

Helsinki, 28 June 2007 Doc: **MB/03/2007 final**

WORK PROGRAMME FOR 2007

(Document adopted by the Management Board)

1. Introduction

Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency (ECHA) enters into force on 1 June 2007. By a decision of Heads of State of 13 December 2003 the seat of the Agency was agreed to be in Helsinki, Finland.

The Agency must be operational, i.e. capable of taking decisions with legal effect as foreseen in the REACH Regulation from 1 June 2008, 12 months after entry into force of REACH. This requires that the Executive Director is in place and has the necessary means at his/her disposal to take these decisions. S/he must, therefore, be able to rely on a middle management and staff which delivers an organizational structure of sufficient competence and capacity to complete the tasks efficiently.

Among the essential tools to support the Agency in these operational tasks, the REACH ITsystems (REACH-IT, IUCLID-5) must be fully operational, together with the necessary administrative IT support systems.

The Work Programme of ECHA in 2007 focuses on the essential steps in setting-up the capacity of the Agency to take operational (REACH-related) decisions, including:

- Putting in place the Management Board
- Selecting the Executive Director
- Recruiting and training staff
- Establishing systems, procedures and operational controls
- Preparing the Agency's committees and the Forum
- Installation of the IT systems and other facilities of the Agency
- Creating the Agency's helpdesks and guidance tool.

In order to succeed in setting up the Agency within the set timeline, the Regulation provides that the Commission shall afford the necessary support towards the establishment of the Agency, e.g. appointing personnel and concluding contracts, using the budget provided for the Agency.

Extensive planning and many preparatory actions have been taken and financed from the internal market budget line since 2004. Most of these activities relate to preparing the implementation of REACH: drafting technical guidance documents for industry and competent authorities, creating a chemicals database (IUCLID-5) and designing the system for processes in the Agency (REACH-IT). With regard to practical preparations, first a building in Helsinki has been secured for the first years. Second, the Commission has launched a selection procedure for the Executive Director and a call of expression of interest for the first temporary agents. The Commission has also nominated, in accordance with the Regulation, an interim Executive Director to execute the administrative functions of the executive director until an Executive Director has been appointed by the Management Board of the Agency and has taken office. While it was decided to leave the recruitment for the management positions for the incoming Executive Director there is a need to secure the

management of the Agency for the first year. This will be realised by seconding experienced Commission staff to Helsinki to occupy the managerial and other key positions in the start-up team of the Agency. They will remain in office up to 18 months or until the Executive Director has nominated his/her management team. Their primary task will be to set-up the Agency and for this to manage the knowledge transfer from the Commission services to the Agency, not only in the scientific/technical area but also with regard to the numerous administrative rules and practices that a well functioning European regulatory agency must respect and apply. They will be supported in their task by a number of non-managerial seconded officials and temporary agents, newly recruited by the Agency but many having undergone an initial training in the Commission services since autumn 2006.

This Work Programme covers the period from 1 June to 31 December 2007. A summary of the authorised budget and personnel for 2007 is attached as an Annex.

2. Mission of the European Chemicals Agency

The REACH Regulation states that the Agency is established for the purposes of managing and in some cases carrying out the technical, scientific and administrative aspects of the Regulation and to ensure consistency at Community level in relation to these aspects. In addition, the Agency shall provide the Member States and the institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals which fall under its remit and which are referred to it in accordance with the provisions of the Regulation.

3. Overall aim for 2007

By the end of 2007, the overall aim is to have a basic working infrastructure and administrative support functions in place and performing.

Of particular importance is that a helpdesk is in place at entry into force, to provide advice and assistance to manufacturers and importers which are registering a substance and to support helpdesks established by Member States. A first version of technical and scientific guidance and tools, as well as explanatory information on REACH will be available for industry and Member State competent authorities at that date.

This overall aim of the Agency requires the following tasks to be executed:

- Run meetings of the Management Board
- Prepare for the setting up of the Agency's Committees and the Forum
- Establish the ECHA-helpdesk and the network of Members States REACH helpdesks for its cooperation with national REACH helpdesks set up by the Member States
- Make available technical guidance
- Maintain and upgrade the websites of the Agency for making essential information available
- Recruit an Executive Director and appoint an Accountant for the Agency
- Recruit up to 40 seconded Commission officials to be installed in Helsinki in summer 2007, and up to 70 temporary agents and, if required, additional short term staff to start in Helsinki from July onwards, mainly in September
- Set up the operational and administrative structures of the Agency

- Ensure sufficient facilities for the Agency
- Set up the IT Data Centre and secure connections to the Member States Competent Authorities and the Commission
- Start the development and testing of standard operating procedures, quality management and internal audit systems
- Develop training material.

4. Management

4.1. Executive tasks

It is the responsibility of the Interim Executive Director, nominated by the Commission, to create the foundations on which an operational independent Agency can be built. He will need to provide in 2007 an overall direction for the activities of the Agency during the set-up phase, *inter alia* planning, organising and prioritising the work. Financial and human resources need to be ensured and used in the most efficient and effective manner.

He will be supported by a management team consisting of seconded Commission officials that will bring to the Agency essential know-how on administrative and other procedures as well as in the scientific/technical or operational field.

The tasks of the management in 2007 include

- Strategic planning
- Ensuring continuity and minimum disruption during and following the transfer of responsibilities and knowledge from the Commission to the Agency
- Establish the systems, procedures and controls for the sound management of the Agency's financial and human resources and achieve financial independence
- Promoting a culture of service orientation throughout the Agency, with a view to establish a good co-operation with the Member States Competent Authorities, Industry and other stakeholders as well as the European institutions
- Laying the foundations of the Agency's internal control system
- Creating a framework for the continuous improvement of the Agency's internal procedures by establishing the foundations of a quality management and internal audit system
- Identifying procedures and tools supporting the internal consistency of the positions of the Agency
- Providing a structured and systematic approach to the identification of performance indicators and their evaluation
- Identifying and developing key processes that influence and potentially support the policy and strategy of the Agency
- Organising opening ceremonies and media events.

4.2. Management Board

The first meetings are scheduled for 27 to 29 June, 18 July and early September, after which 2-3 meetings still need to be organised in 2007.

The main tasks for the Management Board in 2007 are to:

- Appoint the Executive Director
- Appoint an Accounting Officer
- Adopt the internal rules of the Agency, such as
 - . Implementing rules on the Staff Regulation
 - Financial Regulation and implementing rules
 - Its own rules of procedure
- Adopt the work programme of the Agency for 2007 and 2008
- Adopt the budget for 2007 and before the beginning of the financial year the final budget for 2008 (and adjust the amounts if necessary)
- Start producing an estimate of revenue and expenditure for the Agency for 2009
- Decide on the lease agreement for the building and longer-term building options
- Approve the draft seat agreement.

5. Preparing for operations

5.1. Helpdesks and technical guidance

The purpose of the REACH and the IUCLID helpdesks is to provide registrants with best possible advice on questions related to the obligations under REACH and on how to use the chemicals database IUCLID-5, which should be rolled out to potential registrants before June 2007.

Tasks for the helpdesks in 2007 include:

- Transferring the helpdesks initiated at the Commission to the Agency
- Implementing efficient Helpdesk procedures and train the staff
- Ensuring appropriate staffing of the helpdesks, adequate response times and high quality of answers
- Establishing and running a functioning network of Member State REACH helpdesks as initiated by the Commission
- Creating Frequently Asked Questions websites and ensuring their updating

Technical guidance shall enable actors under REACH to understand their role and duties and guide them in how to meet these requirements. The first version of the technical guidance is under preparation by the Commission services and will be made available to the Agency at entry into force; the second version is due by the end of 2007. The task for the Agency consists therefore primarily in making it available on its websites to all interested parties. The Agency will contribute to translating essential parts of the guidance into official community languages.

The questions posed to the REACH helpdesks throughout the Community will indicate if and where improvement of the provided guidance is necessary. The helpdesk and guidance unit will therefore develop methods to analyse the questions and to manage the necessary guidance improvement.

5.2. Communication

Websites, brochures and press material will be the main instruments for achieving the communication objectives. External communication activities aim at informing stakeholders, in particular SMEs, on the key deadlines and obligations under REACH and where companies

can find information and guidance. Internal communication activities will focus on setting up the Agency's communication capabilities and networks.

Tasks in the external communication in 2007 include:

- ECHA website maintenance and updating
 - Provision on general information on REACH and ECHA
 - Develop the site as an access point to sub-sites on guidance, IUCLID-5, REACH dissemination, and classification and labelling
 - Transfer of REACH information from the Commission services to ECHA
- Establishment of regular contacts and exchanges of information with EU institutions, international organizations and stakeholders as well as media
- Production and distribution of REACH brochures, documents and press releases

Tasks in the internal communication in 2007 include:

- Setting up the ECHA internal communication strategy
- Adopting rules and procedures for communication
- Establishing a house style for printed and electronic materials
- Establishing issue management and risk communication systems
- Creating the Agency's press relations
- Interacting with the network of other Agencies' communications staff

5.3. Preparatory work for the Committees and Forum

Tasks in the preparatory work for the Committees in 2007 include:

- Establishing secretariats to the Committees
- Drafting the rules of procedure
- Drafting standard operating procedures
- Preparing a detailed estimation of the workload during the first years of operation
- Planning first meetings and the hand-over from current committees
- Inviting Member States to nominate members to the Member State Committee and Forum
- Inviting Member States to nominate candidates for members to the Risk Assessment (RA) Committee and the Socio-Economic (SEA) Assessment Committee
- Preparing the list of candidates for membership in the RA and SEA Committees to be published by the Executive Director
- Planning and starting to develop the document management system for the Committees.

5.4. Development of REACH IT and secure networks

The successful implementation of REACH is strongly dependant upon the successful functioning of its IT systems, in particular the REACH-specific systems that are 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 2007 the essential elements of the system shall be developed and installed and training modules for Agency staff developed. This is a major challenge for the Agency in terms of scope, complexity, and time pressures. The coding of the REACH-IT system could only start in spring 2007 under a pluriannual contract that needs to be transferred from the Commission to the Agency later this year.

Primary system components, relating to pre-registration and registration, and supporting these processes, are of highest priority but given that Member States Competent Authorities will have access to REACH-IT a secure network must be established and tested in 2007.

The REACH-IT system consists of a central database and a workflow management system supporting the main REACH processes. In addition, other systems will be required to support all the necessary functions for the Agency, including:

- Public dissemination website, including the preparation of the integration with the High Production Volume (HPV) Global Portal
- Chemical Safety Assessment/ Chemical Safety report (CSA/CSR) software
- Maintenance of the IUCLID 5 software, including additional development of required functionality for the Agency and the possible management of the development of future releases
- Discussion groups to support Data Sharing during the pre-registration phase
- Migration of databases on which the REACH-IT system is depending, e.g. EC Inventory, C&L database, GHS database, etc.
- Integration with other IT systems, e.g. financial systems, document management systems, etc.
- Setting up a Data warehouse and Reporting for the Agency Management
- IT system for the Board of Appeal
- Document Management System to support the work of the Committees
- Publishing and maintenance of the XML Schemas and further standardisation and harmonisation efforts with the OECD

Depending on when these IT systems will need to be available, resources will be respectively required for further requirements gathering, analysis & design and/or building the systems.

5.5. Preparatory work for the Board of Appeal

Tasks of the preparatory work for the Board of Appeal in 2007 include:

- Giving input to the Commission on the procedures to be laid down in the implementing rules to be adopted by the Commission
- Planning a registry to deal with appeals and related documentation
- Planning a selection process for registry employees to be started in 2008
- Drafting internal rules for the Board and the registry.

6. Administration

6.1. Infrastructure

The infrastructure tasks encompass the management of the Agency's premises in cooperation with the building owner, who until mid 2008 continues to occupy the majority of the building. Renovation works are needed in stages as more premises will be taken into use. Procuring the services needed is a major task; at the early stage services will be received via the building owner. Long-term security needs to be ensured. Tasks related to infrastructure also include the preparation and implementation of the decision by the Management Board concerning the creation of a conference centre needed for the various committees of the Agency.

Infrastructure tasks during 2007 are:

- Nomination of a Security Officer and a Data Security Officer;
- Prepare and implement Standard Operating Procedures (SOP) for the facility management, safety and security of ECHA;
- Prepare and install any necessary facility management support systems;
- Manage the Agency facility which includes the building and services;
- Draft technical specifications for procurement procedures for Agency facilities and supplies, telecom infrastructure, security aspects, office hardware other than PCs, and other facility related items; manage the resulting contracts;
- Manage the building rental contract;
- Organise and oversee the refurbishment and allocation of offices, furniture and equipment, plan moves, and manage the inventory;
- Oversee implementation of building works and refurbishment contracts;
- Contribute to the drafting of the Agency's facility policy;
- Contribute to the tendering process to construct a conference centre;
- Contribute to organising Management Board meetings and possible other meetings in temporary locations outside the Agency.

6.2. Finance and Accounting

The main objective in 2007 is the creation of a fully operational finance and accounting unit including the full financial independence of the Agency.

For this objective the following tasks need to be completed:

- Nomination of Accountant by the Management Board
- Adoption of the Financial Regulation and its implementing rules by the Management Board
- Adoption of the work programme of the Agency by the Management Board
- Full implementation of the ABAC Financial/Accounting System in use by the Commission
- Adoption of the most important internal rules of procedure for the Finance and Accounting unit
- Programming and testing of an in-house developed fee and invoicing system to support the operations of REACH

Once the finance and accounting unit is fully operational, the work will concentrate on day-today activities of the unit such as:

- Preparation of commitments and payment transactions
- Monitoring of the budget execution
- Setting up contracts in line with the requirements of the work programme, managing these contracts
- Preparation of the budget 2008
- Preparation of reporting in line with the budgetary cycle.

6.3. Human resources management

An efficient and well-organised Human Resources department is of vital importance to the set-up of the Agency. Recruiting the right personnel for it and to train this staff in the appropriate procedure will be a major challenge. The seconded officials will help to meet this

challenge while ensuring the functioning of the infrastructure and the day-to-day operation of the HR department.

The HR management tasks in 2007 are:

- To ensure successful recruitment from the reserve lists provided by the Commission
- Support the establishment of the personnel in Helsinki
- To establish procedures for HR planning and budgeting and monitoring of HR budget lines and the establishment plan;
- To put in place staff, systems, procedures and controls for efficient implementation of the various HR administration functions, such as issuing offers of employment and contracts, grading on recruitment, establishment and management of individual rights and entitlements, establishment and payment salaries and allowances, reimbursement of expenses, absence management, etc.
- To ensure payment of salaries and allowances as well as reimbursement of expenses;
- To manage the service level agreements with PMO, EPSO, Translation Centre, ADMIN-Training and Medical Service;
- To establish and train an efficient recruitment service capable of managing multiple and large-scale selection procedures and following up recruitment and induction of new staff, and launch selection procedures for further staff of the Agency;
- To coordinate the establishment of the Agency's internal control environment, in particular ethics and integrity, establishment of mission statements, job descriptions and definition of individual objectives, establishment of performance appraisal system, business continuity, sensitive functions, etc.
- To adapt the standard implementing rules of the staff regulation to the requirement of the Agency and initiate their adoption by the Management Board
- Develop a coherent framework for staff policy in the Agency.

6.4. Information Technology Infrastructure

The ICT of the Agency is essential as all data should be provided to the Agency and stored there in electronic format.

Tasks in the IT infrastructure area in 2007 include:

- Daily operations and tunings at the Agency Data Centre
- Security, including the daily tasks of the Local Information Security Officer, a further risks analysis, security audit, and development and enforcement of a security policy
- Website for the Agency
- Intranet of the Agency
- Hosting and possible support of several sites developed by 3rd parties: Guidance website and possibly the HPV Global Portal and the IMG portal
- Support for the Metadata Configuration tool
- Operations of the administrative Information Systems (ABAC, Centurio)
- Setting up and monitoring of the network connections to the MSCAs
- Setting up the ICT helpdesk
- Supporting the infrastructure of the IUCLID5, REACH and REACH-IT Helpdesks and the Member State Exchange Forum
- Setting up the document management system
- Setting up an SOP management system
- Planning for the Conference Centre area ICT environment

- Video conferencing equipment
- Analysis of the need of server capacity for REACH-IT and IUCLID5 systems
- Installation and testing, including performance testing, of REACH-IT and IUCLID5 software
- Maintenance and support of the office hardware, software and networks
- Procurement of equipment needed for 2008 (servers and office automation)
- Installation of the office automation environment for the newcomers of 2008
- Telephone networks
- Creation of the disaster recovery plan
- Establishment of the disaster recovery site

6.5. Training

Once the start-up team is established in Helsinki, it will need to prepare the training for the next group of Agency staff, i.e. about 120-150 new colleagues to arrive in early 2008. With regard not only to its tasks, but also to its specific start-up context, the Agency staff will have to possess two main kinds of competencies: a high level of technical expertise and a capacity to adapt and to actively participate to a changing environment.

Tasks in the training area in 2007 include:

- Developing curricula for the different roles in the Agency
- Developing a training plan
- Designing training modules
- Developing training material
- Training trainers to deliver the training
- Delivering a general training for all staff members, including in particular induction sessions on the administrative organisation, the internal rules and the specificities of ECHA.

--000---

Annex

BUDGET AND ESTABLISHMENT PLAN

| Subject | Budget 2007 |
|--|----------------|
| Revenue | |
| - Community Contribution | 15,294 |
| - Fee income | |
| - Other | |
| TOTAL | 15,294 |
| Expenditure | |
| Title 1 | |
| - Staff in active employment and | 9,101 |
| related costs - Other | |
| Total title 1 | 9,101 |
| Title 2 | 9,101 |
| | 0.025 |
| Rental and building charges and associated costs | 0,935 |
| - IT infrastructure and related | 0,928 |
| costs | |
| - Other | 0,718 |
| Total title 2 | 2,581 |
| Total title 1 and 2 | 11,682 |
| Title3 | |
| - REACH IT system | 1,269 |
| - Activities of the Committees, the | |
| Forum, Evaluation and Appeal | |
| Body activities | |
| - Other | 2,343 |
| Total title3 | 3,612 |
| TOTAL | 15,294 |

Commitment credits (Mio Euros with three decimals)

| Categories | 2007 | | | | |
|--------------------|-------|------------------|--|-------|--|
| and grades | | een on 2.2006 | Authorised in the Community Budget | | |
| | | | | | |
| | Perm. | Temp. | Perm. | Temp. | |
| AD 16 | | | | 0 | |
| AD 15 | | | | 1 | |
| AD 14 | | | | 2 | |
| AD 13 | | | | 8 | |
| AD 12 | | | | 8 | |
| AD 11 | | | | 8 | |
| AD 10 | | | | 8 | |
| AD 9 | | | | 9 | |
| AD 8 | | | | 10 | |
| AD 7 | | | | 9 | |
| AD 6 | | | | 8 | |
| AD 5 | | | | 4 | |
| Total grade AD | 0 | 0 | 0 | 75 | |
| AST 11 | | | | 0 | |
| AST 10 | | | | 1 | |
| AST 9 | | | | 2 | |
| AST 8 | | | | 6 | |
| AST 7 | | | | 6 | |
| AST 6 | | | | 1 | |
| AST 5 | | | | 1 | |
| AST 4 | | | | 8 | |
| AST 3 | | | | 1 | |
| AST 2 | | | | 0 | |
| AST 1 | | | | 0 | |
| Total grade AST | 0 | 0 | 0 | 26 | |
| Total | 0 | 0 | 0 | 101 | |
| Total Staff | 0 | | 101 | | |