ongoing maintenance support, development of add-ons to IUCLID for solving specific issues (e.g. the module for verifying the completeness of dossiers) and the building of an interface between IUCLID and other systems in development such as the CSR tool and REACH-IT. This work will be purchased externally based on concluded framework contracts. In addition, the procurement will be initiated for launching the new IUCLID analysis and development of IT projects.

Good relationships with the external users will be further strengthened and, as regards IUCLID 5, formalised via the IUCLID Management Group (IMG) that will also manage the close collaboration with OECD *via* the OECD's IUCLID expert group. The IMG will also be responsible for monitoring and analysing the feedback from the user communities of IUCLID 5 as well as of REACH-IT with a view to initiating any maintenance or new functionality development necessary. It will be responsible for ensuring that the identified user requirements are fully met by the resulting IT projects.

CSR-tool

With assistance from external contractors and stakeholder experts, ECHA will develop a tool to support registrants in building exposure scenarios and carrying out the related CSA process. The CSA/CSR tool will guide the user through the standard workflow of exposure scenario building as described in *Guidance on Information Requirements and Chemicals Safety Assessment.*

Due to the very short time available for the build of the tool it is planned to have a release in a stepwise fashion. An initial version 0.1, mainly used for demonstration and testing should be released in early autumn 2009. It should contain the main functionalities, such as import of relevant data from IUCLID 5, workflow support for ES building, exposure estimation based on existing tier 1 tools, risk characterisation and reporting in standard formats for the CSR and the exposure scenario attachments for the Safety Data Sheet. Version 0.1 should be a robust platform for the development of version 1.0, planned to be released in the first quarter of 2010.

Indicators: Relevant performance indicators are the timely delivery of the CSR-tool and of new functionalities of REACH-IT according to planning and budget; the number of training sessions and user-manuals provided and, for IUCLID 5, the development of updates and upgrades according to the planning developed with OECD and industry.

5 Activities with EU institutions and bodies and Member States

In 2009 the Agency will further develop and streamline its cooperation with the EU institutions, in particular the European Parliament and the Commission. Special emphasis will be put on the procedures for transferring opinions of the Committees to the Commission and on supporting the Commission's decision-making process. In addition, the cooperation with Member States will continue to be an important aspect of the Agency's day-to-day work. This will be enhanced by developing efficient means of data and dossier transfer, including access of MSCA experts to the REACH databases. In addition, ECHA will continue to profit from the cooperation with MSCA via the well-established REACH CA Group. ECHA will actively contribute to the REACH CA Group and their working groups, in particular in collaboration with the JRC the working group on nanomaterials. Data needs of enforcement authorities will be established and efficient procedures set up to support them in their work while respecting the legitimate expectations of industry regarding data security. ECHA will build on the

existing cooperation with the MSCA and complement it, if necessary, with additional *ad-hoc* or permanent events or structures.

The existing networks of helpdesks (REACH-Help-Net), security officers, communication/translation managers, and the risk-communication network will continue to work throughout 2009, each holding two to four meetings and, if required, several (*ad hoc*) working group meetings. They all aim to co-ordinate the activities of the MSCA with those of the Agency, and should be understood as examples that may in 2009 be complemented by others if a need is jointly identified by the Agency and the MSCAs.

The Risk Communication Network will contribute to the development of the Guidance on Risk Communication and offer a structure for exchanging information about best practice and experience when communicating information on risks and safe use of chemicals to the public. The network will hold at least two to three meetings in 2009 that may be prepared by a number of working groups addressing specific topics.

The relation with the MSCAs will continue to be underpinned by offering training of trainers to MSCA-staff, addressing REACH processes and tools for which MSCAs express an interest. Depending on the demand, at least two to three training events are foreseen in 2009.

Indicators: A relevant performance indicator is the number of joint activities with Community institutions, other agencies and Member States. As the cooperation with the Community institution and Member State directly influences most of the Agency's activities, the indicators for the work of the Committees, the Helpdesk and the REACH operations can also be taken as reference.

6 International Activities

The Agency will respond to requests of the Commission for scientific/technical support of its bi- and multilateral international activities relating to the regulatory management of chemicals as far as the budgetary constraints allow. This support for the Commission will be governed by a jointly agreed work plan to be finalised in 2008. An international cooperation team will coordinate ECHA's input into that work plan and ensure efficient use of Agency resources during its implementation. In addition, ECHA will continue developing its direct scientific/technical contacts in fields of relevance for ECHA with institutions and centres of excellence in third countries.

In 2009 the international relations and activities of the Agency will gain momentum. ECHA will participate in a number of OECD activities which are of direct relevance for the implementation of REACH, in particular the project management of the Global Portal to Hazard Data and the further development of the QSAR-Toolbox. ECHA will also contribute to the work of the Task Force on Existing Substances and its subgroups and to the work of the Task Force on Exposure Assessment, the Harmonised Templates Project and the work on

health and environment aspects of nanomaterials. ECHA may also hold joint conferences with the OECD on specific topics.

Beside the OECD-related activities, ECHA will support the Commission's work on the Stockholm Convention on Persistent Organic Pollutants (POPs) and, subject to availability of resources, ECHA will also offer training-for-trainers to third countries and organise and will attend meetings and conferences with third countries to inform on the requirements of REACH. Furthermore, ECHA will contribute to the improved cooperation between the Community and third countries by participating in the exchange of best practices in the area of ECHA's tasks.

Indicators: Relevant performance indicators are the feedback on ECHA participation in international meetings, the number of trainers trained, the range and numbers of third country stakeholders reached through ECHA participation in meetings and conferences, and the number and quality of contacts and scientific/technical exchange with relevant institutions in third countries.

7 Board of Appeal

The first appeals are expected in 2009. Despite a decision taken by the Management Board in June 2008, the Board of Appeal was not fully operational in 2008, due to the rejection of the position offers by two of the three appointed members. Thus, the first priority concerning the Board of Appeal is for the Management Board to finalise the second appointment procedure of the members of the Board of Appeal and to ensure that the appointed members take up their functions as soon as possible.

The independent members of the Board of Appeal, assisted by an well-organised Registry, will have to demonstrate their capacity to adopt justified decisions within tight deadlines, minimising the need for court action by the interested parties. Another main challenge for the Board of Appeal is to adopt its procedural rules and practices and to demonstrate its capability to take high-quality decisions in order to build up the stakeholders' confidence in the appeal procedure. Because some of the procedural rules for the Board of Appeal and for the Registry can only be adopted after the members of the Board of Appeal are appointed, this work needs to be completed as soon as the Board members have taken up their functions. Another priority for the Board of Appeal and its Registry will consist of ensuring that all other basic requirements for an efficient and secure procedure are functioning well.

The Board of Appeal will also need to develop measures to reduce the probability of encountering backlogs. To achieve this, cooperation with potential appellants in the form of efficient communication is foreseen as one of the main objectives. An effective, comprehensive and user-friendly database of relevant case-law needs to be established to enable potential appellants to make confident and informed decisions about whether to and to what extent to appeal. The appellants should also have access to online information and

adequate guidance on the appeal procedure in order to minimise delays or rejections caused by procedural errors. There will be a continual need to focus on the electronic exchange of information. The development of appropriate legal forms and instructions in an understandable and user-friendly format should enhance the efficient processing of appeals.

Particular attention has to be given to the training of the alternates and additional members, in order to keep them informed on the development of the relevant case-law and the procedures so that they can be invited to assist the Board when needed. To ensure an efficient and well timed planning of future needs, a more detailed way to predict the number of appeals should be developed together with the other services of the Agency on the basis of experience gained so far.

Indicators: Relevant performance indicators are the number of appeals processed and the duration of proceedings as well as the quality and legal soundness of the decisions.

8 Administration

ECHA's administration is managing the revenue and expenditure and the accounts in accordance with the relevant legal requirements and is responsible for recruiting, managing and administering staff. With regard to the infrastructure, it is running the necessary services for an effective functioning of the Agency.

8.1 Physical infrastructure

Building work on the Agency's conference centre should have been completed by end 2008, and a major new challenge for 2009 will be bringing this facility into use and managing it, and the forecast influx of 2000 visitors per year who will attend meetings there. The facility development will continue to optimise the use of office space, to promote cost-effective management of the facility and establish and implement appropriate policies on security, health and safety and ecological awareness. Additional facility assistants will be required to manage the conference centre.

Indicators: A relevant performance indicator is the number of meetings taking place in the new conference centre and the number of complaints reported on these and other facilities.

8.2 Information Technology and connectivity services

As part of the integration and harmonisation of the technical solutions deployed in support of the REACH legislation, a review and consolidation of the overall REACH-IT architecture will be carried out in 2009 together with a reinforcement and consolidation of the underlying technical infrastructure and resources. A performance review and enhancement of the ECHA data centre will be conducted in light of actual loads, information flows and network traffic produced during the submission of dossiers and the execution of pre-registration related processes. Disaster recovery facilities and related usage procedures will be adapted and optimised as result of the above mentioned review. Alongside these activities, the ICT unit

will continue providing operational support to the proper functioning, use and further enhancement of the REACH-IT system.

Secure network connections with MSCA will be extended, maintained and monitored in line with the established security policy and procedures. The latter will be further reviewed and tuned according to the ISO 27001 standards during 2009.

In 2009 the wide majority of IT projects, applications and major systems are expected to be managed in accordance with standard Agency governance processes. To this end, the ICT function will deliver in 2009 the support and services required in order to comply with the supportability and maintainability capabilities of the ICT unit while enforcing the Agency's architectural guidelines and ensuring acceptable quality standards during the execution of projects.

The expansion and further optimisation of network, communications, technical infrastructure and user support will continue in order to accommodate the increased number of staff of the Agency and expanded facility (e.g. new Conference centre). Uninterrupted support for the operation and further development of other non-core systems and applications will be provided during 2009 by the front-office ICT Helpdesk function and other specialised technical resources in accordance with the portfolio of IT assets maintained.

Indicators: Relevant performance indicators are the percentage of system "downtime"; the response time of the ICT Helpdesk; the delivery of IT-projects against plan and budget.

8.3 Budget, finance and procurement

Following the first year of financial independence, the main financial systems and structures have been established to carry out the day-to-day operations, which include the overall financial coordination and the development and timely and accurate management of the financial resources. By the start of 2009, seven months of hands-on experience on the functioning of the in-house developed fee and invoicing system will have been gained, following the entry into force of the Fee Regulation. Also, the implementation of the ABAC Assets module for the management of fixed assets and inventories may require fine tuning following first experiences.

Following the publication of the list of pre-registered substances by 1 January 2009, ECHA will use this data to review the estimates for fee revenues in order to identify budgetary constraints that may emerge in 2009 and subsequent years.

The registration volumes and the subsequent number of invoices are expected to further increase ahead of the forecasted peak year of 2010, requiring reinforcement of the invoicing function. Also, the activity on the expenditure side, such as payments following newly procured services and reimbursing Committee rapporteurs, is expected to increase.

A procurement plan is annexed to this Work Programme (Annex 2). It includes a set of information related to procurement in order to ensure adequate transparency.

The operational directorates will have established and be utilising a series of contracts to support their work. These contracts will be managed by applying the standard contract management and procurement rules of the Commission and other Community bodies.

In 2009, a review of the proper continuity of the critical financial functions is likely to be needed. Furthermore, it will be necessary to reinforce internal control procedures related to financial management. The effectiveness of the internal control system will then be evaluated.

Indicators: Relevant performance indicators are the percentage of budget execution, the low number of complaints and the percentage of payments done within the foreseen delays.

8.4 Human resources and training

The Agency is foreseen to grow by more than 100 staff members in 2009 and highly efficient administrative and management systems and procedures must be in place to handle the expected volume of staff. Among the key objectives for 2009 will be the completion of selection procedures to renew reserve lists that will be exhausted by end 2008. Senior scientific posts will be filled on a need basis for specific specialist profiles. Further implementing rules of the Staff Regulations must be adopted by the Management Board, with the agreement of the Commission and after consulting the Staff Committee, by June 2009. In 2009, the first Temporary Agents recruited on an initial five-year contract will have the possibility to undergo written tests which have to be performed by the end of the third year of employment.

On the training front, the main focus of attention will be further developing the training programme for operational staff and a management development programme for the new management staff of the Agency.

Indicators: Relevant performance indicators are the percentage of implementation of the establishment plan, the number of formal complaints received or the number of training sessions organised.

8.5 Internal audit and quality control

Two important factors will contribute to the professionalisation of the Internal Audit and Quality Control functions: the dedication of staff to the "Quality Management" function, who takes in charge the important centralised administration of SOPs, and the cooperation with the Internal Audit Service (IAS) on a common risk assessment of ECHA, with a view to coordinating the audit plans over the next three years. Splitting both functions is a step towards a greater independence of the resident internal audit function.

As the Internal Auditor of ECHA, the IAS is expected to present a fully coordinated multi-annual audit plan (2009-2011) to the Management Board in December 2008. Given the rapid growth of ECHA, the progressive extension of its core areas of operations and its changing control environment, it is expected that the overall risk assessment and the resulting audit rolling plan will be updated and further fine-tuned in 2009. This risk assessment will be an important input for the preparation of the first annual reporting of budget implementation by the Executive Director as the Authorising Officer for the implementation of the Agency's budget.

After setting-up the core of the organisation of internal audit activities, the Agency will focus on consolidating the resources, professionalism and internal status of the resident internal audit function as a reliable contributor to management assurance and risk management. The out-sourcing of IT audits will be considered.

The aim of quality control activity for 2009 will be to assist management in initiating and implementing the Agency's quality policy and "quality manual" with a focus on rigorous administration of the manual's updates and coherent development of SOPs for new tasks and support processes. A particular focus and potential quality assurance commitment could be the correct transposition of the adopted SOPs into the workflow systems that will have been developed in the meantime.

Indicators: Relevant performance indicators for Internal Audit: endorsement of the revised audit rolling plan by the Board, and the execution of the annual/multi-annual audit plan (reports delivered). Indicators for Quality Management: number of policies adopted; number of SOPs approved in each area of activity, and the time taken for processing a new SOP from drafting to internal publication.

ANNEX 1: Resources for operations

Note: These figures are approximate and subject to fluctuation

Activities (Title III of the Budget)	Human resources		Budget (PDB)**	Budget***
The numbering below refers to the WP 2009, not to the numbering in the budget	**AD and AST**	**CA+SNE***		
3. Management, incl. Management Board and Legal Advice	22	1	1.864.000	1.910.000
4. Operations General coordination, management and support	26	3		
4.1 Pre-registration and inquiries	11	1	264.500	75.000
Registration and Notification	11	1	755.000	
4.2 Evaluation	45	2	620.000	550.000
4.3 Classification and labelling, SVHC	18	1	642.000	800.000
4.4 Restrictions and Authorisation	8	1	661.000	800.000
4.5 Communication, including translations	13	4	4.300.000	4.500.000
4.6 Advice and Assistance	34	6	1.172.000	1.172.000
4.7 Preparing Agency opinions and decisions - Committees and Forum	18	2	3.800.000	3.500.000
4.8 IT tools supporting the operations	21	1	6.850.000	6.300.000
5 Activities with other Institutions and MS	7		90.000	60.000
6 International activities	6		500.000	650.000
7 Board of Appeal	16		220.000	400.000
Total	**256**	**23**	**21.738.500**	**20.717.000**

Admin staff (for Info only)	68	11
Total	**324**	**34**

In Establishment plan:

*) Contractual Agents and Seconded National Experts are not specifically mentioned in the Establishment Plan.

**) Estimates forwarded to the Commission and the budgetary authority with the preliminary draft budget (PDB) for 2009 (Feb2008)

***) Updated estimates of expenditure for operations (August 2008)

ANNEX 2: Procurement planning