Helsinki, 17 October 2007
Doc: **MB/18/2007 final**

ECHA WORK PROGRAMME 2008

(Document adopted by the Management Board)

FOREWORD

The first months of ECHA's activities marked a successful start-up and build-up of staff and organisational structures, procedures and systems. The Agency demonstrated that it was able to achieve the many objectives set in the 2007 work programme, including a gradual hand-over of the REACH implementation tasks from the Commission.

Year 2008 poses two major complementary challenges for ECHA. First, the REACH regulation stipulates that the Agency has to be fully operational by 1 June 2008. A key asset for achieving this challenge is the highly competent staff of the Agency, which we will continue to recruit and train. Simultaneously we have to ensure, by developing the scientific and IT tools and procedures, that the Agency is capable of handling pre-registration, registration and other processes triggered on 1 June 2008. For that purpose, we need to complete in time the guidance and upgrade the assistance to registrants. The readiness of the Agency bodies (Committees, Forum and Board of Appeal) to issue quality opinions and work by that pivotal date will also be critical to ECHA's success.

The second core challenge for ECHA is to demonstrate during the last seven months of 2008 its capability to take decisions and actions on registrations or notifications within the strict timeframes set by REACH and to publish the list of pre-registered substances by 31 December 2008.

During 2008 ECHA will start or expand its networking with Member States Competent Authorities and stakeholders, with international bodies and other EU institutions active in chemical risk assessment. The communication strategy will also be implemented and address the information needs of the public.

I am convinced that ECHA will be able to meet these 2008 challenges as planned. The Agency management will also ensure that ECHA achieves a high level of scientific and technical competence and efficiency. Our guiding principles for all ECHA operations shall be transparency and credibility, both internally and towards the external stakeholders.

The preparedness of ECHA staff and bodies should permit a smooth transfer from the chemical legislation that is fading out in 2008 or 2009 to REACH. To make REACH a success depends not just on the Agency, but also on the European Commission, the Member States and the industry. They have assisted us in this intense start-up period, for which I am thankful, and now we can assist them wherever we can and is justified with the fee revenue and resources we will get from the EU budgetary authority. We trust that our partners will deliver their share of the necessary preparatory steps to make this legislation a milestone in European regulatory history and a reference for the rest of the world.

Geert Dancet
Interim Executive Director

ECHA WORK PROGRAMME 2008

Table of contents

ANNEX 1: Necessary resources

1   Main Achievements in 2007 and work in progress

It is worth recalling that ECHA started to function in its premises in Helsinki on 1 June 2007, on the day that the REACH Regulation entered into force. Until 1 September, it had limited staff in place focusing entirely on Management Board meetings, helpdesk activities, website and recruitment. During that period, the Commission services continued to give their support to establishing the Agency. Since 1 September, the support of the Commission services is strictly limited to those areas where a complete handover was either not possible or desirable.

By the time the Management Board approves this report, in October 2007, ECHA will have demonstrated that it has met virtually all the objectives and tasks that were set out in the 2007 Work Programme. With regard to the overall aims of the 2007 Work Programme, ECHA has achieved or is on the way to achieving:

- Efficiently organising meetings of the Management Board
- Setting up the Agency's Committees and Forum
- Establishing the ECHA-helpdesk and the network of Member State helpdesks
- Making available technical guidance
- Maintaining and upgrading ECHA's websites
- Recruiting an Executive Director and appointing an Accountant
- Recruiting up to 40 seconded Commission officials, up to 70 temporary agents and additional short term staff
- Setting up the operational and administrative structures
- Ensuring sufficient facilities
- Setting up the IT data centre and secure connections to the Member States
- Starting the development of standard operating procedures, quality management and internal audit systems
- Developing training material.

With regard to the 2007 tasks listed under Management, Preparing for Operations and Administration, ECHA is in a position to guarantee the successful completion of practically all of the more than 100 tasks identified.

2   Challenges and priorities for 2008

2.1   Challenges and objectives

The Agency has two central challenges for the year 2008, i.e. finalise by 1 June 2008 the preparatory actions for the entry into operation of the titles of the REACH regulation (notably pre-registration, registration – including registration of non phase-in substances –, evaluation and authorisation) and demonstrate the efficient functioning of the REACH operations, which will require immediate activity of the Agency during the first seven months.

These core challenges, which are affecting all ECHA staff, are broken down into many different objectives for all work areas of the Agency and is developed in the chapters below. To achieve these challenges ECHA will need to keep its close contact with the Commission services and in particular secure a smooth transfer of the archived knowledge, the unfinished business from the previous chemicals legislation and the adoption of the implementing regulations.

Also in the EU context, ECHA will build up in 2008 its stakeholder activities and its relations with the Member State Competent Authorities (MSCAs). This is a challenge on its own as the REACH system requires the preparedness of the MSCAs for their share of the work under REACH. The REACH system relies also heavily on the endorsement of the legislation, guidance and committee work by the stakeholders and in particular by the registrants.

As a consequence of these challenges, ECHA will become active on the international scene, in particular in context of the OECD Chemicals Programme.

Finally, the Agency will need to start communicating with the public at large by disseminating relevant information on its activities and on chemicals on its website and by being receptive to inquiries from citizens.

ECHA will have succeeded its mission and challenges for 2008 when it is perceived by the public, the authorities and the stakeholders as an efficient, transparent, trustworthy, helpful and equitable regulatory body.

2.2   Priorities

In order to meet its huge core challenge, ECHA will need to prioritise its resources in 2008 to a number of cross-cutting actions that will determine the success of its activities in this first full year:

1. Recruiting and training the staff of ECHA needed to start operations on 1 June 2008 (notably pre-registration and registration) and deliver results in the subsequent months;
2. Setting up performing scientific committees, forum and Board of Appeal;
3. Developing and implementing procedures and IT support tools (esp. REACH-IT) that ensure a legally sound, user-friendly and efficient execution of the operations of the Agency and its bodies;
4. Developing structured relationships with stakeholders and reinforcing the network of competent authorities including the training of national trainers;
5. Ensuring of proper hand-over of chemical "acquis" and the IT contracts from the Commission services;
6. Finalising guidance and reinforcing the network of national helpdesks and own Agency helpdesks to assist registrants in understanding their requirements.
7. Establishing by 31 December 2008 the list of pre-registered substances that allows efficient data sharing.

2.3   Risk Management for operations in ECHA

The Agency needs a comprehensive risk management in order to meet its challenges and objectives for the first calendar year of its operational responsibilities. Key elements for an overall risk management policy include the definition and implementation of the Agency's future management and reporting tools, in accordance with the Agency's quality policy. These tools have to include key aspects of risk identification, assessment, documentation, coverage and follow-up, which will contribute to disseminate a risk management culture from the early stage of operation.

With regard to the above-mentioned seven priorities for 2008, ECHA foresees a series of special risk management measures in order to safeguard success:

1. Establish service contracts with several European Institutes to provide ad-hoc scientific support on REACH tasks, through framework contracts (open call for tender) allowing also for consortia to be formed to facilitate the procurement of the services
2. Enforce decision-making attitudes within the deadline provided by the legislation.
3. In case of increased complexities that could lead to delays in the requirements and build of critical IT tools, ECHA will ask the contractors to focus on the critical components that are absolute necessary for the basic operationality of the systems and allowing workflows to be performed manually in the starting months.
4. To address the possibility that ECHA is lacking resources for securing its own functionality for the core operations, it will establish a fall-back service contract for providing training of trainers.
5. Acceleration of the installation in ECHA of the ECB databases and documentation in the original formats if the hand-over process from Commission falls behind schedule.
6. As regards guidance, if the Commission is unable to finalise the RIP technical guidance, to take over this process and to ensure consistency between the documents and to consider accelerated adoption procedure and translation.
7. Temporary relocation and training of scientific staff to perform substance ID and the establishment of a framework contract covering support on substance identification.

The successful start of the operations of ECHA does not only depend on the process and risk management by the Agency itself. Operationality of the Agency may also falter by delays in adoption of a series of implementation decisions by the European Commission ahead of the 1st of June, such as the Fee Regulation. It is the intention of the Agency to agree before the end of the year a number of mitigating actions with the Commission services in charge of these measures.

3   Management

3.1   Management Board of ECHA

2008 will be the first year of full and timely involvement of the Management Board in the budgetary cycle of the European Community. At the same time the Board will finalise the arrangements for making the Agency's Committee and the Board of Appeal fully operational. In addition a series of important rules and procedures for the functioning of the Agency will be put in place.

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

- Approval of the draft budget and the estimate and expenditure for 2009
- Adoption of scale of fees for performing tasks for the Agency (Committee members, experts)
- The Agency's internal rules of procedures, including rules on good administration, transparency and on the application of the Aarhus Convention;
- Appointment of the Board of Appeal.
- Approval of the Rules of Procedures of the Committees and the Forum;
- Adoption of the General report 2007.
- Adoption of the Multi-annual work programme and of the work programme 2009

3.2   Managing ECHA

It is the responsibility of the incoming Executive Director, appointed by the Management Board, to ensure the full operationality of ECHA by 1 June 2008 and the successful pre-registration of phase-in substances. He/she will be able to benefit from all the work undertaken by the interim Executive Director in 2007 during the set-up phase of the Agency and from the hand-over note which he will draw up.

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

- Review of the operational structure of the Agency;
- recruitment of all Directors and middle managers;
- finalisation of operational SOPs and REACH-IT work-flows in line with the legal requirements and quality standards;
- refine internal control systems to ensure an efficient resource management that is consistent with the adopted rules.

As the Agency is expected to nearly double in size in 2008, it will also be necessary to adapt its structure to the growth in size. This is in particular relevant for the Co-operation and

Operations Directorates and the originally planned new Directorate for Substances of Very High Concern.

The Co-operation Directorate will need to be reinforced by the creation of a separate unit for communication (now part of the first unit) and international co-operation (now still covered by the Commission).

The Operational Directorate of ECHA has started to develop a matrix structure which caters for the need for the work to be coordinated along three dimensions: scientific topic areas; within REACH processes and between REACH processes. One of the institutional challenges for 2008 will be to implement a dynamic structure which accommodates the increase in size of the operational part of ECHA, catering sufficiently for the need for coordination and efficient exchange of information between the three dimensions, whilst ensuring that all the main tasks for operation on 1 June 2008 are in place. A task force will be set up in 2007 which will evaluate the current operational structure and foreseen expansion, with the aim to make (a) proposal(s) for how this or an altered structure should be designed and how it can effectively be implemented. It will also identify possible choices for the new operational directorates to be created in 2008 and subsequent years.

The organic growth will require the recruitment of new managers for the Agency, which will need to be finalised by September 2008. One of the management aims in 2008 will also be to replace the seconded Commission staff, currently occupying the management posts and whose contracts terminate by the end of 2008, by ECHA temporary agents.

In line with ECHA's Quality Plan, the first two months of 2008 will be dedicated to mapping all activities, Standard Operational Processes ("SOPs") and, if necessary, sub-processes of the Agency, identifying their relative relevance and the hierarchy/ interactions among them, and to define a set of relevant indicators to measure the performance of these processes. Also, the legal correctness of the SOPs will be verified.

The Agency's aim is to have by 1 June 2008 at least those SOPs which are essential by Entry Into Operation ("EIO") described in a "Quality Manual", translated into the workflows of REACH-IT and properly tested. Where necessary, this will be complemented by working instructions and appropriate staff training. Operational and administrative systems will be customised to properly report on the related tasks, outputs, and exceptions, in order to enable timely corrective actions.

2008 will also be the first year of financial independence of the Agency from the Commission and first year of fee revenues and fee reimbursements to Member States. These challenges require the set-up of internal financial and accounting procedures consistent with the Agency's financial regulation to be adopted end December 2007.

Finally, ECHA has the intention to reinforce the network of Competent Authorities with the view to optimise co-ordination and co-operation, improve resource allocation to REACH implementation and exchange best practices.

4   Administration

4.1   Infrastructure

The infrastructure tasks encompass the management of the Agency's premises in co-operation with the building owner, who until September 2008 continues to occupy the majority of the building. The owner's move will trigger many infrastructure measures and procurement of renovation works, goods and services that need to be properly planned and implemented. The new long term lease agreement creates long term stability on the location of the Agency and holds also a purchase option. It requires the Agency and the owner to agree before October 2008 on an occupation plan for the coming two years.

Long term security needs to be ensured. The Agency will implement a series of recommendations coming from the security health check in conformity with ISO 27001 realized in 2007.

The construction of the conference centre will continue during 2008 and should, according to the plan, finalize at the end of the year. This will require a regular input into the Project Management Group that monitors the building progress and invoicing.

4.2   Finance and Accounting

The Agency will become financially independent as from 1 January 2008 by which date the implementation of the ABAC financial/accounting system will have been completed. However, the first half of the year will still require resources to optimize the utilization of the ABAC system in terms of adjustment of technical parameterization and fine-tuning of the reporting.

The financial regulation and the implementing rules are due to have been adopted in December 2007 but it will be necessary to continue the work on establishing the internal rules and procedures for the finance and accounting domain, on which new staff will also need to be trained.

An important milestone for the Agency is 1 June 2008 by which the Fee Regulation of the European Commission should enter into force. By this date at the latest, the in-house developed fee and invoicing system to support the operations of REACH must be completed and operational to enable the collection of registration fees to the Agency**.**

That milestone is also the target date for putting in place a system for reimbursing the rapporteurs of the scientific committees that should together with other contributions to Member States set limits to the part of the fees that can be paid by the Agency to Member States in order to safeguard its own finances.

Apart from day-to-day activities in 2008, the following special projects will require close involvement of the Finance unit in 2008:

- Continuous monitoring of the spending from the project to build a conference centre in the premises of the Agency
- Implementation of the ABAC Assets module for the management of fixed assets and inventories during the first quarter of 2008. Also the possibility of using the module for all types of purchase orders will be explored.
- Carrying out a complete inventory exercise on existing equipment in cooperation with the infrastructure unit during the first half of 2008 and continuous management of inventory items.

4.3 Internal Audit and Quality Control

In 2008, the Agency will start its internal audit activities. A risk-based audit plan to be presented to the Management Board in February will, in accordance with international standards of auditing, identify the key auditable processes, take stock of risks and key mitigating controls and prioritise audits after the risk assessment has been shared with management and the Commission's Internal Audit Service (IAS).

This will be followed by setting up the core of the organisation of internal audit activities, which will assess resources needed to cover the audit plan and the adequacy of in- or out-sourcing, define SOP's and working instructions for all internal audit activities and defining relate quality assurance procedures, in particular with regard to possible out-sourcing.

First audit engagements should be launched in September. However, the exact audit planning will depend on the scope and objectives contained in the approved audit plan.

The objective of quality control activity for 2008 will be to assist management in initiating and implementing the Agency's quality policy and "quality manual" in parallel to, and coherence with, the formalisation of SOPs by operational Directorates.

4.4 Human Resources and Training

Legally correct and effective management of human resources is a prerequisite for successful completion of the Agency's set-up phase. Timely recruitment of qualified staff will continue, and it is estimated that the remaining candidates on the 2007 reserve lists for eight job profiles together with the candidates on the new reserve lists for six job profiles will cover most of the recruitment needs in 2008. The contracts of the seconded Commission officials will end in 2008, and procedures for recruitment of their replacements will need to be launched. A significant number of staff will be evaluated for the probation period reports, and the human resources management (HRM) unit will establish the procedure in co-operation with the other Agency units. The Agency becomes financially autonomous, and the payroll and other financial procedures related to HRM will be verified and adjusted in co-operation with the financial unit, ensuring that the requirements of the financial regulations are met.

Apart from in-service training, new ECHA staff members will receive in 2008 a training curriculum clearly oriented towards operationality, i.e. focused on the knowledge and skills they need most urgently to run the operations of the Agency, and in particular the specific tasks they will have been assigned in their respective directorate/unit. The Agency will also train a maximum of two persons per Member State; the aim of these trainings will be to give all the necessary knowledge and know-how to make the trainees able to deliver trainings in their own institutions ("training for trainers"). For that purpose, two training sessions of three days would be organised in the spring of 2008.

4.5   IT Infrastructure and connectivity

The ICT infrastructure and connectivity of the Agency is essential as all data will be provided to the Agency over secure networks and stored at the data centre in electronic format.

The main activity in the IT infrastructure area in 2008 will be installing new own software applications (e.g. REACH-IT) and applications purchased to cover specific needs, in particular the document management system, system integration of all the applications that will need to run on the Agency's servers, the security improvements, setting up and monitoring of the secure networks with the Member States Competent Authorities and the implementation of the disaster recovery plan.

5   Ensuring full functionality

5.1   Helpdesks and technical guidance

REACH and IUCLID Helpdesks

The REACH and IUCLID-helpdesks of ECHA will continue to provide high-quality and legally sound advice with adequate response times. The existing structures will be further consolidated by recruiting more staff and improving the IT tools. The working procedure will be further streamlined and formalised into Standard Operating Procedures by February 2008. These will guide the staff in their day-to-day work and also form the basis for training activities for new helpdesk staff and for colleagues in ECHA that provide specialised input to the ECHA helpdesk. Quarterly reports will be produced to report on the work of the helpdesks and training courses will be developed.

The network of the national REACH-helpdesks (REACH-Help-Net) will be strengthened and at least three meetings of the REACH-Helpdesk-Correspondents Network (REHCORN) will be held (February, May, and October 2008, depending on the availability of the correspondents). The REACH-Help-Net exchange platform (RHEP) will be further developed in order to provide the helpdesks with an efficient tool to support each other when responding to questions. The REACH-Help-Net will regularly provide input on updating the FAQ section on the ECHA website and ECHA will strive to improve further the accessibility of this information source. ECHA will also use REACH-Help-Net for analysing the questions posed

throughout the EU with a view to endeavour to identify areas that would lead to an up-date of the guidance. Finally, it is planned to establish via the REACH-Help-Net an EU-wide cooperation of the REACH-helpdesks on a pro-active information exchange (brochures, standard presentations, information leaflets).

These activities will also require the improvement of existing or development of new IT tools.

Guidance

The work on the guidance in 2008 will focus on making guidance documents finalised by the Commission available on the web, partly or fully translated into the Community languages. This will be finished in stages and be completed by June 2008. ECHA and the Commission services will closely co-operate to finalise guidance in time for publication. Updates of guidance documents finalised and put on the web in 2007 will become necessary during the first semester of 2008, requiring an adequate procedure of stakeholder consultation, including the organisation of stakeholder-meetings aiming at the broadest possible acceptance, prior to approval of the update by the Executive Director of ECHA. This procedure is foreseen to be developed in 2007 and will require implementation throughout 2008.

By end September 2008 a report will be prepared summarizing the guidance related activities and the conclusions drawn from the comments gathered from guidance users via the helpdesks (including REACH help-net), the operational units of ECHA, and from Member State Competent Authorities. Based on this report a more fundamental review will be planned, if necessary by holding a series of consultative meetings, notwithstanding the fact that urgent issues will be addressed throughout the year by interim solutions, such as corrigenda or FAQ that clarify critical aspects.

To make the guidance accessible, IT tools will be made available or improved, notably the Navigator tool and the keyword search that will help REACH stakeholders identifying their obligations and finding the necessary guidance.

5.2 Communication

External communication

Throughout 2008, ECHA's communication policy adopted in December 2007 will be implemented. Maintenance and further development of the ECHA website will be the main activity in this context. The aim is to ensure among stakeholders a good awareness level of the site as a single point of access to REACH and Agency related information. An additional section providing information on pre-registered and registered chemicals will be implemented by 1 June and the classification and labelling section will expand when the new EU Classification and Labelling (C&L) legislation is adopted.

ECHA commits to publish guidance in the English language on the different titles of the REACH regulation ahead of their entry into operation and to have translations in the EU languages of its essential parts as close as possible to these dates. The guidance documents and translations will be published on the website of the Agency and "fact sheets", summarising the documents will be developed. A translation monitoring team will be established that will focus on managing the translation and in particular the co-ordination of proof-reading of translations received from the Translations Agency (CDT) by experienced and knowledgeable agency, and in certain specific cases Member State Competent Authority staff. It will be necessary to create a specific translation management tool for this task or to implement and adapt existing software solutions.

ECHA e-news will be published quarterly on the website of the Agency and circulated to stakeholders. Various documents including the 2007 Annual Report, brochures and REACH awareness building material will be published electronically. Limited number of copies may also be produced in print form in accordance with the 2008 publication plan.

Three stakeholder conferences/events will be organised during the year. One will take place in Brussels in April 2008 and be organised together with the European Commission. It will focus on the registration requirements of REACH. A second event will constitute the formal inauguration of the agency and its Executive Director, to be nominated in December 2007, and should also take place in the first semester. A third event will be organised in the autumn of 2008.

The Agency will establish a network and co-operation with EU institutions, international organisations and third country partners. This activity will be carried out in close co-operation with the Commission.

The Agency will work together with the competent authorities on the area of risk-communication on chemicals. Pilot work on this topic will start in 2008 in the context of an initiative taken by the Slovenian Presidency, and will include the organisation of 2 to 3 expert meetings and possibly an expertise network.

Internal communication

The main tasks during the year will be to establish and ensure sufficient information flow in the fast growing Agency, and to create a publication policy and corporate identity for printed and electronic communications.

5.3   The Committees and the Forum

In 2008 the three Committees will have their first meetings and the Forum its second (the first Forum meeting is scheduled for December 2007), in the first half of 2008. It is planned that all the Committees and the Forum agree on their draft rules of procedure before 1 June 2008 and submit them for approval (for the three committees, art.85/9) and adoption (for the

Forum, art.86/4) to the Management Board. Moreover, all four bodies are assumed to start defining their detailed working methods by June 2008.

For the Risk Assessment Committee (RAC) two meetings will be held in the first half of 2008 in order to, in addition to the ROPs and other setting-up tasks, agree on and implement the necessary working procedures for dealing with C&L dossiers and with the taking-over of unfinished work from the previous legislation. This is needed because both tasks must be handled by ECHA by 1 June 2008 onwards. Accordingly, two to three additional meetings will be held by the RAC in the second half of 2008, depending on the amount of incoming C & L dossiers.

For the Member State Committee (MSC), four meetings are tentatively planned for the second half of 2008, in order to be ready to deal with a possible high workload.

The Socio-economic Analysis Committee (SEAC) and the Forum are planned to each have one additional meeting in the second half of 2008, depending on the progress made with developing their working procedures and structures and the incoming workload.

As none of the Committees or the Forum have yet been established, the planning for 2008 cannot yet take into account the wishes of the Members themselves. Moreover, the uncertainty about the actual number of Annex XV dossiers for harmonised C&L and proposals for substances of very high concern (SVHC) is posing a significant risk and therefore the plans for meetings need to be sufficiently flexible.

Working group meetings may be needed to support the activities of the Committees and the Forum.

All Committees and the Forum will develop co-operation procedures with the other ECHA Committees and with other scientific bodies. This will particularly concern the RAC that may have overlapping interests with other committees and bodies operating at Community level.

Work will also start on developing rules of procedures for dealing with substances that are not only covered by REACH but also by Community legislation on food or workers' protection. This is particularly relevant for the RAC and the SEAC but may also concern the MSC with regard to the identification of SVHC. ECHA will establish contacts with the responsible Commission services (for the food and workers' protection legislation) and the secretariats of the relevant scientific committees to develop joint approaches that then can be discussed in the relevant bodies before common texts can be agreed as a basis for the rules of procedure required by Article 110 of the REACH Regulation. It is foreseen to identify the appropriate partner-services/bodies in the first six months of 2008 and have joint discussion documents before November 2008, thus allowing discussion in the concerned ECHA Committees to start before the end of the year.

5.4   REACH – IT and IUCLID5

REACH-IT

The successful implementation of REACH is strongly dependent upon the successful functioning of its IT systems, in particular the REACH-IT system that is currently under development.

REACH-IT handles the chemicals data on which the entire REACH system is based and is therefore essential for the functioning of the Agency. In 2008 the essential elements of the system shall be further developed, tested and installed and training modules for Agency and MSCA staff developed. The project is more complex than originally expected and is a major challenge for the Agency in terms of scope, resources and time pressures because primary system functionality relating to pre-registration, inquiries, registration and process or product-oriented research and development (PPORD), evaluation of test proposals, public dissemination of non-confidential information and associated workflows, are of the highest priority.

The REACH-IT system consists of a central database, a workflow management system supporting the main REACH processes and a public dissemination website. As ECHA needs to be fully operational by 1 June 2008, it has been planned that the release (version 3) of REACH-IT with the core functionality and workflows required for the Entry-into-Operation of the Agency will be delivered by the contractor in March 2008 after which there will be two months left for installation and acceptance testing at the Agency and in the Member States. After 1 June 2008, more releases of REACH-IT are planned with functionality that is not critical for the Agency at Entry into Operation.

Close cooperation with all REACH-IT stakeholders will be sought. For instance, this will include several meetings with the REACH-IT stakeholders and the Security Officers Network in 2008 as well as interaction with industry on the development of the SIEF portal.

IUCLID 5 and CSR tool

In 2008, the IUCLID 5 application will be handed over from the Commission to ECHA including intellectual property, the IUCLID 5 meta-database, and all related processes e.g. the remaining operations of the IUCLID Helpdesk and the management of the IUCLID websites. As a result, ECHA will take over the further project management of IUCLID 5 and set up a new framework contract (foreseen to be active before 1 September 2008) for the maintenance and future development.

The IUCLID Management Group (IMG) will be established in ECHA and become responsible for the IUCLID and REACH-IT helpdesks and the further configuration, change and release management of IUCLID 5. During 2008 the first projects might be launched by the IMG.

The Agency will publish the IUCLID format (XML Schemas) on its website and further coordinate the development of the IUCLID format with the OECD to ensure maximum standardisation and harmonisation with OECD (see also chapter 7).

Finally, the Agency will start to build the chemical safety report (CSR) tool, whose design and analysis project undertaken by the Commission will end in March 2008, supported by ECHA experts. This tool should assist registrants in producing the chemical safety report which registrants of chemicals above 10 tonnes need to integrate for registration purposes with the chemical data report produced by IUCLID 5.

5.5 Operations

The operational part of REACH enters into force on 1 June 2008. The first five months of 2008 will therefore be dedicated to continuing the work from 2007 aimed at establishing the necessary operational capacities and supporting infrastructures to allow the Agency to perform its duties as of 1 June 2008. The main short term objectives for 2008 are therefore closely linked to this date:

1. the Agency is operational on 1 June 2008, with a high scientific, technical and regulatory capacity;
2. the Agency operates legally correct, efficiently and transparently;
3. the Agency has on 1 June 2008 structures in place which ensure consistency with other Community work on chemicals;
4. the current legislative work has by 31 December 2008 been handed over to and installed in the Agency for efficient use.

To achieve these objectives, 13 projects, dubbed Agency Set-up Action Projects (ASAP), were established in September 2007 covering all the REACH operational processes:

1. Pre-registration, inquiries and substance identification;
2. Data sharing;
3. Registration and screening tools
4. Classification and labelling inventory
5. Process and product oriented research and development;
6. Evaluation ;
7. Annex XV dossiers, covering harmonised classification and labelling, identification of substances of very high concern and restrictions;
8. Confidentiality and dissemination of information;
9. Socio-economic analysis;
10. Chemical safety report tool;
11. REACH – IT and standard operating procedures;
12. Authorisation, except the identification of substances of very high concern;
13. Categories and analytic techniques (e.g. QSAR), including building Agency capacities;

Finally, it is also planned to start a new RIP project with equivalent processes on developing guidance for the safety data sheet in line Annex II of REACH. It should also be recalled that the operational part of ECHA will also be closely associated with the finalisation of the RIP projects initiated by the Commission services.

The aim of each of the ASAP and new RIP projects is to:

1. identify all REACH related legal and operational obligations of the Agency ;
2. determine all the detailed tasks which the Agency needs to carry out to meet these obligations;
3. detail the work flows for all processes needed to carry out the tasks, as well as the resources (human and otherwise) needed and timing for establishing the resources, taking into account the lead times required for establishing contracts, training new staff and testing IT;
4. develop, for each process relevant to a project, the necessary user input to the different IT systems in process, in particular the REACH–IT as well as the standard operating procedures (in line with the quality policy), the corresponding training material and any hand-over issues of the current legislation
5. develop the plan for establishing operations, including training;
6. execute the plan.

The target is to complete the planning phase of most projects by end January 2008 (i.e. up to step 5) and start the actual execution of the plan in February 2008. For the less urgent projects the planning phase will be finished by October 2008. It is also envisaged to test a number of REACH processes with industry prepared dossiers at an early stage and to have established an active participation in the OECD assessment meetings of the high production volume chemicals programme.

REACH operations will start on 1 June 2008 with the following tasks:

1. Pre-registration and inquiries, including data sharing;
2. Registration;
3. Evaluation, relating to testing proposals and compliance check;
4. Classification and Labelling, covering the inventory;
5. Notification of process and product oriented research and development (PPORD) (possibly before 1 June 2008).

In addition, the operational part of the Agency will evaluate the relevant dossiers, support the rapporteurs, the Chairpersons and work of the Committees, and any possible sub-committees, regarding

6. The first step of the Authorisation process: Identification of substances of very high Concern (Annex XV dossier);
7. Classification and Labelling, covering the harmonised classification and labelling proposals

8. Restrictions, in particular the Annex XV dossiers, covering the priority substances for which the risk assessment and risk assessment and risk reduction strategy work could not be finalised in time under Regulation 793/93.

5.6 Board of Appeal

The Commission predicted the arrival of a limited number of appeals during the first six months after entry into application of the operational titles of the REACH Regulation. Therefore, during the first semester of 2008 the necessary steps will be taken to ensure that the members of the Board of Appeal are appointed by the Management Board and will be able to examine these early appeals properly.

By the end of 2008, the overall objective is to have the infrastructure and internal rules for the Board of Appeal and for the Registry in place. Some of the rules can be adopted only after the members of the Board of Appeal are nominated. The preparatory work for these rules will however start well in advance. The first staff members of the Registry will be recruited and sufficient reserve lists of suitable candidates will be established. The necessary premises for holding hearings and a system for storing the documents relating to appeals in a safe and reliable way need also to be prepared. The eventual translation and interpretation services need to be ensured and possibly procured.

6 Activities of ECHA with other EU institutions and Member States

In order to ensure an efficient implementation of REACH, the Agency will need to maintain a close cooperation with the Commission services co-responsible for REACH and with the JRC, in particular its European Chemicals Bureau. This will not only be important with regard to the transfer of databases, archives, open dossiers and knowledge from the previous chemical legislation, but also with regard to the work undertaken by the European Commission for the implementation of REACH.

The Agency will, where appropriate, take measures during 2008 structures to efficiently give scientific and technical support to the Commission when carrying out its tasks under REACH. In particular, the lead services of the Commission will be supported in their work with:

- The REACH Competent Authority (CA) Meeting
- The REACH Comitology Committee
- REACH stakeholder information activities, notably a conference foreseen to be held in April 2008 addressing (pre-)registration.

Furthermore, to meet the obligation to ensure coordination and to provide information (e.g. data for biocides and pesticides) on the scientific and technical work on REACH by the Agency at Community level, the Agency will, in co-operation with the relevant Commission

services, develop structures to ensure coordination and increase synergies between the work of the Agency and the scientific and technical work related to the following community policy areas (see also chapter 5.3):

- Worker Legislation, including the development of rules for the co-operation on substances that fall under REACH as well as under the worker legislation;
- Consumer Legislation, including cosmetics, pesticides and food, covering also the co-operation with EFSA and the development of rules for the co-operation on substances falling under REACH and the food legislation;
- Environment legislation, including detergents, water framework directive, IPPC, waste, POPs, biocides;
- Medicines, including EMEA;
- Animal welfare legislation, including experimental laboratory animals directive;
- Research activities, in particular those of the JRC related to QSAR and test methods and research projects of DG RTD related to chemicals and alternative test methods;
- Development cooperation, in particular with regard to the sound management of chemicals in developing countries.

7   International Activities

It is planned that the Commission will ask the Agency before 1 June 2008 to contribute to a number of other international activities.

Where feasible and appropriate, these could cover the provision of scientific, technical, and capacity building support to the implementation of international or bilateral agreements concerning industry and environmental protection policies, in particular with the USA, Canada, China and Russia, and support to the Commission's work in OECD, in particular in the OECD Chemicals Programme relating to:

- Existing Chemicals Task Force
- SIDS Initial Assessment Meeting
- OECD Global Portal
- OECD IUCLID5 User Expert Panel
- OECD QSAR Toolbox
- New Chemicals Task Force
- Globally Harmonised System for C&L
- QSAR Task Force
- Task Force on Exposure Assessment
- Test Guidelines Programme
- Nanomaterials

8   Personnel and budget

The principal objectives and tasks in the personnel and budget area are the development and the timely and accurate management of ECHA's human and financial resources, including budget estimation, overall financial coordination, personnel administration, recruitment procedures and professional training. An annex has been added to the Work Programme that details the use by the different Directorates of human resources and the operational budget for the calendar year 2008.

ANNEX: Resources for operations

Note: These figures are approximate and subject to fluctuation

| Activities | Staff | | | Operational expenditure | | | | | Total |
| | Human resources | | | meetings committees etc. | Conferences | Missions | Contracts | Translations + Others | |
	AD and AST	CA*+ SNE*+ Int*	TOT	€	€	€	€	€	€
5.1 Helpdesk and technical guidance	26	4	30	300		30	1 000	200	1 530
5.2 Communication	8	2	10		300	25	600	6 024	6 949
5.3 The committees and the Forum	19	3	22	2 000		50	1 100	400	3 550
5.4 REACH-IT and IUCLID 5	5	2	7			65	3 250		3 315
5.5 Operations	90	6	96	120		66	1 850	235	2 271
5.6 Board of appeals	8		8			4		200	204
6 Activities with other Inst.and MS	7		7	30		80			110
7 International activities	5		5	50		40	2 000		2 090
Administration**	52	12	64						
Total	**220**	**29**	**249**	**2 500**	**300**	**360**	**9 800**	**7 059**	**20 019**

In Establishment plan: **220**

*) CAs, SNEs and Interims are not specifically mentioned in the establishment plan.

**) Not part of operational resources, added for coherence with the 2008 establishment plan.

For information only:	
Figures in the ADB, Title 3 of article 020303	
REACH-IT system	1 468 000
Activities of the committees, the Forum, Evaluation and Appeal Body activities	6 465 000
Other	12 086 000
Total	**20 019 000**