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INTRODUCTION/MISSION

This general report presents the work that the European Chemicals Agency (ECHA) carried out in 2007 in accordance with its work programme for the same year, which was prepared by the Commission services and adopted by the Management Board on 28 June 2007.

ECHA was set up on 1 June 2007 to ensure the effective management of the technical, scientific and administrative aspects of the REACH Regulation¹.

The Regulation establishes a new regulatory system for the chemical substances in the European Union. The purpose of this new system is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for the assessment of hazards of chemicals, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

In practical terms, the new regime is aimed at closing a knowledge gap in relation to chemical substances placed on the European market before 1981, speeds up the placing of safe and innovative chemicals on the market and turns the risk management of these substances in general more efficient.

According to the REACH Regulation, the Management Board shall before 30 April of each year adopt the general report of the Agency for the previous year. Following approval by the Management Board the Executive Director will forward the general report to the Member States, the European Parliament, the Council, the Commission, the European Economic and Social Committee and the Court of Auditors, and will have it published.

¹ Regulation (EC) No 1907/2006 of 18/12/2006 (Official Journal of the European Union L396 of 30/12/2006 and L136 of 29/05/2007).

1. SETTING UP OF THE EUROPEAN CHEMICALS AGENCY

In fulfilment of the European Commission's duty to afford the necessary support towards the establishment of the Agency², it appointed Geert Dancet as Interim Executive Director as of 1 June 2007. The Commission furthermore seconded 37 experienced officials to ensure the smooth setting-up of the Agency and it fully executed the Agency's 2007 budget to allow the Agency to build up its own financial systems, rules and resources before becoming fully financial independent.

This set up, which was based on documented working arrangements for the transitional period, results in the fact that the European Chemicals Agency does not establish independent financial accounts for the budget year 2007. The budget execution will be reported within the Commission's annual accounts.

2. MANAGEMENT BOARD

The Management Board of the European Chemicals Agency (ECHA) is the Agency's highest decision-making body. The 35-strong Management Board consists of 27 representatives from each of the EU Member States, three Members representing the European Commission, two independent individuals appointed by the European Parliament and three representatives of interested parties (without voting rights).

Three weeks after the establishment of ECHA on 1 June 2007, the Management Board held its constitutive meeting and elected Mr Jukka Malm (Finland) as Chair and Mr Antonello Lapalorcia (Italy) as Vice-Chair. Moreover, the Board also adopted Rules of Procedure, the work programme for 2007 as well as the budget and establishment plan.

At the following four meetings until the end of 2007, the Management Board continued to focus on making the Agency fully operational. It carried out the selection procedure for the position of ECHA's Executive Director: Mr Geert Dancet was appointed to this post on 17 December 2007. Financial rules for the Agency were adopted and the Board appointed an Accounting Officer. The Board discussed on several occasions the necessary infrastructure for the Agency and decided to build a conference centre on the Agency's premises.

The Board also examined a series of general policy documents on the cooperation between the Agency and its stakeholders, the cooperation with the Member States' Competent Authorities (MSCAs), the nomination of the Agency's committees, the structure of the Board of Appeal and the procedure for the preparation of guidance documents.

Finally, the Board organised the Agency's future actions by adoption of a work programme and budget for 2008 and by agreeing on a rolling plan for the Board's own activities.

² In line with Article 134 of the REACH Regulation (EC) N° 1907/2006 of 18 December 2006

3. PREPARING FOR OPERATIONS

3.1 Helpdesk & technical guidance

Both the REACH and IUCLID helpdesks were successfully transferred from the Commission to ECHA in 2007.

Efficient operations were established in June 2007 and by the end of 2007 nearly 2000 enquiries were received and responded to. Enquiries were generally handled with a high level of quality and responded in a timely manner.

The REACH Helpdesk Correspondents Network (REHCORN) was successfully established in 2007 aiming to provide an EU-wide harmonised approach to responding to questions on REACH. It met three times in 2007 and drew up rules of procedure and its mission statement. It also oversaw a major review of the REACH frequently asked questions (FAQ) document at the end of 2007 and ways to further strengthen the network have been considered and agreed.

The REACH Help Net Exchange Platform (RHEP) tool was successfully established to provide an electronic means of exchanging information on day-to-day issues arising and for discussing more difficult questions. By the end of 2007 ninety questions had been uploaded for either discussion or information.

The Guidance Team became fully operational late in 2007 due to delays in staffing. Nevertheless, it managed the first update of the guidance documents on registration, Process-Oriented Research and Development (PPORD), intermediates and monomers and polymers which received endorsement at the December REACH Competent Authorities meeting.

3.2 Communication

On 1 June the Agency launched its web site (www.echa.europa.eu). It functions as ECHA's main communication channel and a single point of access to all relevant information regarding REACH and ECHA. Large parts of it are multilingual in 22 official EU languages³.

With the support of the Commission, the Agency organised two press events. On 1 June over 30 journalists participated in the event linked to the opening of ECHA. The second event was linked to the first Management Board meeting. In total five press releases were distributed to local and EU media contacts. In addition, ECHA provided over 40 media interviews and wrote seven articles to European magazines.

Over 600 press, information, and web enquiries were processed during the seven months of the operations. The Commission developed jointly with the Agency two information leaflets on REACH, one intended for the EU companies and the other one for companies in the third countries.

³ Bulgarian, Czech, Danish, German, Greek, English, Spanish, Estonian, French, Italian, Latvian, Lithuanian, Hungarian, Maltese, Dutch, Polish, Portuguese, Romanian, Slovakian, Slovenian, Finnish and Swedish.

ECHA contributed to the inter-agency web site and the 2007 edition of the Agencies' joint publication.

Internal communication activities focussed on setting up intranet and establishing an information providers' network.

3.3 Preparatory work for the Committees & Forum

Setting up the three ECHA Committees and the Forum with the aim of having them fully operational by 1 June 2008 was one of the main objectives in 2007. Responding to the invitation sent by the Agency in September 2007, each Member State appointed a Member to the Member State Committee (MSC) and a Member to the Forum for Exchange of Information on Enforcement by the end of November 2007. The compositions of these bodies in 2007 are laid down in Annexes 2-3.

Most of the Member States nominated also, in accordance with Article 86 of the REACH Regulation, candidates for membership of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC). The interim Executive Director established and published the list of nominees in December 2007. On the basis of the list, the Management Board decided on the appointment of the RAC members at its December meeting, whilst the decision on the appointment of the SEAC members was postponed to February 2008. The composition of the RAC is laid down in Annex 4.

The first meeting of the Forum was organised already 11-12 December 2007. The Forum had a first discussion on its Rules of Procedure and established three ad-hoc Working Groups: "Annex XVII of REACH Regulation – Advice on enforceability", "Information needed by enforcers from REACH IT" and "Development of the first Forum Work Programme".

3.4 Development of REACH-IT, IUCLID5 & secure networks

The successful implementation of REACH is dependent upon the functioning of its IT systems, in particular the REACH-IT and the IUCLID5 systems to handle the chemical data on which the entire REACH system is based and to support the communication with industry and workflows of the Agency and the Member States.

IUCLID 5 is the software tool, which is provided free of charge to industry in order to be able to create electronic submission dossiers. The Commission and ECHA have rolled out IUCLID5 to industry.

REACH-IT is the main operational IT system of the Agency, which will be used by the Agency and the Member States to comply with its obligations under the Regulation. In addition, REACH-IT will provide a website where the chemicals industry can sign-up and submit their data and it will contain also a public dissemination website.

The REACH-IT project is a major challenge for the Agency in terms of scope, complexity, and time pressure. The coding of the REACH-IT system could only start in spring 2007 and it is planned to be ready for Entry into Operations in June 2008.

Primary system components, relating to pre-registration and registration, and supporting these processes, were of highest priority and the first versions of these components were delivered and installed at ECHA in the second half of 2007.

The REACH-IT contract has been handed over from the Commission in January 2008.

MSCAs need to have access to the industry submitted data in REACH-IT. In order to handle this access properly, a group called the Security Officers Network was set up early 2007 to discuss security issues affecting the Agency and the MSCAs. The network had two meetings during 2007 and came up with a proposal on how to establish a secure connection between the MSCAs and the Agency via a VPN based solution.

3.5 Preparatory work for the Board of Appeal

The Board of Appeal will be responsible for appeals lodged against certain decisions of the Agency. Although this organ is part of the Agency, it will take its decisions independently and will not be bound by any instruction in making them. The Board of Appeal will consist of a Chairman and two members. It will be assisted in the performance of its functions by the Registry.

In 2007 preparatory work was undertaken for the Board of Appeal and its Registry. In its September meeting, the Management Board decided on the general structure of the future Board of Appeal in favour of one full-time Chairman of the Board and two members and a group of alternates and additional members on call. The Commission Regulation on the qualifications of the members of the Board of Appeal was adopted in October. The preparations to appoint the members were initiated by providing the Commission with a draft call for expression of interest. The members of the Board of Appeal can only be appointed by the Management Board after receiving a list of candidates proposed by the Commission.

Pursuant to an informal working arrangement with the responsible Commission services, a first Draft for Rules of Organisation and Procedure was also submitted to the Commission as a preparatory contribution towards the adoption of a Commission Regulation laying down the rules of organisation and procedure in 2008.

4. ADMINISTRATION

4.1 Infrastructure

With the help of the Finnish Government, the Commission had selected the Agency's seat in the centre of Helsinki, Annankatu 18. They had also agreed on the rental agreement with the owner, Varma Insurance Company, and the first renovation. It is foreseen that the Agency will gradually take the building over from Varma, who will move out by September 2008.

In June 2007, the Agency occupied most of the second floor of the building. Part of the third floor was also refurbished by the owner for the Agency for the occupation by 50 extra staff in the beginning of 2008. The premises were managed in cooperation with Varma who also provided the necessary services such as security, cleaning, cafeteria and utilities.

Approval of the Management Board and the budgetary authority was received for construction of a conference centre in the basement of the building. The works started in the autumn of 2007 according to plan.

4.2 Finance & accounting

Not yet being financially independent, the Agency's finances for the exercise 2007 were managed by DG ENTR until the Executive Director was appointed by the Management Board on 17 December 2007. At the same meeting, the Agency's financial regulation was adopted and the Commission's accounting system "ABAC" was available to ECHA from 19 December onwards. With these essential elements in place, the Agency was in a position to establish its financial independence as of 1 January 2008.

The Agency's budget in 2007 was € 15.294.000 in commitment appropriations, of which € 13.371.411,44 (87.5%) were committed. More than half of this amount was used for staff expenditure, around € 2.5 million were used for infrastructure and other operating expenditure, whereas around € 3.5 million were used for operating expenditure (mainly IT support for REACH-IT and communication).

To ensure the necessary liquidity of the Agency at the beginning of 2008, the Commission paid at the end of 2007 an operating grant of € 1.922.588,56 to the Agency. This amount, which was on the Agency's bank account as of 31 December 2007, will have to be reimbursed or compensated with future subsidies.

The establishment plan foresaw 101 posts for Temporary Agents at the end of the year, of which 97 posts (96%) were actually filled.

4.3 Human Resources

Between June and December, the statutory staff grew from zero to 102. The first to arrive were the 38 experienced Commission officials seconded in the interest of the service for the start up phase of the Agency. The seconded officials will be replaced by long-term temporary agents in the course of 2008, including all management except for the post of Executive Director who was nominated by the Management Board in December.

A steady rhythm of growth in operational and administrative staff was ensured by recruitments from the reserve lists established for 8 profiles of temporary agents (Senior Scientific Officer, Scientific Officer, Junior Scientific Officer, IT Officer, Legal Advisor, IT Assistant, Human Resources Assistant and Financial Assistant) for which the European Commission had published the call for expression of interest at the beginning of the year. A call for expressions of interest covering a further 6 profiles (Assistant Scientific Officer, Junior Assistant Scientific Officer, IT Assistant – IUCLID/REACH IT, Webmaster, Facility Manager and Facility Management Assistant) was launched in September.

In addition to statutory staff (97 temporary and 5 contract agents), 6 seconded national experts joined the Agency. Secretarial and clerical assistance as well as IT helpdesk services were provided by external interim services.

Mission statements, job descriptions and individual objectives were established, and the staff signed declarations of commitment, confidentiality and their interests. Performance

evaluations were carried out for the staff whose intermediate probation period reports were due. A system for flexible working time was introduced. Various other Human Resources administration functions were put in place, including the procedures and controls necessary for the related budgeting and financial management, most importantly the payroll.

4.4 IT Infrastructure

As all data will be provided to the Agency and stored there in electronic format a well functioning ICT infrastructure is essential for the success of ECHA. The ICT infrastructure is the backbone of ECHA office automation and network connections to the stakeholders and later also for the operational information systems like REACH-IT and IUCLID5.

The Agency's Data Centre and a preliminary disaster recovery site were set up with the help of the European Commission taking into account the REACH-IT security study. Office automation environment with e-mail systems as well as telephone networks based on VoIP technology and video-conferencing and tele-conferencing facilities were established for the staff of ECHA. Daily operations and tunings at the Data Centre commenced at entry into force.

Administrative information systems to support independent financial management and human resources management were set up later.

Internal ICT Helpdesk supporting the growing end-user community of ECHA was established following the ITIL best practices.

Procurement of hardware, software and services needed for the coming years continued, taking into account the growing needs for storage and processing power for REACH-IT as well as the challenges in recruiting statutory ICT staff for ECHA.

4.5 Training

A training task force was created, with a training correspondent from each unit of the Agency to develop and implement the first "Internal training catalogue".

Regular administrative induction sessions were organised for the new staff members, whom information was given on administrative rules and procedures.

Several administrative and operational training courses were carried out in 2007. The topics varied from technical and REACH-related matters such as IUCLID5 to much more transversal issues like selection interviewing and use of financial systems and applications. Away-days gave a chance for directorates to instruct the staff undisturbed and to discuss trans-directorate issues such as helpdesks and committees.

5. MANAGEMENT AND INTERNAL CONTROL

Throughout 2007 the Director General of the Directorate General Enterprise and Industry (DG ENTR) of the Commission acted as authorising officer for commitments and for

payments related to the budget of ECHA. It follows that the related financial data is covered by the annual activity report of DG ENTR⁴.

Only the Commission was entitled to enter into legal and budgetary commitments for the Agency, except for some cases where administrative decisions could be based on provisional commitments authorised by the Commission (DG ENTR). Therefore, the tasks of the Interim Executive Director were limited to concluding contracts that were covered by provisional commitments. In this function, he signed a number of contracts for routine administrative expenditure, mission orders and expenses and invitations to tender, and acted as appointing authority. His task as authorising officer for budgetary commitments was only taken up after he had been appointed « Executive Director » by the Management Board's decision on 17 December with effect as of 1 January 2008. At this date the Agency became financially independent.

Documented working arrangements for the transitional period, as well as hand-over notes, have been the basis for the cooperation and the internal control mechanisms in place between DG ENTR and ECHA.

⁴ Art. 60(7) of the Financial Regulation applicable to the general budget of the European Communities.

ANNEXES

Annex 1 List of members of the ECHA Management Board (status in December 2007)

ADAMIS, Zoltan
ALAJÕE, Maria
ANDREASEN, Helge
BAJORAITIENE, Aurelija
BLAHA, Karel
CIRAJ, Marta
FARRUGIA, Francis
FORSBERG, Ethel
FRESNO RUIZ, Ana
GAUTHIER, Odile
GECHEVA-ZAHARIEVA, Ekaterina
GEIMER, Claude
GONCALVES HENRIQUES, António
JAKL, Thomas
KIRSTUKA, Ilze
KITAJEWSKA, Katarzyna
LAPALORCIA, Antonello
LEEMANS, Marc
LYNCH, Martin
MALM, Jukka
MOROHOI, Rodica
NICOLAIDES, Leandros
NIES, Alexander
NOVAKOVA, Edita
ROBERTS, John
VAN DER WIELEN, Arnoldus
XEPAPADAKI-TOMARA, Maria-Miranda

LAWRENCE, Grant
PAULI, Anneli
ZOUREK, Heinz

DE ROO, Alexander
LANGE, Bernd

MUSU, Tony
PALLEMAERTS, Marc
PERROY, Alain

Annex 2 Members of the Member States Committee (status in December 2007)

ANGELOPOULOU Ionna, Greece
BÖHLEN Elmar, Germany
CAMILLERI Tristan, Malta
COSGRAVE Majella, Ireland
DEIM Szilvia, Hungary
DIMA Ancuta Manuela, Romania
FAIRHURST Steve, United Kingdom
FAJFAR Simona, Slovenia
FERREIRA MARQUES Jeanine, Belgium
FLODSTRÖM Sten, Sweden
FRATELLO Francesca, Italy
GEUSS Erik, Czech Republic
KORENROMP René, The Netherlands
KYPRIANIDOU-LEODIDOU Tasoula, Cyprus
LARSEN Henrik Søren, Denmark
LUDBORZS Arnis, Latvia
LUKINSKIENE Lina, Lithuania
LULEVA Parvoleta Angelova, Bulgaria
MAJKA Jerzy, Poland
MARTÍN Esther, Spain
MOREAU Emmanuel, France
PALMA Maria do Carmo Ramalho Figueira, Portugal
RAUTALAHTI Katariina, Finland
RUSNAK Peter, Slovakia
STESSEL Helmut, Austria
VESKIMÄE Enda, Estonia
WELFRING Joëlle, Luxemburg

Annex 3 Members of the Forum for Exchange of Information on Enforcement
(status in December 2007)

ALONSO FERNÁNDEZ Rosario, Spain
ANGELOPOULOU Ionna, Greece
ARO Tiiu, Estonia
BARROQUEIRO Álvaro António, Portugal
BISHOP Richard, United Kingdom
BLENKERS Joop, The Netherlands
BORG Ingrid, Malta
BORGLUM Birte Nielsen, Denmark
CUYPERS Paul, Belgium
EKMAN Annette, Finland
FORINT Pavel, Czech Republic
ISTRATI Daniela, Romania
KOLESAR Dušan, Slovakia
KOWALSKI Ulrike, Germany
KYPRIANIDOU-LEODIDOU Tasoula, Cyprus
MAJOR Jenő, Hungary
MIEGOC Edyta, Poland
O' SULLIVAN Tom, Ireland
PALLO Parsla, Latvia
PEZDIR Mojca Jeraj, Slovenia
PISTOLESE Pietro, Italy
SAVOV Nikolay Stanimirov, Bulgaria
SCHMIT Gaston, Luxemburg
SESKAUSKAS Viktoras, Lithuania
THORAN Karin, Sweden
VIERS Stéphanie, France
WURM Gernot, Austria

Annex 4 Members of the Risk Assessment Committee (appointed by the Management Board 17/12/2007) (status in December 2007)

ANDRIJEWSKI, Michal
BINETTI, Roberto
BORGES, Maria Teresa
DUNGEY, Stephen
ERICSSON, Gunilla
GREIM, Helmut
GRUIZ, Katalin
HOYAUX, Daphne
KADIKIS, Normunds
KORJUS, Pia
LE CURIEUX-BELFOND, Olivier
LEINONEN, Riitta
LOSERT, Annemarie
LUKINSKIENE, Lina
LUND, Bert-Ove
MELANITOU, Maria
MEZZANOTTE, Roberto
MULLOOLY, Yvonne
NAKOPOULOU, Chrysanthi
NUNES, Céu
ORPHANOU, Maria
PICHARD, Annick
POLAKOVICOVA, Helena
POSPISCHIL, Erich
PRONK, Marja
RUPPRICH, Norbert
SCHULTE, Agnes
SMERHOVSKY, Zdenek
SMITH, Andrew
STOLZENBERG, Hans-Christian
SULG, Helen
TARAZONA, Jose
TOMSONE, Margita
TYLE, Henrik
VAN MALDEREN, Karen
VILANOVA, Eugenio
ZGLOBIU, Mariana-Elena